

# Detail Report

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<b>CR Number:</b> 2023333139	<b>Implementation Date:</b> 02-May-24	<b>Related CR:</b> 2023333139	<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>
Proposed PT	Anorectal warts	Rejected After Suspension	

**MSSO Comment:** The proposal to add a new PT Anorectal warts is not approved after suspension. Warts often caused by some strains of human papillomavirus, are usually located in the anogenital region, although they can also spread into the rectum. The intention to group anal terms under anorectal terms for consistency reasons, cannot be supported from a medical perspective for this particular concept. In addition, please consider LLT/PT Anorectal human papilloma virus infection as an option of representing the infectious nature, without the link to the long-term consequence (warts). Warts are the morphological outcome of the infection, and should be considered independently as a neoplasm type of lesion.

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<b>CR Number:</b> 2023333140	<b>Implementation Date:</b> 02-May-24	<b>Related CR:</b> 2023333140	<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Promote an LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>
Proposed LLT	Herpes simplex anorectal	Approved After Suspension	Proposed LLT
From PT	Proctitis herpes		Herpes simplex anorectal 10054244
			From PT
			Proctitis herpes 10036780
			HLT primary
			Herpes viral infections 10019972
			SOC primary
			Infections and infestations 10021881
			HLT secondary
			Anal, rectal, perianal and perirectal infections 10002114
			SOC secondary
			Gastrointestinal disorders 10017947

**MSSO Comment:** The proposal to promote the LLT Herpes simplex anorectal from PT Proctitis herpes is approved as requested after suspension. Herpes simplex anorectal will be promoted from an LLT under PT Proctitis herpes to PT level with primary HLT Herpes viral infections and secondary HLT Anal, rectal, perianal and perirectal infections. Herpes simplex anorectal was promoted since the infection does not always manifest as proctitis.

# Detail Report

<b>CR Number:</b> 2023333141		<b>Implementation Date:</b> 02-May-24	<b>Related CR:</b> 2023333141	
<u>Change Requested</u>	Add a New PT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Anorectal herpes	Approved After Suspension	Proposed PT	
			Anorectal herpes	10091077
			HLT primary	
			Herpes viral infections	10019972
			SOC primary	
			Infections and infestations	10021881
			HLT secondary	
			Anal, rectal, perianal and perirectal infections	10002114
			SOC secondary	
			Gastrointestinal disorders	10017947

**MSSO**  
**Comment:** The proposal to add a new PT Anorectal herpes is approved as requested after suspension. Anorectal herpes is an unqualified term including the virus family and the specific anatomic location. Anorectal herpes will be added as PT to primary HLT Herpes viral infections and secondary HLT Anal, rectal, perianal and perirectal infections. In a related change, LLT Anal herpes will be moved from PT Genital herpes to the new PT Anorectal herpes.

<b>CR Number:</b> 2024127001		<b>Implementation Date:</b> 06-May-24	<b>Related CR:</b> 2023333141	
<u>Change Requested</u>	Link (move) an LLT to another PT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Anal herpes	Approved as Requested	Proposed LLT	
From PT	Genital herpes		Anal herpes	10084891 Current
To PT	Anorectal herpes		From PT	
			Genital herpes	10018150
			To PT	
			Anorectal herpes	10091077

**MSSO**  
**Comment:**

# Detail Report

CR Number: 2023333142		Implementation Date: 02-May-24	Related CR: 2023333142	
<a href="#">Change Requested</a>	Link (move) an LLT to another PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Perianal herpes simplex</i>	Approved After Suspension	Proposed LLT	
From PT	<i>Genital herpes simplex</i>		<i>Perianal herpes simplex</i>	10065050 Current
To PT	<i>Herpes simplex anorectal</i>		From PT	
			<i>Genital herpes simplex</i>	10073931
			To PT	
			<i>Herpes simplex anorectal</i>	10054244
<b>MSSO Comment:</b> The proposal to move the LLT Perianal herpes simplex from PT Genital herpes simplex to PT Herpes simplex anorectal is approved as requested after suspension. The term "perianal" refers to the area immediately surrounding the anus, and it is part of the anorectal region. The anorectal region includes both the anal canal and the surrounding areas, such as the perianal region, while the term "genital region" typically refers to the external reproductive organs, such as the penis and scrotum in males or the vulva in females.				

CR Number: 2023333143		Implementation Date: 02-May-24	Related CR: 2023333143	
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Herpes zoster anorectal</i>	Approved Not as Requested After Suspension	Proposed PT	
			<i>Anorectal herpes zoster</i>	10091078
			HLT primary	
			<i>Herpes viral infections</i>	10019972
			SOC primary	
			<i>Infections and infestations</i>	10021881
			HLT secondary	
			<i>Anal, rectal, perianal and perirectal infections</i>	10002114
			SOC secondary	
			<i>Gastrointestinal disorders</i>	10017947
<b>MSSO Comment:</b> The proposal to add a new PT Herpes zoster anorectal is approved but not as requested after suspension. Herpes zoster anorectal includes information on the genus and the specific anatomic location. The proposed term will be modified for natural word order and added as PT Anorectal herpes zoster with primary HLT Herpes viral infections and secondary HLT Anal, rectal, perianal and perirectal infections. In a related change, LLT Perianal herpes zoster will be moved from PT Genital herpes zoster to new PT Anorectal herpes zoster.				

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<b>CR Number:</b> 2024127002		<b>Implementation Date:</b> 06-May-24	<b>Related CR:</b> 2023333143	
<a href="#">Change Requested</a>	Link (move) an LLT to another PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Perianal herpes zoster</i>	Approved as Requested	Proposed LLT	10080101 Current
From PT	<i>Genital herpes zoster</i>		<i>Perianal herpes zoster</i>	
To PT	<i>Anorectal herpes zoster</i>		From PT	10072210
			<i>Genital herpes zoster</i>	
			To PT	10091078
			<i>Anorectal herpes zoster</i>	

MSSO  
Comment:

<b>CR Number:</b> 2023333144		<b>Implementation Date:</b> 02-May-24	<b>Related CR:</b> 2023333144	
<a href="#">Change Requested</a>	Rename PT/LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Term to modify	<i>Perianal streptococcal infection</i>	Rejected After Suspension		
Replacement term	<i>Streptococcal infection anorectal</i>			

MSSO  
Comment: The proposal to rename PT/LLT Perianal streptococcal infection to Streptococcal infection anorectal is not approved after suspension. Perianal streptococcal infection follows the MedDRA rules for term placement, as all new terms are added in natural word order. Terms are not usually renamed, except for correction of misspellings. In case there is a specific need for the term Streptococcal infection anorectal in addition to the existing term, please consider submitting a new change request.

<b>CR Number:</b> 2023337000		<b>Implementation Date:</b> 08-Jan-24	<b>Related CR:</b> 2023337000	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Photothermal therapy</i>	Approved as Requested	Proposed PT	10090662
			<i>Photothermal therapy</i>	
			HLT primary	10034976
			<i>Phototherapies</i>	
			SOC primary	10042613
			<i>Surgical and medical procedures</i>	

MSSO  
Comment: The proposal to add a new term Photothermal therapy is approved as requested. Photothermal therapy (PTT) is a method of heat ablation in which light energy is utilized to induce localized heat within the tissue and destroy the pathologic cells. Photothermal therapy will be added as PT under the HLT Phototherapies.

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<b>CR Number:</b> 2023338000		<b>Implementation Date:</b> 08-Jan-24	<b>Related CR:</b> 2023338000	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	THORACODYNIA	Approved Not as Requested	Proposed LLT Thoracodynia	10090671 Current
			To PT Chest pain	10008479

**MSSO Comment:** The proposal to add a new LLT THORACODYNIA is approved but not as requested. Thoracodynia will be rephrased to meet MedDRA capitalization conventions and added as a synonym LLT under PT Chest pain.

<b>CR Number:</b> 2023338001		<b>Implementation Date:</b> 08-Jan-24	<b>Related CR:</b> 2023338001	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	Vasoproliferative retinal tumour	Approved as Requested	Proposed PT Vasoproliferative retinal tumour	10090663
			HLT primary Ocular neoplasms malignancy unspecified	10030053
			SOC primary Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10029104
			HLT secondary Ocular neoplasms malignancy unspecified	10030053
			SOC secondary Eye disorders	10015919

**MSSO Comment:** The proposal to add a new term Vasoproliferative retinal tumour is approved as requested. Vasoproliferative retinal tumor is characterized by one or more retinal nodules. The tumor in question consists mostly of glial cells, capillaries and hyalinized blood vessels. These lesions cause retinal exudates, macular edema, and epiretinal membranes. Vasoproliferative retinal tumour will be added as a PT linked to bi-axial HLT Ocular neoplasms malignancy unspecified (primary SOC Neoplasms benign, malignant and unspecified (incl cysts and polyps) and secondary SOC Eye disorders) and to secondary HLT Ocular vascular disorders NEC. In a related change, the American English spelled counterpart LLT Vasoproliferative retinal tumor will also be added to new PT Vasoproliferative retinal tumour.

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<b>CR Number:</b> 2024008002		<b>Implementation Date:</b> 08-Jan-24	<b>Related CR:</b> 2023338001		
<a href="#">Change Requested</a>	Link a PT to a HLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed PT	<i>Vasoproliferative retinal tumour</i>	Approved as Requested	Proposed PT		
To HLT	<i>Ocular vascular disorders NEC</i>		<i>Vasoproliferative retinal tumour</i>	10090663	
			To HLT		
			<i>Ocular vascular disorders NEC</i>	10030067	

MSSO  
Comment:

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<b>CR Number:</b> 2024008003		<b>Implementation Date:</b> 08-Jan-24	<b>Related CR:</b> 2023338001		
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed LLT	<i>Vasoproliferative retinal tumor</i>	Approved as Requested	Proposed LLT		
To PT	<i>Vasoproliferative retinal tumour</i>		<i>Vasoproliferative retinal tumor</i>	10090666	Current
			To PT		
			<i>Vasoproliferative retinal tumour</i>	10090663	

MSSO  
Comment:

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<b>CR Number:</b> 2023338002		<b>Implementation Date:</b> 08-Jan-24	<b>Related CR:</b> 2023338002		
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed Term	<i>Abdominal Angina</i>	Approved Not as Requested	Proposed LLT		
			<i>Abdominal angina</i>	10090667	Current
			To PT		
			<i>Intestinal angina</i>	10022640	

MSSO  
Comment: The proposal to add a new term Abdominal Angina is approved but not as requested. The proposed term will be rephrased to meet MedDRA capitalization conventions and will be added as a synonym LLT Abdominal angina under PT Intestinal angina.

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# Detail Report

<b>CR Number:</b> 2023338003		<b>Implementation Date:</b> 08-Jan-24	<b>Related CR:</b> 2023338003	
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Succenturiate Placenta</i>	Approved Not as Requested	Proposed PT <i>Succenturiate placenta</i>	10090664
			HLT primary <i>Placental abnormalities (excl neoplasms)</i>	10035130
			SOC primary <i>Pregnancy, puerperium and perinatal conditions</i>	10036585

**MSSO Comment:** The proposal to add a new LLT Succenturiate Placenta is approved but not as requested. Placenta succenturiate is a morphological abnormality of the placenta in which one or more accessory lobes are present outside the placental body. These can have different sizes and are connected by blood vessels to the main placenta. The accessory lobe develops from the chorionic villi that did not involute from the mild chorion. The proposed term will be modified for MedDRA capitalization conventions and added as PT Succenturiate placenta to HLT Placental abnormalities (excl neoplasms).

<b>CR Number:</b> 2023338004		<b>Implementation Date:</b> 08-Jan-24	<b>Related CR:</b> 2023338004	
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Transcranial doppler ultrasound</i>	Approved as Requested	Proposed LLT <i>Transcranial doppler ultrasound</i>	10090670 Current
To PT	<i>Ultrasound head</i>		To PT <i>Ultrasound head</i>	10085915

**MSSO Comment:** The proposal to add a new LLT Transcranial doppler ultrasound to PT Ultrasound head is approved as requested aligned with synonym LLT Cerebrovascular doppler ultrasound.

<b>CR Number:</b> 2023338005		<b>Implementation Date:</b> 08-Jan-24	<b>Related CR:</b> 2023338005	
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>NON-SECRETORY MULTIPLE MYELOMA</i>	Rejected		

**MSSO Comment:** The proposal to add a new LLT NON-SECRETORY MULTIPLE MYELOMA is not approved. LLT Nonsecretory myeloma is already available in MedDRA for coding purposes.

# Detail Report

CR Number: 2023338006		Implementation Date: 08-Jan-24	Related CR: 2023338006		
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed LLT	MICROWAVE COAGULO-NECROTIC THERAPY	Rejected			

MSSO Comment: The proposal to add a new LLT MICROWAVE COAGULO-NECROTIC THERAPY is not approved. LLT Microwave therapy, LLT Microwave ablation and LLT Microwave coagulation are already available in MedDRA for coding purposes.

CR Number: 2023338007		Implementation Date: 08-Jan-24	Related CR: 2023338007		
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed Term	PERICARDIAL DECOMPRESSION SYNDROME	Approved Not as Requested	Proposed PT		
			Pericardial decompression syndrome	10090665	
			HLT primary		
			Heart failures NEC	10019281	
			SOC primary		
			Cardiac disorders	10007541	
			HLT secondary		
			Cardiac and vascular procedural complications	10007602	
			SOC secondary		
			Injury, poisoning and procedural complications	10022117	

MSSO Comment: The proposal to add a new term PERICARDIAL DECOMPRESSION SYNDROME is approved but not as requested. Pericardial decompression syndrome is defined as a paradoxical worsening of hemodynamics and development of pulmonary edema after an uncomplicated pericardial drainage in patients with pericardial effusions or cardiac tamponade. The proposed term will be rephrased to meet MedDRA capitalization conventions and will be added as PT Pericardial decompression syndrome with primary link to HLT Heart failures NEC and to secondary HLT Cardiac and vascular procedural complications and to secondary HLT Vascular hypotensive disorders.



# Detail Report

CR Number: 2024008004		Implementation Date: 08-Jan-24	Related CR: 2023338007	
<a href="#">Change Requested</a>	Link a PT to a HLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Pericardial decompression syndrome	Approved as Requested	Proposed PT	
To HLT	Vascular hypotensive disorders		Pericardial decompression syndrome	10090665
			To HLT	
			Vascular hypotensive disorders	10057181

MSSO  
Comment:

CR Number: 2023338008		Implementation Date: 08-Jan-24	Related CR: 2023338008	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	Morgagnian cataract	Approved as Requested	Proposed LLT	
			Morgagnian cataract	10090669 Current
			To PT	
			Cataract	10007739

MSSO  
Comment: The proposal to add a new term Morgagnian cataract is approved as requested. A Morgagnian cataract is a form of hypermature cataract characterized by the liquefaction of the lens cortex along with the displacement of the dense lens nucleus into the bottom of the capsular bag. Morgagnian cataract will be added as a sub-concept LLT to PT Cataract.

CR Number: 2023338009		Implementation Date: 08-Jan-24	Related CR: 2023338009	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	Alcoholic chronic pancreatitis	Rejected		

MSSO  
Comment: The proposal to add a new term Alcoholic chronic pancreatitis is not approved. Alcoholic pancreatitis already exists as a PT in MedDRA under the HLT Acute and chronic pancreatitis. It is not practical to populate MedDRA with separate PTs or LLTs for both the "acute" and "chronic" forms of a disorder, especially when the clinical distinction between the time frames is often subjective.

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<b>CR Number:</b> 2023338010		<b>Implementation Date:</b> 08-Jan-24	<b>Related CR:</b> 2023338010	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	MAIGNE'S SYNDROME	Approved Not as Requested	Proposed LLT Maigne's syndrome	10090668 Current
			To PT Dorsal ramus syndrome	10082295
<b>MSSO Comment:</b> The proposal to add a new term MAIGNE'S SYNDROME is approved but not as requested. The proposed term will be modified for MedDRA capitalization standards to LLT Maigne's syndrome PT Dorsal ramus syndrome, aligned with existing LLT Thoracolumbar junction syndrome.				

<b>CR Number:</b> 2023338011		<b>Implementation Date:</b> 08-Jan-24	<b>Related CR:</b> 2023338011	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	Pulmonary inflammatory pseudotumor	Approved as Requested	Proposed LLT Pulmonary inflammatory pseudotumor	10090673 Current
			To PT Pulmonary inflammatory pseudotumour	10090672
<b>MSSO Comment:</b> The proposal to add a new term Pulmonary inflammatory pseudotumor is approved as requested. Inflammatory pseudotumour of the lung is an inflammatory, reactive, and nonneoplastic process characterized by unregulated growth of inflammatory cells. It occurs most commonly in children and young adults and is usually found incidentally. Inflammatory pseudotumour may mimic lung cancer and thereby poses a diagnostic dilemma for the clinician. Pulmonary inflammatory pseudotumor will be added as an LLT to British English spelled PT Pulmonary inflammatory pseudotumour which will be added, in a related change to HLT Parenchymal lung disorders NEC.				

<b>CR Number:</b> 2024008005		<b>Implementation Date:</b> 08-Jan-24	<b>Related CR:</b> 2023338011	
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Pulmonary inflammatory pseudotumour	Approved as Requested	Proposed PT Pulmonary inflammatory pseudotumour	10090672
HLT primary	Parenchymal lung disorders NEC		HLT primary Parenchymal lung disorders NEC	10033979
SOC primary	Respiratory, thoracic and mediastinal disorders		SOC primary Respiratory, thoracic and mediastinal disorders	10038738

MSSO  
Comment:

# Detail Report

<b>CR Number:</b> 2023338012		<b>Implementation Date:</b> 08-Jan-24	<b>Related CR:</b> 2023338012	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Fazekas grade 1</i>	Approved as Requested	Proposed LLT <i>Fazekas grade 1</i>	10090675 Current
			To PT <i>Fazekas scale abnormal</i>	10090674

**MSSO Comment:** The proposal to add a new term Fazekas grade 1 is approved as requested. The Fazekas scale is used to simply quantify the amount of white matter T2 hyperintense lesions usually attributed to chronic small vessel ischaemia, although clearly not all such lesions are due to this. Fazekas grade 1 will be added as an LLT to new PT Fazekas scale abnormal, which will be added, in a related change to HLT Neurologic diagnostic procedures.

<b>CR Number:</b> 2024008006		<b>Implementation Date:</b> 08-Jan-24	<b>Related CR:</b> 2023338012	
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Fazekas scale abnormal</i>	Approved as Requested	Proposed PT <i>Fazekas scale abnormal</i>	10090674
HLT primary	<i>Neurologic diagnostic procedures</i>		HLT primary <i>Neurologic diagnostic procedures</i>	10029285
SOC primary	<i>Investigations</i>		SOC primary <i>Investigations</i>	10022891

**MSSO Comment:**

<b>CR Number:</b> 2023338016		<b>Implementation Date:</b> 10-Jan-24	<b>Related CR:</b> 2023338016	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Multivisceral failure</i>	Rejected		

**MSSO Comment:** The proposal to add a new term Multivisceral failure is not approved. The requested term represents a colloquial expression which may not have a universally accepted international interpretation. Please consider existing terms, such as suitable LLTs under PT Multiple organ dysfunction syndrome for your coding needs.

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<b>CR Number:</b> 2023339000		<b>Implementation Date:</b> 08-Jan-24	<b>Related CR:</b> 2023339000	
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Removal of foreign body from cornea	Approved Not as Requested	Proposed LLT	
HLT primary	Corneal and scleral therapeutic procedures		Removal of foreign body from cornea	10090676 Current
SOC primary	Surgical and medical procedures		To PT	
			Removal of foreign body from eye	10038327
<b>MSSO Comment:</b> The proposal to add a new PT Removal of foreign body from cornea to primary HLT Corneal and scleral therapeutic procedures in SOC Surgical and medical procedures is approved but not as requested. A corneal foreign body is an object (eg, metal, glass, wood, plastic, sand) either superficially adherent to or embedded in the cornea of the eye. The removal of a corneal foreign body is a procedure commonly performed in the clinic or emergency department setting. Removal of foreign body from cornea will be added as a sub-concept LLT to PT Removal of foreign body from eye. In a related change, PT Removal of foreign body from conjunctiva will be demoted under PT Removal of foreign body from eye.				

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<b>CR Number:</b> 2024008007		<b>Implementation Date:</b> 08-Jan-24	<b>Related CR:</b> 2023339000	
<a href="#">Change Requested</a>	Demote a PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
PT to merge	Removal of foreign body from conjunctiva	Approved as Requested	PT to merge	
To PT	Removal of foreign body from eye		Removal of foreign body from conjunctiva	10038324 Current
			To PT	
			Removal of foreign body from eye	10038327
<b>MSSO Comment:</b>				

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# Detail Report

<b>CR Number:</b> 2023339002		<b>Implementation Date:</b> 10-Jan-24	<b>Related CR:</b> 2023339002	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Gut derived infection</i>	Approved Not as Requested	Proposed PT <i>Gut derived infection</i>	10090701
			HLT primary <i>Infections NEC</i>	10021902
			SOC primary <i>Infections and infestations</i>	10021881
			HLT secondary <i>Intestinal infections</i>	10022678
			SOC secondary <i>Gastrointestinal disorders</i>	10017947

**MSSO Comment:** The proposal to add a new LLT Gut derived infection is approved but not as requested. Disruption of the epithelial barrier and increased gut permeability frequently observed in critically ill patients characterized by overgrowth of pathogenic organisms and the loss of commensal bacteria contributing to bacterial translocation. Gut derived infection will be placed as a PT under the primary HLT Infections NEC and secondary HLT Intestinal infections.

<b>CR Number:</b> 2023339003		<b>Implementation Date:</b> 10-Jan-24	<b>Related CR:</b> 2023339003	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Catheter urinary tract infection</i>	Rejected		

**MSSO Comment:** The proposal to add a new LLT Catheter urinary tract infection is not approved. The proposed term implies a causal relationship and therefore represents a combination term. The MSSO refrains from adding such terms as to avoid overpopulation of MedDRA. Please note that Section 3.5.4 of the MedDRA Term Selection: Points to Consider document provides the options on when to "split" into more than one MedDRA term.

<b>CR Number:</b> 2023339018		<b>Implementation Date:</b> 10-Jan-24	<b>Related CR:</b> 2023339018	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Central hyperthermia</i>	Approved as Requested	Proposed LLT <i>Central hyperthermia</i>	10090702 Current
			To PT <i>Hyperthermia</i>	10020843

**MSSO Comment:** The proposal to add a new term Central hyperthermia is approved as requested. Central hyperthermia has a rapid onset of temperature with marked fluctuations. It may be a result of damage or dysfunction to central fever control centers, such as at the level of the diencephalon. This region regulates core temperatures. Any damage to this area can disrupt the thermoregulatory apparatus of the body. Central hyperthermia will be added as an LLT under PT Hyperthermia.

# Detail Report

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<b>CR Number:</b> 2023340001	<b>Implementation Date:</b> 10-Jan-24	<b>Related CR:</b> 2023340001	<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Change Status of LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>
LLT to change	<i>Vaccination site lividity</i>	Rejected	
Status	<i>non-current</i>		

**MSSO Comment:** The proposal to change status of LLT Vaccination site lividity to non-current is not approved. Although lividity may refer to descriptions in forensic medicine it may also refer to having a discolored, bluish appearance caused by a bruise, congestion of blood vessels, strangulation, etc., such as the face, flesh, hands, or nails.

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<b>CR Number:</b> 2023340010	<b>Implementation Date:</b> 10-Jan-24	<b>Related CR:</b> 2023340010	<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>
Proposed LLT	<i>Vanilmandelic acid urine increased</i>	Rejected	
To PT	<i>Catecholamines urine increased</i>		

**MSSO Comment:** The proposal to add a new LLT Vanilmandelic acid urine increased to PT Catecholamines urine increased is not approved. The proposed concept already exists in MedDRA as LLT/PT Vanillyl mandelic acid urine increased.

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<b>CR Number:</b> 2023342000	<b>Implementation Date:</b> 09-Jan-24	<b>Related CR:</b> 2023342000	<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>
Proposed Term	<i>Death grip syndrome</i>	Rejected	

**MSSO Comment:** The proposal to add a new term Death grip syndrome is not approved. Death grip syndrome is a colloquial expression to refer to a condition where the penis loses sensation due to over-masturbation leading to unsatisfactory experience when engaging in regular sexual intercourse. Term will be rejected, since it is not a valid concept in medical literature.

# Detail Report

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CR Number: 2023342001		Implementation Date: 09-Jan-24	Related CR: 2023342001		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed Term	<i>Lazy bowel syndrome</i>	Rejected			

MSSO Comment: The proposal to add a new term Lazy bowel syndrome is not approved. The concept is a colloquial expression of existing LLT Slow transit constipation.

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CR Number: 2023342002		Implementation Date: 09-Jan-24	Related CR: 2023342002		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed Term	<i>Commotio Cordis</i>	Approved Not as Requested	Proposed PT <i>Commotio cordis</i>		10090682
			HLT primary <i>Ventricular arrhythmias and cardiac arrest</i>		10047283
			SOC primary <i>Cardiac disorders</i>		10007541
			HLT secondary <i>Cardiovascular injuries</i>		10007654
			SOC secondary <i>Injury, poisoning and procedural complications</i>		10022117

MSSO Comment: The proposal to add a new term Commotio Cordis is approved but not as requested. Commotio cordis is defined as sudden cardiac arrest or death secondary to a blunt, nonpenetrating precordial impact. It is provoked by the simultaneous occurrence of specific mechanistic elements (e.g., timing, location, and velocity of impact) that result in ventricular fibrillation. The proposed term will be modified in accordance with MedDRA capitalization conventions, and added as the PT Commotio cordis, with a primary link to HLT Ventricular arrhythmias and cardiac arrest and a secondary link to HLT Cardiovascular injuries.

# Detail Report

<b>CR Number:</b> 2023342003		<b>Implementation Date:</b> 09-Jan-24	<b>Related CR:</b> 2023342003	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	KALEIDOSCOPE VISION	Approved Not as Requested	Proposed PT Kaleidoscope vision	10090683
			HLT primary Visual disorders NEC	10047541
			SOC primary Eye disorders	10015919
			HLT secondary Ocular signs and symptoms NEC	10030952
			SOC secondary Nervous system disorders	10029205

**MSSO Comment:** The proposal to add a new term KALEIDOSCOPE VISION is approved but not as requested. Kaleidoscope vision is a type of visual disturbance which causes a similar effect to that looking through a kaleidoscope. The images are bright in color, fractured and, sometimes, shiny or blurry. The proposed term will be modified in accordance with MedDRA capitalization conventions and added as the PT Kaleidoscope vision with a primary link to HLT Visual disorders NEC and a secondary link to HLT Ocular signs and symptoms NEC.

<b>CR Number:</b> 2023342004		<b>Implementation Date:</b> 09-Jan-24	<b>Related CR:</b> 2023342004	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	VENTRICULAR SEPTUM THICKENING	Approved Not as Requested	Proposed LLT Ventricular septum thickening	10090685 Current
			To PT Cardiac septal hypertrophy	10057576

**MSSO Comment:** The proposal to add a new term VENTRICULAR SEPTUM THICKENING is approved but not as requested. The proposed term will be modified according MedDRA capitalization guidelines and added as sub-concept LLT Ventricular septum thickening to PT Cardiac septal hypertrophy.



# Detail Report

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<b>CR Number:</b> 2023342005	<b>Implementation Date:</b> 09-Jan-24	<b>Related CR:</b> 2023342005	<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>
Proposed Term	<i>HYPERTROPHY UPPER LIMB</i>	Rejected	

**MSSO Comment:** The proposal to add a new term HYPERTROPHY UPPER LIMB is not approved. Muscle hypertrophy is the normal physiological response to muscle work and results from enlargement of myofibers. The proposed term is a mere anatomical location of the PT Muscle hypertrophy. If the requested concept is around the congenital condition named Upper limb congenital muscular hypertrophy (also Congenital monomelic muscular hypertrophy of the upper extremity), please re-submit a more specific change request.

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<b>CR Number:</b> 2023342006	<b>Implementation Date:</b> 09-Jan-24	<b>Related CR:</b> 2023342006	<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>
Proposed Term	<i>HYPERTROPHY LOWER LIMB</i>	Rejected	

**MSSO Comment:** The proposal to add a new term HYPERTROPHY LOWER LIMB is not approved. Muscle hypertrophy is the normal physiological response to muscle work and results from enlargement of myofibers. The proposed term is a mere anatomical location of the PT Muscle hypertrophy. If the requested concept is around the congenital condition named congenital lower limb hypertrophy, please resubmit a more specific change request.

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<b>CR Number:</b> 2023342007	<b>Implementation Date:</b> 09-Jan-24	<b>Related CR:</b> 2023342007	<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>
Proposed Term	<i>UNGUIS INCARNATUS</i>	Approved Not as Requested	Proposed LLT <i>Unguis incarnatus</i> 10090684 Current To PT <i>Ingrowing nail</i> 10022013

**MSSO Comment:** The proposal to add a new term UNGUIS INCARNATUS is approved but not as requested. Unguis incarnatus is a Latin synonym of ingrowing nail. The proposed term will be modified to comply with MedDRA capitalization conventions and added as the LLT Unguis incarnatus to the PT Ingrowing nail.

# Detail Report

<b>CR Number:</b> 2023342008		<b>Implementation Date:</b> 09-Jan-24	<b>Related CR:</b> 2023342008	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	CREATINE KINASE ABNORMAL	Approved Not as Requested	Proposed LLT Creatine kinase abnormal	10090686 Current
			To PT Blood creatine phosphokinase abnormal	10005468
<b>MSSO Comment:</b> The proposal to add a new term CREATINE KINASE ABNORMAL is approved but not as requested. Creatine kinase abnormal is the term representing the abnormal result of existing LLT Creatine kinase and, once modified to comply with MedDRA capitalization conventions, will be added as an LLT under the PT Blood creatine phosphokinase abnormal.				
<b>CR Number:</b> 2023342009		<b>Implementation Date:</b> 10-Jan-24	<b>Related CR:</b> 2023342009	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Pigtail catheter removal	Approved as Requested	Proposed LLT Pigtail catheter removal	10090700 Current
			To PT Catheter removal	10052916
<b>MSSO Comment:</b> The proposal to add a new LLT Pigtail catheter removal is approved as requested. Pigtail catheter is a catheter ending in a tightly curled tip that resembles the tail of a pig, it is made of a polymer which can recover the curled shape after being stretched, used to drain fluid from cavities. Pigtail drains must be uncoiled prior to removal. Failure to uncoil a pigtail drain prior to removal can cause severe pain and internal tissue damage to the patient. Pigtail catheter removal will be added as a sub-concept LLT under PT Catheter removal.				
<b>CR Number:</b> 2023342010		<b>Implementation Date:</b> 08-Jan-24	<b>Related CR:</b> 2023342010	
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Haemorrhage intracranial (symptomatic)	Approved Not as Requested	Proposed LLT Symptomatic intracranial haemorrhage	10090678 Current
			To PT Haemorrhage intracranial	10018985
<b>MSSO Comment:</b> The proposal to add a new PT Haemorrhage intracranial (symptomatic) is approved but not as requested. Not every intracranial hemorrhage detected by computed tomography or magnetic resonance imaging worsens neurological symptoms and impairs outcomes. Consequently, intracranial hemorrhages after ischemic stroke and reperfusion therapy are classified by both imaging characteristics and the association with clinical worsening. Mixed radiological-clinical classification adds clinical symptoms to the presence of radiological hemorrhage to classify intracranial hemorrhages as symptomatic or asymptomatic. The proposed term will be modified in accordance with MedDRA naming conventions and added as the LLT Symptomatic intracranial haemorrhage to the PT Haemorrhage intracranial. In a related change, the American spelled counterpart Symptomatic intracranial hemorrhage will also be added as LLT to PT Haemorrhage intracranial.				

# Detail Report

CR Number: 2024008008		Implementation Date: 08-Jan-24	Related CR: 2023342010		
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed LLT	<i>Symptomatic intracranial hemorrhage</i>	Approved as Requested	Proposed LLT		
To PT	<i>Haemorrhage intracranial</i>		<i>Symptomatic intracranial hemorrhage</i>	10090680	Current
			To PT		
			<i>Haemorrhage intracranial</i>	10018985	

MSSO  
Comment:

CR Number: 2023342011		Implementation Date: 08-Jan-24	Related CR: 2023342011		
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed PT	<i>Haemorrhage intracranial (asymptomatic)</i>	Approved Not as Requested	Proposed LLT		
			<i>Asymptomatic intracranial haemorrhage</i>	10090677	Current
			To PT		
			<i>Haemorrhage intracranial</i>	10018985	

MSSO  
Comment: The proposal to add a new PT Haemorrhage intracranial (asymptomatic) is approved but not as requested. Not every intracranial hemorrhage detected by computed tomography or magnetic resonance imaging worsens neurological symptoms and impairs outcomes. Consequently, intracranial hemorrhages after ischemic stroke and reperfusion therapy are classified by both imaging characteristics and the association with clinical worsening. Mixed radiological-clinical classification adds clinical symptoms to the presence of radiological hemorrhage to classify intracranial hemorrhages as symptomatic or asymptomatic. The proposed term will be modified in accordance with MedDRA naming conventions and added as the LLT Asymptomatic intracranial haemorrhage to the PT Haemorrhage intracranial. In a related change, the American spelled counterpart LLT Asymptomatic intracranial hemorrhage will also be added as LLT to PT Haemorrhage intracranial.

CR Number: 2024008009		Implementation Date: 08-Jan-24	Related CR: 2023342011		
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed LLT	<i>Asymptomatic intracranial hemorrhage</i>	Approved as Requested	Proposed LLT		
To PT	<i>Haemorrhage intracranial</i>		<i>Asymptomatic intracranial hemorrhage</i>	10090679	Current
			To PT		
			<i>Haemorrhage intracranial</i>	10018985	

MSSO  
Comment:

# Detail Report

CR Number: 2023345000		Implementation Date: 08-Jan-24	Related CR: 2023345000	
<a href="#">Change Requested</a>	Link (move) an LLT to another PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Facial puffiness	Rejected		
From PT	Swelling face			
To PT	Face oedema			
MSSO Comment:	The proposal to move the LLT Facial puffiness from PT Swelling face to PT Face oedema is not approved. Puffiness is a colloquial expression for swelling (not always due to edema). Therefore current placement is considered more appropriate.			

CR Number: 2023345001		Implementation Date: 22-Jan-24	Related CR: 2023345001	
<a href="#">Change Requested</a>	Link (move) an LLT to another PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	TURBT	Rejected		
From PT	Transurethral bladder resection			
To PT	Bladder neoplasm surgery			
MSSO Comment:	The proposal to move the LLT TURBT from PT Transurethral bladder resection to PT Bladder neoplasm surgery is not approved. The leading concept of this PT is centered around the technical approach which is a very relevant procedure in urology. Any changes would greatly impact legacy data. The same reasoning applies to LLT Transurethral resection of bladder tumour and LLT Transurethral resection of bladder tumor.			

# Detail Report

CR Number: 2023345003		Implementation Date: 09-Jan-24	Related CR: 2023345003	
<a href="#">Change Requested</a>	Link (move) an LLT to another PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Catheter site discomfort	Approved Not as Requested	Proposed LLT	
From PT	Catheter site related reaction		Catheter site discomfort	10054232
To PT	Catheter site pain		From PT	
			Catheter site related reaction	10007811
			HLT primary	
			Implant and catheter site reactions	10021544
			SOC primary	
			General disorders and administration site conditions	10018065
			HLT secondary	
			Implant and catheter site reactions	10021544
			SOC secondary	
			Injury, poisoning and procedural complications	10022117

**MSSO Comment:** The proposal to move the LLT Catheter site discomfort from PT Catheter site related reaction to PT Catheter site pain is approved but not as requested. Discomfort related terms are generally represented at the PT level in MedDRA. For consistency, the LLT Catheter site discomfort will be promoted from PT Catheter site related reaction to a PT level and linked to HLT Implant and catheter site reactions, which is a bi-axial HLT (primary SOC General disorders and administration site conditions and to secondary SOC Injury, poisoning and procedural complications). In a related change, and for the same reason, the LLT Incision site discomfort will also be promoted from PT Incision site complication to a PT level and placed under HLT Non-site specific procedural complications.

# Detail Report

CR Number: 2024009001

Implementation Date: 09-Jan-24

Related CR: 2023345003

Change Requested

Promote an LLT

Final Disposition

Approved as Requested

Final Placement

MedDRA  
Code #

Proposed LLT

*Incision site discomfort*

Proposed LLT

*Incision site discomfort*

10065619

From PT

*Incision site complication*

From PT

*Incision site complication*

10059048

HLT primary

*Non-site specific procedural complications*

HLT primary

*Non-site specific procedural complications*

10029559

SOC primary

*Injury, poisoning and procedural complications*

10022117

MSSO

Comment:

CR Number: 2023346000

Implementation Date: 10-Jan-24

Related CR: 2023346000

Change Requested

Add a New PT

Final Disposition

Approved as Requested

Final Placement

MedDRA  
Code #

Proposed PT

*Testicular hypotrophy*

Proposed PT

*Testicular hypotrophy*

10090707

HLT primary

*Testicular and epididymal disorders NEC*

HLT primary

*Testicular and epididymal disorders NEC*

10043296

SOC primary

*Reproductive system and breast disorders*

SOC primary

*Reproductive system and breast disorders*

10038604

HLT secondary

*Male gonadal function disorders*

10013322

SOC secondary

*Endocrine disorders*

10014698

MSSO

Comment:

The proposal to add a new PT Testicular hypotrophy to primary HLT Testicular and epididymal disorders NEC in SOC Reproductive system and breast disorders is approved as requested. Testicular hypotrophy represents a reversible decrease in testicular volume during the state of hypospermia associated to a medical cause (e.g. varicocele) or when receiving a male hormonal contraceptive treatment. Contrariwise to testicular atrophy (e.g. fibrosis and hyalination of the tubules) the decrease in volume is always reversible when sperm production resumes. The new PT Testicular hypotrophy will be added after reconsideration of the decision taken in change request 2023262004, and will also receive a secondary link to the HLT Male gonadal function disorders.

# Detail Report

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<b>CR Number:</b> 2023346001		<b>Implementation Date:</b> 10-Jan-24	<b>Related CR:</b> 2023346001	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Gemella morbillorum infection</i>	Approved as Requested	Proposed LLT <i>Gemella morbillorum infection</i>	10090709 Current
			To PT <i>Gemella infection</i>	10090708

MSSO  
Comment: The proposal to add a new LLT *Gemella morbillorum* infection is approved as requested. *Gemella morbillorum* is a facultative anaerobic organism and seem to be a normal commensal organism of the upper respiratory tract. Identification of *Gemella* species in the clinical laboratory is difficult because of its close resemblance to *Streptococcus viridans*. *Gemella morbillorum* infection will be added as a LLT and linked under new PT *Gemella infection* added in a related change to HLT Bacterial infections NEC.

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<b>CR Number:</b> 2024010002		<b>Implementation Date:</b> 10-Jan-24	<b>Related CR:</b> 2023346001	
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Gemella infection</i>	Approved as Requested	Proposed PT <i>Gemella infection</i>	10090708
HLT primary	<i>Bacterial infections NEC</i>		HLT primary <i>Bacterial infections NEC</i>	10004047
SOC primary	<i>Infections and infestations</i>		SOC primary <i>Infections and infestations</i>	10021881

MSSO  
Comment:

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<b>CR Number:</b> 2023346002		<b>Implementation Date:</b> 10-Jan-24	<b>Related CR:</b> 2023346002	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Sacroiliac joint pain</i>	Rejected		

MSSO  
Comment: The proposal to add a new term *Sacroiliac joint pain* is not approved. The requested concept can be represented by existing LLT *Sacro-iliac pain* and LLT *Pain sacroiliac* which are both under PT *Sacral pain*.

# Detail Report

CR Number: 2023346003		Implementation Date: 10-Jan-24	Related CR: 2023346003	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	Paraneoplastic polymyalgia rheumatica	Rejected		
MSSO Comment:	The proposal to add a new term Paraneoplastic polymyalgia rheumatica is not approved. The association between malignancy and polymyalgia rheumatica (or the closely associated giant cell arteritis) is uncertain and seems to lack strong supportive evidence to consider it a diagnostic entity. Please review the MedDRA Term Selection: Points to Consider document, Section 3.5.			

CR Number: 2023347000		Implementation Date: 25-Apr-24	Related CR: 2023347000	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Osteochondral lesion of the talus	Approved After Suspension	Proposed LLT Osteochondral lesion of the talus To PT Osteochondral defects	10091030 Current  10072617
MSSO Comment:	The proposal to add a new LLT Osteochondral lesion of the talus is approved as requested after suspension. An osteochondral lesion of the talus is an area of abnormal, damaged cartilage and bone on the top of the talus bone. This condition is also known as osteochondritis dissecans of the talus or a talar osteochondral lesion. Osteochondral lesion of the talus will be added as an LLT to PT Osteochondral defects. In a related change LLT Osteochondral defects will be promoted to PT level under primary HLT Cartilage disorders and secondary HLT Bone and joint injuries NEC.			



# Detail Report

CR Number: 2024116009		Implementation Date: 25-Apr-24	Related CR: 2023347000	
<a href="#">Change Requested</a>	Promote an LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Osteochondral defects</i>	Approved as Requested	Proposed LLT	
From PT	<i>Osteochondrosis</i>		<i>Osteochondral defects</i>	10072617
HLT primary	<i>Cartilage disorders</i>		From PT	
			<i>Osteochondrosis</i>	10031233
			HLT primary	
			<i>Cartilage disorders</i>	10007709
			SOC primary	
			<i>Musculoskeletal and connective tissue disorders</i>	10028395
			HLT secondary	
			<i>Bone and joint injuries NEC</i>	10074485
			SOC secondary	
			<i>Injury, poisoning and procedural complications</i>	10022117

MSSO  
Comment:

CR Number: 2023347001		Implementation Date: 10-Jan-24	Related CR: 2023347001	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>ORIF - Spinopelvic fixation</i>	Approved Not as Requested	Proposed PT	
			<i>Spinopelvic fixation</i>	10090710
			HLT primary	
			<i>Spine and spinal cord therapeutic procedures</i>	10041590
			SOC primary	
			<i>Surgical and medical procedures</i>	10042613

MSSO  
Comment: The proposal to add a new LLT ORIF - Spinopelvic fixation is approved but not as requested. Sacropelvic fixation is indicated in various clinical settings, most notably long spinal arthrodesis, reduction of high-grade spondylolisthesis, and complex sacral fractures. Spinopelvic fixation is an effective method in vertical instability of the pelvis and sacral fractures with spinopelvic dissociations, with good to excellent radiological and functional outcomes. Proposed term will be added as new PT Spinopelvic fixation under HLT Spine and spinal cord therapeutic procedures.

# Detail Report

<b>CR Number: 2023347002</b>		<b>Implementation Date:</b> 10-Jan-24	<b>Related CR:</b> 2023347002	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Duodenal hamartoma</i>	Approved as Requested	Proposed LLT <i>Duodenal hamartoma</i>	10090705 Current
			To PT <i>Benign duodenal neoplasm</i>	10004251
<b>MSSO Comment:</b> The proposal to add a new term Duodenal hamartoma is approved as requested. Brunner's gland hamartoma is an uncommon benign tumor of the duodenum with non-specific clinical manifestations, which has malignant potential with a very low risk of progression into adenocarcinoma. Duodenal hamartoma will be added as an LLT under the PT Benign duodenal neoplasm.				
<b>CR Number: 2023347003</b>		<b>Implementation Date:</b> 10-Jan-24	<b>Related CR:</b> 2023347003	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Ankylenteron</i>	Approved as Requested	Proposed LLT <i>Ankylenteron</i>	10090703 Current
			To PT <i>Abdominal adhesions</i>	10000050
<b>MSSO Comment:</b> The proposal to add a new LLT Ankylenteron is approved as requested. Intestinal adhesion, also called ankylenteron, refers to the abnormal adhesion between intestine and peritoneum, between intestine and abdominal organs caused by various reasons. The clinical symptoms can vary depend on the degree and location of adhesion. Ankylenteron will be added as an LLT to the PT Abdominal adhesions aligned with its existing synonym LLT Intestinal adhesions.				
<b>CR Number: 2023347004</b>		<b>Implementation Date:</b> 10-Jan-24	<b>Related CR:</b> 2023347004	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Aspergillosis serology</i>	Approved Not as Requested	Proposed LLT <i>Aspergillus serology</i>	10090706 Current
			To PT <i>Aspergillus test</i>	10070450
<b>MSSO Comment:</b> The proposal to add a new term Aspergillosis serology is approved but not as requested. Several test options for serologic diagnosis of aspergillus infection exist. These include Aspergillus-specific IgG or IgM detection, as well as Aspergillus galactomannan assay, which detects galactomannan a cell wall component of Aspergillus species. The proposed term will be modified for better alignment to LLT Aspergillus serology under PT Aspergillus test.				

# Detail Report

<b>CR Number:</b> 2023347005		<b>Implementation Date:</b> 10-Jan-24	<b>Related CR:</b> 2023347005	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Percutaneous transluminal septal myocardial ablation</i>	Approved as Requested	Proposed LLT <i>Percutaneous transluminal septal myocardial ablation</i>	10090704
			To PT <i>Alcohol septal ablation</i>	10072744 Current

**MSSO Comment:** The proposal to add a new LLT Percutaneous transluminal septal myocardial ablation is approved as requested. Percutaneous transluminal septal myocardial ablation causes a kind of localised "therapeutic infarction" induced as a result of ethanol injection into a septal perforator artery leading to thinning of the involved septal area, with expansion of the left ventricular outflow tract, and elimination or reduction of systolic anterior movement of the mitral valve and outflow obstruction. After a local remodelling process, the morphologic as well as the haemodynamic result resembles that of a surgical myectomy with a channel like scar in place of the septal bulge. Percutaneous transluminal septal myocardial ablation will be added as an LLT under PT Alcohol septal ablation. In a related change, PT Alcohol septal ablation will be swapped with LLT Percutaneous transluminal septal myocardial ablation.

<b>CR Number:</b> 2024010001		<b>Implementation Date:</b> 10-Jan-24	<b>Related CR:</b> 2023347005	
<a href="#">Change Requested</a>	Swap a PT with an LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Alcohol septal ablation</i>	Approved as Requested	Proposed PT <i>Alcohol septal ablation</i>	10072744 Current
With LLT	<i>Percutaneous transluminal septal myocardial ablation</i>		With LLT <i>Percutaneous transluminal septal myocardial ablation</i>	10090704

**MSSO Comment:**

<b>CR Number:</b> 2023348002		<b>Implementation Date:</b> 09-Jan-24	<b>Related CR:</b> 2023348002	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Egg retrieval</i>	Approved as Requested	Proposed LLT <i>Egg retrieval</i>	10090687 Current
To PT	<i>Oocyte harvest</i>		To PT <i>Oocyte harvest</i>	10051936

**MSSO Comment:** The proposal to add a new LLT Egg retrieval to PT Oocyte harvest is approved as requested. Typically, transvaginal ultrasound aspiration is used for egg retrieval. During this procedure, an ultrasound probe is inserted into the vagina to identify follicles. A needle is guided through the vagina and into the follicles where the eggs are removed from the follicles through the needle.

# Detail Report

CR Number: 2023349000		Implementation Date: 10-Jan-24	Related CR: 2023349000	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	Early branching of renal artery	Approved as Requested	Proposed PT Early branching of renal artery	10090711
			HLT primary Vascular anomalies congenital NEC	10047047
			SOC primary Congenital, familial and genetic disorders	10010331
			HLT secondary Vascular malformations and acquired anomalies	10047091
			SOC secondary Vascular disorders	10047065

MSSO  
Comment: The proposal to add a new term Early branching of renal artery is approved as requested. The renal arteries originate from the abdominal aorta and enter the renal hila to supply the kidneys. Any variant in arterial supply is important to clinicians undertaking surgery or other interventional renal procedures. Early-branching occurs in ~10% of the population and occurs within 1.5-2.0 cm of origin in the left renal artery or in the retrocaval segment of the right renal artery. Early branching of renal artery will be added as a new PT under primary HLT Vascular anomalies congenital NEC and secondary HLT Vascular malformations and acquired anomalies and secondary HLT Renal vascular and ischaemic conditions.

CR Number: 2024010012		Implementation Date: 10-Jan-24	Related CR: 2023349000	
<a href="#">Change Requested</a>	Link a PT to a HLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Early branching of renal artery	Approved as Requested	Proposed PT Early branching of renal artery	10090711
To HLT	Renal vascular and ischaemic conditions		To HLT Renal vascular and ischaemic conditions	10038543

MSSO  
Comment:

# Detail Report

CR Number: 2023352000		Implementation Date: 09-Jan-24	Related CR: 2023352000	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Lymphorrhagia	Approved as Requested	Proposed LLT Lymphorrhagia	10090689 Current
			To PT Lymphorrhoea	10050979
MSSO Comment:	The proposal to add a new LLT Lymphorrhagia is approved as requested. Lymphorrhoea is defined as a flow of lymph from cut or ruptured lymph vessels. Lymphorrhagia will be added as synonym LLT under PT Lymphorrhoea.			

CR Number: 2023352001		Implementation Date: 09-Jan-24	Related CR: 2023352001	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	Acromioclavicular joint arthritis	Approved Not as Requested	Proposed LLT Acromioclavicular joint osteoarthritis	10090690 Current
			To PT Osteoarthritis	10031161
MSSO Comment:	The proposal to add a new term Acromioclavicular joint arthritis is approved but not as requested. The joint formed between the acromion bone and the clavicle is called the acromio-clavicular joint and it can be affected by arthritis, usually wear and tear – type known as osteoarthritis. Proposed term will be modified for greater clarity and more precise representation and added as sub-concept LLT Acromioclavicular joint osteoarthritis under PT Osteoarthritis.			

# Detail Report

<b>CR Number:</b> 2023352002		<b>Implementation Date:</b> 09-Jan-24	<b>Related CR:</b> 2023352002	
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Enterocolic lymphocytic phlebitis</i>	Approved Not as Requested	Proposed PT	
HLT primary	<i>Gastrointestinal necrosis and vascular insufficiency</i>		<i>Enterocolic lymphocytic phlebitis</i>	10090691 Current
SOC primary	<i>Vascular disorders</i>		HLT primary	
			<i>Gastrointestinal inflammatory disorders NEC</i>	10017921
			SOC primary	
			<i>Gastrointestinal disorders</i>	10017947
			HLT secondary	
			<i>Phlebitis NEC</i>	10052780
			SOC secondary	
			<i>Vascular disorders</i>	10047065
<b>MSSO Comment:</b> The proposal to add a new PT Enterocolic lymphocytic phlebitis to primary HLT Gastrointestinal necrosis and vascular insufficiency in SOC Vascular disorders is approved but not as requested. Enterocolic lymphocytic phlebitis is a recently described entity. It is characterized by phlebitis of the bowel wall and mesentery, without arterial involvement or evidence of systemic vasculitis. Features include venous thrombi and acute ischemic changes of the intestine. Enterocolic lymphocytic phlebitis will be added as PT with primary HLT Gastrointestinal inflammatory disorders NEC and secondary HLT Phlebitis NEC.				

<b>CR Number:</b> 2023353000		<b>Implementation Date:</b> 10-Jan-24	<b>Related CR:</b> 2023353000	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Infective bronchiectasis</i>	Approved as Requested	Proposed LLT	
			<i>Infective bronchiectasis</i>	10090712 Current
			To PT	
			<i>Infective exacerbation of bronchiectasis</i>	10070295
<b>MSSO Comment:</b> The proposal to add a new term Infective bronchiectasis is approved as requested. Infective bronchiectasis is a frequently used expression for the medically more correct infective exacerbation of bronchiectasis and will be added as a synonym LLT under PT Infective exacerbation of bronchiectasis.				

# Detail Report

CR Number: 2023353001		Implementation Date: 10-Jan-24	Related CR: 2023353001	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Lower limb fatigue	Rejected		

MSSO Comment: The proposal to add a new LLT Lower limb fatigue is not approved. It is not possible to represent fatigue in every possible anatomical area. Concept may be represented by the broader terms such as LLT/PT Muscle fatigue.

CR Number: 2023353002		Implementation Date: 10-Jan-24	Related CR: 2023353002	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Peripheral nerve hyperexcitability	Approved Not as Requested	Proposed PT Peripheral nerve hyperexcitability	10090713
			HLT primary Neuromuscular disorders NEC	10029318
			SOC primary Nervous system disorders	10029205
			HLT secondary Muscle related signs and symptoms NEC	10028326
			SOC secondary Musculoskeletal and connective tissue disorders	10028395

MSSO Comment: The proposal to add a new LLT Peripheral nerve hyperexcitability is approved but not as requested. Peripheral nerve hyperexcitability is a heterogeneous disorder involving the peripheral nerves. Associated muscle diseases are frequent in the form of myositis, myasthenia gravis, or nonspecific myopathic pathologic findings. Peripheral nerve hyperexcitability will be added as a PT to primary HLT Neuromuscular disorders NEC and to secondary HLT Muscle related signs and symptoms NEC.

# Detail Report

CR Number: 2023353023		Implementation Date: 13-May-24	Related CR: 2023353023	
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Embryo-fetal toxicity	Approved Not as Requested After Suspension	Proposed PT Embryo-foetal toxicity	10091119
			HLT primary Congenital disorders NEC	10010445
			SOC primary Congenital, familial and genetic disorders	10010331
			HLT secondary Foetal and neonatal conditions associated with product exposure	10073321
			SOC secondary Injury, poisoning and procedural complications	10022117

MSSO  
Comment: The proposal to add a new PT Embryo-fetal toxicity is approved but not as requested after suspension. Embryo-fetal toxicity is any morphological or functional alteration caused by chemical or physical agents that interferes with normal growth, homeostasis, development, and differentiation of the embryo-fetus. The proposed term will be modified into the British English spelling and added as new PT Embryo-foetal toxicity to primary HLT Congenital disorders NEC and secondary HLT Foetal and neonatal conditions associated with product exposure and secondary HLT Foetal complications NEC. In a related change the American English spelled counterpart LLT Embryo-fetal toxicity will also be added to PT Embryo-foetal toxicity.

CR Number: 2024134008		Implementation Date: 13-May-24	Related CR: 2023353023	
<a href="#">Change Requested</a>	Link a PT to a HLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Embryo-foetal toxicity	Approved as Requested	Proposed PT Embryo-foetal toxicity	10091119
To HLT	Foetal complications NEC		To HLT Foetal complications NEC	10016850

MSSO  
Comment:



# Detail Report

CR Number: 2024134009		Implementation Date: 13-May-24	Related CR: 2023353023		
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed LLT	Embryo-fetal toxicity	Approved as Requested	Proposed LLT		
To PT	Embryo-foetal toxicity		Embryo-fetal toxicity	10091120	Current
			To PT		
			Embryo-foetal toxicity	10091119	

MSSO  
Comment:

CR Number: 2023353024		Implementation Date: 10-Jan-24	Related CR: 2023353024		
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed PT	Wrong device error	Rejected			

MSSO  
Comment: The proposal to add a new PT Wrong device error is not approved. Proposed term may be represented by existing LLT/PT Wrong device used.

CR Number: 2023354002		Implementation Date: 09-Jan-24	Related CR: 2023354002		
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed LLT	Cardiac myectomy	Rejected			

MSSO  
Comment: The proposal to add a new LLT Cardiac myectomy is not approved. A septal myectomy is an open-heart procedure in which the thickened, overgrown part of septum between the ventricles is removed. Cardiac myectomy refers to a septal myectomy and is represented by existing LLT/PT Septal myectomy.

# Detail Report

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<b>CR Number:</b> 2023354003		<b>Implementation Date:</b> 09-Jan-24	<b>Related CR:</b> 2023354003	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Cockett's procedure</i>	Approved Not as Requested	Proposed LLT <i>Perforator vein surgery</i>	10090688 Current
			To PT <i>Varicose vein operation</i>	10062168
<b>MSSO Comment:</b> The proposal to add a new term Cockett's procedure is approved but not as requested. The management of perforator incompetence of the lower limb veins was modified by Cockett and Dodd's procedure in 1956. It involved an extrafascial or subfascial approach, with a long incision extending almost the whole length of the calf, either medially or posteriorly, with a recommendation that any pre-existing ulcer should also be excised. The eponym proposed represents an outdated procedure rarely found in current literature. The proposed term will be represented by the broader procedure LLT Perforator vein surgery to PT Varicose vein operation.				

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<b>CR Number:</b> 2023354004		<b>Implementation Date:</b> 10-Jan-24	<b>Related CR:</b> 2023354004	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Gastric xanthelasma</i>	Rejected		
<b>MSSO Comment:</b> The proposal to add a new term Gastric xanthelasma is not approved. Gastric xanthomas, also known as "xanthelasmas," are plaque-like red lesions defined by the presence of histiocytic containing lipids. Incidentally, they are discovered during the upper endoscopy of the gastrointestinal tract. Proposed term is already in MedDRA as LLT/PT Gastric xanthoma.				

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<b>CR Number:</b> 2023355000		<b>Implementation Date:</b> 11-Jan-24	<b>Related CR:</b> 2023355000	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Buccopharyngectomy</i>	Approved as Requested	Proposed LLT <i>Buccopharyngectomy</i>	10090714 Current
			To PT <i>Pharyngectomy</i>	10051473
<b>MSSO Comment:</b> The proposal to add a new term Buccopharyngectomy is approved as requested. Buccopharyngectomy is a radical mutilating surgery for head and neck cancers. Buccopharyngectomy will be added as an LLT under PT Pharyngectomy.				

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# Detail Report

<b>CR Number:</b> 2023355001		<b>Implementation Date:</b> 11-Jan-24	<b>Related CR:</b> 2023355001	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Supraclavicular edema</i>	Approved as Requested	Proposed LLT <i>Supraclavicular edema</i>	10090715 Current
			To PT <i>Localised oedema</i>	10048961
<b>MSSO Comment:</b> The proposal to add a new term Supraclavicular edema is approved as requested. Swelling of the left supraclavicular fossa should raise suspicion and may lead to numerous differential diagnoses; some of which include an intermittent cyst in the terminal portion of the thoracic duct, as a reaction to infection or because of metastatic cancer, or a sign of upper extremity deep venous thrombosis. Supraclavicular edema will be added as LLT under PT Localised oedema. In a related change, the British English spelled counterpart LLT Supraclavicular oedema will also be added under PT Localised oedema.				

<b>CR Number:</b> 2024011001		<b>Implementation Date:</b> 11-Jan-24	<b>Related CR:</b> 2023355001	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Supraclavicular oedema</i>	Approved as Requested	Proposed LLT <i>Supraclavicular oedema</i>	10090716 Current
To PT	<i>Localised oedema</i>		To PT <i>Localised oedema</i>	10048961

**MSSO Comment:**

<b>CR Number:</b> 2023360000		<b>Implementation Date:</b> 11-Jan-24	<b>Related CR:</b> 2023360000	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Mesenteric thickening</i>	Approved as Requested	Proposed PT <i>Mesenteric thickening</i>	10090717
			HLT primary <i>Peritoneal and retroperitoneal disorders</i>	10034653
			SOC primary <i>Gastrointestinal disorders</i>	10017947

**MSSO Comment:** The proposal to add a new term Mesenteric thickening is approved as requested. Mesenteric thickening refers to the abnormal thickening of the mesentery, a fold of the peritoneum that attaches the intestines to the abdominal wall. Thickening of the mesentery can be a result of various underlying medical conditions. Mesenteric thickening will be added as a PT under HLT Peritoneal and retroperitoneal disorders.

# Detail Report

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<b>CR Number:</b> 2023361000	<b>Implementation Date:</b> 09-Jan-24	<b>Related CR:</b> 2023361000	<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>
Proposed LLT	CHRONIC RADICULOPATHY	Rejected	

**MSSO Comment:** The proposal to add a new LLT CHRONIC RADICULOPATHY is not approved. Radiculopathy typically occurs when the spinal nerve roots become pinched or damaged, often due to conditions such as herniated discs, spinal stenosis, or degenerative disc disease. The term "chronic" indicates that the symptoms have persisted over an extended period, usually for more than three months. In general, the MSSO refrains from adding new terms with qualifiers "acute" or "chronic", unless "acute" or "chronic" are integral to the universally recognized name of the PT concept, or the term is of particular clinical relevance.

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<b>CR Number:</b> 2023361001	<b>Implementation Date:</b> 09-Jan-24	<b>Related CR:</b> 2023361001	<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>
Proposed LLT	Ascitic fluid culture	Approved as Requested	Proposed LLT Ascitic fluid culture To PT Culture
			10090681 Current 10061447

**MSSO Comment:** The proposal to add a new LLT Ascitic fluid culture is approved as requested. Ascitic fluid culture refers to the process of collecting a sample of ascitic fluid from the peritoneal cavity and cultivating it under controlled conditions to identify and analyze microorganisms present in the fluid. Ascitic fluid culture will be added as sub-concept LLT to PT Culture aligned with LLT Culture peritoneum.

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<b>CR Number:</b> 2023361002	<b>Implementation Date:</b> 11-Jan-24	<b>Related CR:</b> 2023361002	<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>
Proposed Term	Endoscopic Band Ligation	Rejected	

**MSSO Comment:** The proposal to add a new term Endoscopic Band Ligation is not approved. There are several techniques of gastrointestinal ligations in literature. Please specify the context in which you need this term.

# Detail Report

<b>CR Number:</b> 2023361003		<b>Implementation Date:</b> 11-Jan-24	<b>Related CR:</b> 2023361003	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	Neutrophil CD64 expression increased	Approved as Requested	Proposed PT Neutrophil CD64 expression increased	10090718
			HLT primary Cell marker analyses	10072981
			SOC primary Investigations	10022891

**MSSO Comment:** The proposal to add a new term Neutrophil CD64 expression increased is approved as requested. Neutrophil CD64 also known as Fc receptor 1 (FcR1), is a high-affinity receptor present on neutrophils for Fc part of immunoglobulin-G (IgG) heavy chain. Its expression gets strongly upregulated in response to proinflammatory cytokines of infection within 4–6 hours. Neutrophil CD64 expression increased will be added as new PT under HLT Cell marker analyses.

<b>CR Number:</b> 2023361004		<b>Implementation Date:</b> 11-Jan-24	<b>Related CR:</b> 2023361004	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	Neutrophil CD64	Approved Not as Requested	Proposed PT Neutrophil CD64 expression	10090719
			HLT primary Cell marker analyses	10072981
			SOC primary Investigations	10022891

**MSSO Comment:** The proposal to add a new term Neutrophil CD64 is approved but not as requested. Neutrophil CD64 also known as Fc receptor 1 (FcR1), is a high-affinity receptor present on neutrophils for Fc part of immunoglobulin-G (IgG) heavy chain. Its expression gets strongly upregulated in response to proinflammatory cytokines of infection within 4–6 hours. Proposed term will be modified for greater clarity and added as PT Neutrophil CD64 expression under HLT Cell marker analyses.

<b>CR Number:</b> 2023361005		<b>Implementation Date:</b> 11-Jan-24	<b>Related CR:</b> 2023361005	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	FC receptor 1	Approved Not as Requested	Proposed LLT Neutrophil Fc receptor 1 expression	10090720 Current
			To PT Neutrophil CD64 expression	10090719

**MSSO Comment:** The proposal to add a new term FC receptor 1 is approved but not as requested. Neutrophil CD64 also known as Fc receptor 1 (FcR1), is a high-affinity receptor present on neutrophils for Fc part of immunoglobulin-G (IgG) heavy chain. Its expression gets strongly upregulated in response to proinflammatory cytokines of infection within 4–6 hours. Proposed term will be modified for greater clarity as Neutrophil Fc receptor 1 expression and added as synonym LLT under new PT Neutrophil CD64 expression (added in change request 2023361004).

# Detail Report

<b>CR Number:</b> 2023361006		<b>Implementation Date:</b> 11-Jan-24	<b>Related CR:</b> 2023361006	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Fc receptor 1 expression increased</i>	Approved Not as Requested	Proposed LLT <i>Neutrophil Fc receptor 1 expression increased</i>	10090721 Current
			To PT <i>Neutrophil CD64 expression increased</i>	10090718

**MSSO Comment:** The proposal to add a new term Fc receptor 1 expression increased is approved but not as requested. Neutrophil CD64 also known as Fc receptor 1 (FcR1), is a high-affinity receptor present on neutrophils for Fc part of immunoglobulin-G (IgG) heavy chain. Its expression gets strongly upregulated in response to proinflammatory cytokines of infection within 4–6 hours. The proposed term will be modified for clarity and added as LLT Neutrophil Fc receptor 1 expression increased to new PT Neutrophil CD64 expression increased added in change request 2023361003.

<b>CR Number:</b> 2023361007		<b>Implementation Date:</b> 11-Jan-24	<b>Related CR:</b> 2023361007	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>CD14 monocytes increased</i>	Approved as Requested	Proposed LLT <i>CD14 monocytes increased</i>	10090723 Current
			To PT <i>Monocyte count increased</i>	10027880

**MSSO Comment:** The proposal to add a new term CD14 monocytes increased is approved as requested. Monocyte subsets with differing functional properties have been defined by their expression of CD14 and CD16. CD14 is a surface antigen and a key marker used to identify and characterize monocytes. CD14 monocytes increased will be added as a sub-concept LLT to PT Monocyte count increased.

<b>CR Number:</b> 2023361008		<b>Implementation Date:</b> 11-Jan-24	<b>Related CR:</b> 2023361008	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>CD14 monocytes</i>	Approved Not as Requested	Proposed LLT <i>CD14 monocyte count</i>	10090722 Current
			To PT <i>Monocyte count</i>	10027876

**MSSO Comment:** The proposal to add a new term CD14 monocytes is approved but not as requested. Monocyte subsets with differing functional properties have been defined by their expression of CD14 and CD16. CD14 is a surface antigen and a key marker used to identify and characterize monocytes. CD14 monocytes will be renamed for clarity to CD14 monocyte count and added as a sub-concept LLT to PT Monocyte count.

# Detail Report

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<b>CR Number:</b> 2023362000	<b>Implementation Date:</b> 09-Jan-24	<b>Related CR:</b> 2023362000	<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>
Proposed Term	Immunotherapy induced adrenal insufficiency	Rejected	

**MSSO Comment:** The proposal to add a new term Immunotherapy induced adrenal insufficiency is not approved. Adrenal insufficiency, also known as Addison's disease, is a medical condition characterized by the inability of the adrenal glands to produce an adequate amount of the hormones cortisol and, in some cases, aldosterone. Immunotherapy induced adrenal insufficiency is a combination term. In general, the MSSO does not add combination terms including additional "induced" or "due to" terms as because causality is not inherent in the coded term but is instead determined by the reporter/investigator or by the sponsor.

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<b>CR Number:</b> 2023362001	<b>Implementation Date:</b> 09-Jan-24	<b>Related CR:</b> 2023362001	<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>
Proposed LLT	Reversed clock phenomenon	Approved Not as Requested	Proposed PT
			Clock drawing test abnormal
			10090692
			HLT primary
			Neurologic diagnostic procedures
			10029285
			SOC primary
			Investigations
			10022891

**MSSO Comment:** The proposal to add a new LLT Reversed clock phenomenon is approved but not as requested. The Clock Drawing Test is a simple neuropsychometric instrument that can be easily applied to assess several neuropsychiatric functions. The proposed term will be modified to represent a broad investigative finding and added as PT Clock drawing test abnormal to HLT Neurologic diagnostic procedures.

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<b>CR Number:</b> 2023362002	<b>Implementation Date:</b> 09-Jan-24	<b>Related CR:</b> 2023362002	<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>
Proposed Term	Nail Canthoplasty	Rejected	

**MSSO Comment:** The proposal to add a new term Nail Canthoplasty is not approved. Canthoplasty is usually referring to a plastic surgery of the eye with nearly no references to a surgical procedure for ingrown toenails in English literature. The granularity of terms in SOC Surgical and medical procedures is lower than in disorder SOC. Consider to code to a less specific procedure like e.g. Nail operation or Toenail wedge resection depending on the specific situation.

# Detail Report

<b>CR Number: 2023363000</b>		<b>Implementation Date:</b> 09-Jan-24	<b>Related CR:</b> 2023363000	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	UTUC	Approved as Requested	Proposed LLT UTUC	10090694 Current
			To PT Transitional cell cancer of the renal pelvis and ureter	10044407
<b>MSSO Comment:</b> The proposal to add a new LLT UTUC is approved as requested. UTUC the acroynm for LLT Upper tract urothelial carcinoma and will be added to PT Transitional cell cancer of the renal pelvis and ureter. LLT Upper tract urothelial carcinoma was added was in change request 2023363001 to PT Transitional cell cancer of the renal pelvis and ureter.				

<b>CR Number: 2023363001</b>		<b>Implementation Date:</b> 09-Jan-24	<b>Related CR:</b> 2023363001	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Upper Tract Urothelial Carcinoma	Approved Not as Requested	Proposed LLT Upper tract urothelial carcinoma	10090693 Current
			To PT Transitional cell cancer of the renal pelvis and ureter	10044407
<b>MSSO Comment:</b> The proposal to add a new LLT Upper Tract Urothelial Carcinoma is approved but not as requested. Upper tract urothelial carcinoma (UTUC) is a type of cancer that originates in the lining of the urinary tract, specifically in the renal pelvis or ureter. Upper Tract Urothelial Carcinoma will be modified according to MedDRA capitalization rules and added as LLT Upper tract urothelial carcinoma to PT Transitional cell cancer of the renal pelvis and ureter in line with existing LLT Urothelial carcinoma ureter.				

<b>CR Number: 2024001000</b>		<b>Implementation Date:</b> 09-Jan-24	<b>Related CR:</b> 2024001000	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	INVASIVE LUNG FUNGAL INFECTION	Rejected		
<b>MSSO Comment:</b> The proposal to add a new term INVASIVE LUNG FUNGAL INFECTION is not approved. Invasive lung fungal infection refers to a serious condition in which fungi invade and infect the lung tissue, often spreading beyond the respiratory system. The lungs are a common site for fungal infections, particularly in individuals with compromised immune systems or underlying respiratory conditions. The proposed term is a combination term and unspecific with respect to location and pathogen. More specific terms for the location and pathogen are available, e.g. LLT Invasive bronchopulmonary aspergillosis as well as non-specific terms like LLT Invasive mycosis, LLT Lung infection fungal, which can be considered for coding depending on the specific situation.				



# Detail Report

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<b>CR Number:</b> 2024002000	<b>Implementation Date:</b> 09-Jan-24	<b>Related CR:</b> 2024002000	<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>

Proposed LLT	<i>Fractured dental restorative material with loss of material</i>	Rejected
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**MSSO Comment:** The proposal to add a new LLT Fractured dental restorative material with loss of material is not approved. The term describes a complication of tooth restoration. This can occur due to various reasons, including trauma, decay, wear and tear, or a combination of factors. The justification does not describe the specific need for addition of the term. Please consider LLT Dental restoration damage if appropriate.

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<b>CR Number:</b> 2024002001	<b>Implementation Date:</b> 09-Jan-24	<b>Related CR:</b> 2024002001	<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>

Proposed LLT	<i>Tooth Scaling &amp; Root Planing</i>	Approved Not as Requested	Proposed LLT <i>Tooth scaling</i>	10090695 Current
			To PT <i>Dental cleaning</i>	10051047

**MSSO Comment:** The proposal to add a new LLT Tooth Scaling & Root Planing is approved but not as requested. The proposed term represents multiple concepts and will be modified to LLT Tooth scaling and LLT Root planing and both will be added as sub-concepts to PT Dental cleaning.

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<b>CR Number:</b> 2024009002	<b>Implementation Date:</b> 09-Jan-24	<b>Related CR:</b> 2024002001	<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>

Proposed LLT	<i>Root planing</i>	Approved as Requested	Proposed LLT <i>Root planing</i>	10090696 Current
To PT	<i>Dental cleaning</i>		To PT <i>Dental cleaning</i>	10051047

**MSSO Comment:**

# Detail Report

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<b>CR Number:</b> 2024002002		<b>Implementation Date:</b> 09-Jan-24	<b>Related CR:</b> 2024002002	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Amputation fingertip</i>	Approved Not as Requested	Proposed LLT <i>Fingertip traumatic amputation</i>	10090697 Current
			To PT <i>Limb traumatic amputation</i>	10061404
<b>MSSO Comment:</b> The proposal to add a new LLT Amputation fingertip is approved but not as requested. The proposed term will be modified for clarity and added as LLT Fingertip traumatic amputation under PT Limb traumatic amputation.				

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<b>CR Number:</b> 2024002003		<b>Implementation Date:</b> 11-Jan-24	<b>Related CR:</b> 2024002003	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Triple M syndrome</i>	Rejected		
<b>MSSO Comment:</b> The proposal to add a new LLT Triple M syndrome is not approved. Triple M can stand for an emerging overlap syndrome of life-threatening immune-related adverse events, manifesting as a triad of myositis, myocarditis and myasthenia gravis in immune check-point inhibitor (ICI) treated patients. Triple M has been referred to in different contexts in medical literature: e.g. Triple M effect in dental amalgam leakage, triple M trial, triple M chemotherapy. As the term is not descriptive as such and not yet completely established, the MSSO refrains from adding this term at present.				

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<b>CR Number:</b> 2024002004		<b>Implementation Date:</b> 11-Jan-24	<b>Related CR:</b> 2024002004	
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Endogenous endophthalmitis</i>	Approved Not as Requested	Proposed LLT <i>Endogenous endophthalmitis</i>	10090725 Current
			To PT <i>Endophthalmitis</i>	10014801
<b>MSSO Comment:</b> The proposal to add a new PT Endogenous endophthalmitis is approved but not as requested. Endogenous endophthalmitis results from seeding of the eye with pathogens during systemic infection. Endogenous endophthalmitis will be added as LLT to PT Endophthalmitis.				

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# Detail Report

CR Number: 2024002005		Implementation Date: 11-Jan-24	Related CR: 2024002005	
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Myasthenia Gravis-Myositis-Myocarditis syndrome</i>	Approved Not as Requested	Proposed PT	
			<i>Myocarditis-myositis-myasthenia gravis overlap syndrome</i>	10090724
			HLT primary	
			<i>Neuromuscular junction dysfunction</i>	10029320
			SOC primary	
			<i>Nervous system disorders</i>	10029205
			HLT secondary	
			<i>Muscular autoimmune disorders</i>	10003821
			SOC secondary	
			<i>Immune system disorders</i>	10021428

MSSO Comment: The proposal to add a new PT Myasthenia Gravis-Myositis-Myocarditis syndrome is approved but not as requested. Emerging overlap syndrome of life-threatening immune-related adverse events, manifesting as a triad of myositis, myocarditis and myasthenia gravis in immune check-point inhibitor (ICI) treated patients also called triple M syndrome. Myasthenia Gravis-Myositis-Myocarditis syndrome will be modified for MedDRA capitalization rules and to the sequence found most frequently in current literature to Myocarditis-myositis-myasthenia gravis overlap syndrome and added as a new PT linked to primary HLT Neuromuscular junction dysfunction, secondary HLT Muscular autoimmune disorders, secondary HLT Myasthenia gravis and related conditions and secondary HLT Noninfectious myocarditis.

CR Number: 2024011002		Implementation Date: 11-Jan-24	Related CR: 2024002005	
<a href="#">Change Requested</a>	Link a PT to a HLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Myocarditis-myositis-myasthenia gravis overlap syndrome</i>	Approved as Requested	Proposed PT	
			<i>Myocarditis-myositis-myasthenia gravis overlap syndrome</i>	10090724
To HLT	<i>Myasthenia gravis and related conditions</i>		To HLT	
			<i>Myasthenia gravis and related conditions</i>	10071942

MSSO Comment:

# Detail Report

CR Number: 2024011003		Implementation Date: 11-Jan-24	Related CR: 2024002005	
<a href="#">Change Requested</a>	Link a PT to a HLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Myocarditis-myositis-myasthenia gravis overlap syndrome	Approved as Requested	Proposed PT	
			Myocarditis-myositis-myasthenia gravis overlap syndrome	10090724
To HLT	Noninfectious myocarditis		To HLT	
			Noninfectious myocarditis	10029548
MSSO Comment:				

CR Number: 2024002006		Implementation Date: 11-Jan-24	Related CR: 2024002006	
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Multifactorial chylomicronemia syndrome	Approved Not as Requested	Proposed LLT	
			Multifactorial chylomicronemia syndrome	10090727 Current
			To PT	
			Type V hyperlipidaemia	10060755
MSSO Comment: The proposal to add a new PT Multifactorial chylomicronemia syndrome is approved but not as requested. Multifactorial chylomicronemia syndrome (MCS or type V hyperlipoproteinemia) is the most frequent cause of severe hypertriglyceridemia and is associated with an increased risk of acute pancreatitis, cardiovascular disease, and non-alcoholic steatohepatitis. Multifactorial chylomicronemia syndrome will be added as LLT to PT Type V hyperlipidaemia. In a related change, British English spelled counterpart LLT Multifactorial chylomicronaemia syndrome will also be added to PT Type V hyperlipidaemia.				

CR Number: 2024011005		Implementation Date: 11-Jan-24	Related CR: 2024002006	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Multifactorial chylomicronaemia syndrome	Approved as Requested	Proposed LLT	
			Multifactorial chylomicronaemia syndrome	10090728 Current
To PT	Type V hyperlipidaemia		To PT	
			Type V hyperlipidaemia	10060755
MSSO Comment:				

# Detail Report

<b>CR Number:</b> 2024002007		<b>Implementation Date:</b> 11-Jan-24	<b>Related CR:</b> 2024002007	
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Surgically Induced Necrotizing Scleritis</i>	Approved Not as Requested	Proposed LLT <i>Surgically induced necrotizing scleritis</i>	10090726 Current
			To PT <i>Necrotising scleritis</i>	10048851
<b>MSSO Comment:</b> The proposal to add a new PT Surgically Induced Necrotizing Scleritis is approved but not as requested. Surgically Induced Necrotizing Scleritis (SINS) is characterized by necrotizing scleritis following multiple ocular procedures. This most often occurs after multiple ocular surgeries and is believed to be a type IV hypersensitivity reaction. Surgically Induced Necrotizing Scleritis will be modified according to MedDRA capitalization rules and added as LLT Surgically induced necrotizing scleritis to PT Necrotising scleritis. In a related change, the British English spelled LLT Surgically induced necrotising scleritis will also be added to PT Necrotising scleritis.				

<b>CR Number:</b> 2024011004		<b>Implementation Date:</b> 11-Jan-24	<b>Related CR:</b> 2024002007	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Surgically induced necrotising scleritis</i>	Approved as Requested	Proposed LLT <i>Surgically induced necrotising scleritis</i>	10090729 Current
To PT	<i>Necrotising scleritis</i>		To PT <i>Necrotising scleritis</i>	10048851
<b>MSSO Comment:</b>				

<b>CR Number:</b> 2024002008		<b>Implementation Date:</b> 09-Jan-24	<b>Related CR:</b> 2024002008	
<a href="#">Change Requested</a>	Link (move) an LLT to another PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Knee reconstruction</i>	Approved as Requested	Proposed LLT <i>Knee reconstruction</i>	10087261 Current
From PT	<i>Ligament operation</i>		From PT <i>Ligament operation</i>	10065122
To PT	<i>Knee arthroplasty</i>		To PT <i>Knee arthroplasty</i>	10023469
<b>MSSO Comment:</b> The proposal to move the LLT Knee reconstruction from PT Ligament operation to PT Knee arthroplasty is approved as requested. For consistency with other concepts the LLT Knee reconstruction will be moved from PT Ligament operation to PT Knee arthroplasty.				

# Detail Report

CR Number: 2024002009		Implementation Date: 09-Jan-24	Related CR: 2024002009	
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Hads score abnormal</i>	Approved Not as Requested	Proposed LLT <i>HADS score abnormal</i>	10090699 Current
			To PT <i>Hospital anxiety and depression scale abnormal</i>	10090698
MSSO Comment: The proposal to add a new PT Hads score abnormal is approved but not as requested. Hospital Anxiety and Depression Scale (HADS) is a 14-item measure designed to assess anxiety and depression symptoms in medical patients. The proposed term will be modified according to MedDRA capitalization rules and added as LLT HADS score abnormal to a new PT Hospital anxiety and depression scale abnormal, added in a related change, to HLT Psychiatric investigations.				

CR Number: 2024009003		Implementation Date: 09-Jan-24	Related CR: 2024002009	
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Hospital anxiety and depression scale abnormal</i>	Approved as Requested	Proposed PT <i>Hospital anxiety and depression scale abnormal</i>	10090698
HLT primary	<i>Psychiatric investigations</i>		HLT primary <i>Psychiatric investigations</i>	10067226
SOC primary	<i>Investigations</i>		SOC primary <i>Investigations</i>	10022891

MSSO  
Comment:

CR Number: 2024002010		Implementation Date: 09-Jan-24	Related CR: 2024002010	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Occlusive syndrome</i>	Rejected		

MSSO Comment: The proposal to add a new term Occlusive syndrome is not approved. Occlusive syndrome is not exclusively linked to ileus, but can also refer to other pathologies like Aortoiliac occlusive disease, Hepatic sinusoidal obstruction syndrome (SOS), also called veno-occlusive disease (VOD), Follicular occlusion syndrome. The MSSO refrains from adding terms which can be ambiguous.

# Detail Report

<b>CR Number:</b> 2024002011		<b>Implementation Date:</b> 11-Jan-24	<b>Related CR:</b> 2024002011	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	Simple liver cysts	Approved Not as Requested	Proposed LLT Simple liver cyst	10090730 Current
			To PT Hepatic cyst	10019646
<b>MSSO Comment:</b> The proposal to add a new term Simple liver cysts is approved but not as requested. Simple liver cysts are fluid-filled cavities in the liver. Usually, they cause no signs or symptoms and need no treatment. However, they may become large enough to cause pain or discomfort in the upper right part of the abdomen. The proposed term will be modified to its singular form and added as the LL Simple liver cyst to the PT Hepatic cyst.				

<b>CR Number:</b> 2024003000		<b>Implementation Date:</b> 09-Jan-24	<b>Related CR:</b> 2024003000	
<a href="#">Change Requested</a>	Link (move) an LLT to another PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Orthostatic headache	Approved Not as Requested	Proposed LLT Orthostatic headache	10081555
From PT	Post lumbar puncture syndrome		From PT Post lumbar puncture syndrome	10060854
To PT	Headache		HLT primary Headaches NEC	10019233
			SOC primary Nervous system disorders	10029205

**MSSO Comment:** The proposal to move the LLT Orthostatic headache from PT Post lumbar puncture syndrome to PT Headache is approved but not as requested. Orthostatic headache refers to a type of headache that occurs or worsens when a person is in an upright or standing position and improves when lying down. There are several potential reasons for orthostatic headaches, and they may be associated with various underlying medical conditions. LLT Orthostatic headache will be promoted from PT Post lumbar puncture syndrome to PT level and linked to HLT Headaches NEC.

<b>CR Number:</b> 2024003001		<b>Implementation Date:</b> 09-Jan-24	<b>Related CR:</b> 2024003001	
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Morphological changes in corneal endothelial cell	Rejected		
HLT primary	Corneal disorders NEC			
SOC primary	Eye disorders			

**MSSO Comment:** The proposal to add a new PT Morphological changes in corneal endothelial cell to primary HLT Corneal disorders NEC in SOC Eye disorders is not approved. Morphological changes in corneal endothelial cell is an unspecific description of histopathology/specialized imaging findings in a specific cell type, which do not directly lead to a pathologic diagnosis. It is not possible to accommodate terms for all possible results of imaging studied or histopathology findings in MedDRA. MedDRA cannot represent a high level of granularity for imaging and histopathologic findings.

# Detail Report

CR Number: 2024003002		Implementation Date: 11-Jan-24	Related CR: 2024003002	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Anterior cutaneous nerve entrapment syndrome</i>	Approved as Requested	Proposed PT	
			<i>Anterior cutaneous nerve entrapment syndrome</i>	10090731
			HLT primary	
			<i>Peripheral neuropathies NEC</i>	10034607
			SOC primary	
			<i>Nervous system disorders</i>	10029205
			HLT secondary	
			<i>Nerve injuries NEC</i>	10052639
			SOC secondary	
			<i>Injury, poisoning and procedural complications</i>	10022117

**MSSO Comment:** The proposal to add a new term Anterior cutaneous nerve entrapment syndrome is approved as requested. Anterior cutaneous nerve entrapment syndrome is one of the most frequent causes of abdominal pain in adults and children. The condition occurs when nerves within the abdominal wall — the anterior cutaneous abdominal nerves — become pinched or entrapped within the abdominal wall muscle. Anterior cutaneous nerve entrapment syndrome will be added as new PT under primary HLT Peripheral neuropathies NEC and secondary HLT Nerve injuries NEC.

CR Number: 2024004000		Implementation Date: 09-Jan-24	Related CR: 2024004000	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Undetectable serum magnesium</i>	Rejected		

**MSSO Comment:** The proposal to add a new LLT Undetectable serum magnesium is not approved. Typically, only PTs representing investigation procedures and qualitative results (e.g., increased/decreased, normal/abnormal) appear in SOC Investigations are represented for laboratory values of a lab test. Other qualifiers used in SOC Investigations are “normal,” “present,” or “absent” for descriptive laboratory tests, “positive” or “negative” for qualitative, “prolonged,” or “shortened” for tests measured in time, and “toxic,” “therapeutic,” or “subtherapeutic” for drug level monitoring tests. It is not possible to represent a “undetectable” qualifier for every lab test.



# Detail Report

CR Number: 2024004001		Implementation Date: 11-Jan-24	Related CR: 2024004001	
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Vaginal leiomyoma</i>	Approved as Requested	Proposed PT	
HLT primary	<i>Vaginal neoplasms benign</i>		<i>Vaginal leiomyoma</i>	10090732
SOC primary	<i>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</i>		HLT primary	
			<i>Vaginal neoplasms benign</i>	10046934
			SOC primary	
			<i>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</i>	10029104
			HLT secondary	
			<i>Vulvovaginal cysts and neoplasms</i>	10047785
			SOC secondary	
			<i>Reproductive system and breast disorders</i>	10038604

**MSSO Comment:** The proposal to add a new PT Vaginal leiomyoma to primary HLT Vaginal neoplasms benign in SOC Neoplasms benign, malignant and unspecified (incl cysts and polyps) is approved as requested. Leiomyomas are common benign tumors in the uterus. However, vaginal leiomyomas remain an uncommon entity with only about 300 reported cases. They may present with a variety of clinical features and may be mistaken preoperatively for cervical fibroid. PT Vaginal leiomyoma will also be linked to secondary HLT Vulvovaginal cysts and neoplasms.

CR Number: 2024005000		Implementation Date: 11-Jan-24	Related CR: 2024005000	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Pelvic floor muscle spasm</i>	Approved as Requested	Proposed LLT	
			<i>Pelvic floor muscle spasm</i>	10090733 Current
			To PT	
			<i>Pelvic floor dysfunction</i>	10083246

**MSSO Comment:** The proposal to add a new LLT Pelvic floor muscle spasm is approved as requested. Hypertonic pelvic floor is a condition where the muscles in the lower pelvis are in a spasm or state of constant contraction. This can be temporary or constant. Pelvic floor muscle spasm will be added as LLT to PT Pelvic floor dysfunction in alignment with its quasi-synonym LLT Pelvic floor muscle hypertonicity.

# Detail Report

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<b>CR Number:</b> 2024005001		<b>Implementation Date:</b> 15-Jan-24	<b>Related CR:</b> 2024005001	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Cameron erosions</i>	Approved Not as Requested	Proposed LLT <i>Cameron erosion</i>	10090747 Current
			To PT <i>Gastritis erosive</i>	10017865

**MSSO Comment:** The proposal to add a new term Cameron erosions is approved but not as requested. Cameron erosions are linear erosions or ulcerations of the mucosal folds lining the stomach where it is constricted by the thoracic diaphragm in persons with large hiatal hernias. The proposed term will be modified to the singular form and added as LLT Cameron erosion to PT Gastritis erosive.

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<b>CR Number:</b> 2024005002		<b>Implementation Date:</b> 15-Jan-24	<b>Related CR:</b> 2024005002	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Ewart's sign</i>	Approved as Requested	Proposed PT <i>Ewart's sign</i>	10090743
			HLT primary <i>Pericardial disorders NEC</i>	10034469
			SOC primary <i>Cardiac disorders</i>	10007541
			HLT secondary <i>Parenchymal lung disorders NEC</i>	10033979
			SOC secondary <i>Respiratory, thoracic and mediastinal disorders</i>	10038738

**MSSO Comment:** The proposal to add a new term Ewart's sign is approved as requested. Ewart's sign refers to the dullness to percussion in the left lower lung field from the atelectasis caused by a large pericardial effusion compressing the lung. Ewart's sign will be added as PT with a primary link to HLT Pericardial disorders NEC and a secondary link to HLT Parenchymal lung disorders NEC.

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# Detail Report

CR Number: 2024005003		Implementation Date: 15-Jan-24	Related CR: 2024005003	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Intestinal methanogenic overgrowth</i>	Approved as Requested	Proposed LLT <i>Intestinal methanogenic overgrowth</i>	10090746 Current
			To PT <i>Gastrointestinal microorganism overgrowth</i>	10090744
MSSO Comment:	The proposal to add a new term Intestinal methanogenic overgrowth is approved as requested. Intestinal methanogenic overgrowth is a newer term to characterize an overgrowth of archaea throughout the intestinal tract. Archaea and bacteria are both domains of single-celled microorganisms, but they differ in terms of their genetic, biochemical, and structural characteristics. Intestinal methanogenic overgrowth will be added as an LLT to a new PT Gastrointestinal microorganism overgrowth, which will be added with a primary link to HLT Infections NEC and a secondary link to HLT Gastrointestinal infections, site unspecified. In a related change, PT Gastrointestinal bacterial overgrowth will be demoted under the new PT Gastrointestinal microorganism overgrowth.			

CR Number: 2024015004		Implementation Date: 15-Jan-24	Related CR: 2024005003	
<a href="#">Change Requested</a>	Demote a PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
PT to merge	<i>Gastrointestinal bacterial overgrowth</i>	Approved as Requested	PT to merge <i>Gastrointestinal bacterial overgrowth</i>	10078158 Current
To PT	<i>Gastrointestinal microorganism overgrowth</i>		To PT <i>Gastrointestinal microorganism overgrowth</i>	10090744
MSSO Comment:				

# Detail Report

CR Number: 2024015003		Implementation Date: 15-Jan-24	Related CR: 2024005003	
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Gastrointestinal microorganism overgrowth	Approved as Requested	Proposed PT	
HLT primary	Infections NEC		Gastrointestinal microorganism overgrowth	10090744
SOC primary	Infections and infestations		HLT primary	
			Infections NEC	10021902
			SOC primary	
			Infections and infestations	10021881
			HLT secondary	
			Gastrointestinal infections, site unspecified	10017968
			SOC secondary	
			Gastrointestinal disorders	10017947

MSSO  
Comment:

CR Number: 2024005004		Implementation Date: 15-Jan-24	Related CR: 2024005004	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	Atticoantrostomy	Approved as Requested	Proposed LLT	
			Atticoantrostomy	10090745 Current
			To PT	
			Atticotomy	10074670

MSSO  
Comment: The proposal to add a new term Atticoantrostomy is approved as requested. Atticotomy is used for disease that is limited to the attic (epitympanum) and involves the removal of the outer attic wall. When additional opening of the mastoid antrum is needed the procedure is named as atticoantrostomy. Atticoantrostomy will be added as sub-element LLT to PT Atticotomy.

# Detail Report

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<b>CR Number:</b> 2024005154		<b>Implementation Date:</b> 11-Jan-24	<b>Related CR:</b> 2024005154	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	MASTOID INFLAMMATION	Approved Not as Requested	Proposed LLT Mastoid inflammation	10090734 Current
			To PT Noninfective mastoiditis	10086116

**MSSO Comment:** The proposal to add a new LLT MASTOID INFLAMMATION is approved but not as requested. Mastoid inflammation generally refers to the inflammation of the mastoid process. There are some non-infectious factors that can contribute to inflammation in the mastoid process. MASTOID INFLAMMATION will be modified for MedDRA capitalization rules and added as LLT Mastoid inflammation linked to PT Noninfective mastoiditis.

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<b>CR Number:</b> 2024005155		<b>Implementation Date:</b> 11-Jan-24	<b>Related CR:</b> 2024005155	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	RASopathy	Rejected		

**MSSO Comment:** The proposal to add a new LLT RASopathy is not approved. The RASopathies are a clinically defined group of medical genetic syndromes caused by germline mutations in genes that encode components or regulators of the Ras/mitogen-activated protein kinase (MAPK) pathway. RASopathy is not a single clinical entity but a grouping term and therefore does not fulfil the criteria for addition to MedDRA.

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<b>CR Number:</b> 2024005156		<b>Implementation Date:</b> 11-Jan-24	<b>Related CR:</b> 2024005156	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Hemoglobin H-constant spring disease	Approved as Requested	Proposed LLT Hemoglobin H-constant spring disease	10090736 Current
			To PT Thalassaemia alpha	10043390

**MSSO Comment:** The proposal to add a new LLT Hemoglobin H-constant spring disease is approved as requested. Hemoglobin H-Constant Spring is a specific mutation associated with alpha thalassemia, which affects the synthesis of alpha globin chains in hemoglobin. Hemoglobin H-Constant Spring disease is caused by a nondeletional mutation in the alpha-globin gene, leading to the production of an abnormal hemoglobin variant known as Hemoglobin H-Constant Spring. Hemoglobin H-constant spring disease will be added as LLT to PT Thalassaemia alpha. In a related change, British English spelled counterpart Haemoglobin H-constant spring disease will also be added as LLT to PT Thalassaemia alpha.

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# Detail Report

CR Number: 2024011006		Implementation Date: 11-Jan-24	Related CR: 2024005156		
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed LLT	Haemoglobin H-constant spring disease	Approved as Requested	Proposed LLT		
To PT	Thalassaemia alpha		Haemoglobin H-constant spring disease	10090738	Current
			To PT		
			Thalassaemia alpha	10043390	

MSSO  
Comment:

CR Number: 2024005157		Implementation Date: 11-Jan-24	Related CR: 2024005157		
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed LLT	CardioMEMS monitoring	Approved Not as Requested	Proposed LLT		
			Ambulatory pulmonary artery pressure monitoring	10090737	Current
			To PT		
			Pulmonary arterial pressure	10060196	

MSSO  
Comment: The proposal to add a new LLT CardioMEMS monitoring is approved but not as requested. CardioMEMS™ is a trademark of a device for monitoring advanced heart failure. Trademark names are not added as MedDRA terms. The proposed term will be modified as a general medical investigative term and added as LLT Ambulatory pulmonary artery pressure monitoring to PT Pulmonary arterial pressure.

CR Number: 2024005158		Implementation Date: 11-Jan-24	Related CR: 2024005158		
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed LLT	Cytofluorometry	Approved as Requested	Proposed LLT		
			Cytofluorometry	10090735	Current
			To PT		
			Flow cytometry	10065440	

MSSO  
Comment: The proposal to add a new LLT Cytofluorometry is approved as requested. Cytofluorometry is a technique used to analyze and quantify the physical and chemical characteristics of cells or particles in a fluid suspension. Cytofluorometry will be added as an LLT to PT Flow cytometry.

# Detail Report

CR Number: 2024007000		Implementation Date: 11-Jan-24	Related CR: 2024007000	
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Splenic sarcoidosis</i>	Approved as Requested	Proposed PT	
HLT primary	<i>Spleen disorders</i>		<i>Splenic sarcoidosis</i>	10090740
SOC primary	<i>Blood and lymphatic system disorders</i>		HLT primary	
			<i>Spleen disorders</i>	10041635
			SOC primary	
			<i>Blood and lymphatic system disorders</i>	10005329
			HLT secondary	
			<i>Acute and chronic sarcoidosis</i>	10039487
			SOC secondary	
			<i>Immune system disorders</i>	10021428

**MSSO Comment:** The proposal to add a new PT Splenic sarcoidosis to primary HLT Spleen disorders in SOC Blood and lymphatic system disorders is approved as requested. Sarcoidosis is a multisystem inflammatory disorder characterized by the formation of granulomas in various organs throughout the body. In splenic sarcoidosis, granulomas can form in the spleen, leading to enlargement and potential dysfunction of the organ. The symptoms of splenic sarcoidosis may vary and can include abdominal pain, discomfort, or fullness. Splenic sarcoidosis will be added as a PT to primary HLT Spleen disorders and secondary HLT Acute and chronic sarcoidosis.

CR Number: 2024007001		Implementation Date: 11-Jan-24	Related CR: 2024007001	
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>MUTYH-associated polyposis</i>	Approved as Requested	Proposed PT	
HLT primary	<i>Intestinal disorders congenital</i>		<i>MUTYH-associated polyposis</i>	10090739
SOC primary	<i>Congenital, familial and genetic disorders</i>		HLT primary	
			<i>Intestinal disorders congenital</i>	10022646
			SOC primary	
			<i>Congenital, familial and genetic disorders</i>	10010331
			HLT secondary	
			<i>Gastrointestinal neoplasms NEC</i>	10017993
			SOC secondary	
			<i>Gastrointestinal disorders</i>	10017947

**MSSO Comment:** The proposal to add a new PT MUTYH-associated polyposis to primary HLT Intestinal disorders congenital in SOC Congenital, familial and genetic disorders is approved as requested. MUTYH-associated polyposis is an autosomal recessive polyposis syndrome caused by biallelic pathogenic germline variants in the MUTYH gene. Affected patients have multiple colorectal adenomas and an increased risk for developing colorectal cancer. MUTYH-associated polyposis will be added as PT with primary HLT Intestinal disorders congenital, secondary HLT Gastrointestinal neoplasms NEC and secondary HLT Colorectal and anal neoplasms malignancy unspecified.

# Detail Report

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<b>CR Number:</b> 2024011007		<b>Implementation Date:</b> 11-Jan-24	<b>Related CR:</b> 2024007001	
<u>Change Requested</u>	Link a PT to a HLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>MUTYH-associated polyposis</i>	Approved as Requested	Proposed PT	
To HLT	<i>Colorectal and anal neoplasms malignancy unspecified</i>		<i>MUTYH-associated polyposis</i>	10090739
			To HLT	
			<i>Colorectal and anal neoplasms malignancy unspecified</i>	10010039

MSSO  
Comment:

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<b>CR Number:</b> 2024007002		<b>Implementation Date:</b> 11-Jan-24	<b>Related CR:</b> 2024007002	
<u>Change Requested</u>	Add a New PT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Breast transillumination</i>	Approved as Requested	Proposed PT	
HLT primary	<i>Reproductive organ and breast imaging procedures</i>		<i>Breast transillumination</i>	10090742
SOC primary	<i>Investigations</i>		HLT primary	
			<i>Reproductive organ and breast imaging procedures</i>	10038602
			SOC primary	
			<i>Investigations</i>	10022891

MSSO  
Comment: The proposal to add a new PT Breast transillumination to primary HLT Reproductive organ and breast imaging procedures in SOC Investigations is approved as requested. Breast transillumination is a medical technique used to examine the breast tissue by shining light through it. This method is primarily employed to assess the characteristics of breast masses or lesions, particularly in the context of breast cancer screening. Transillumination can help differentiate between solid and fluid-filled masses within the breast. Breast transillumination will be added as PT to HLT Reproductive organ and breast imaging procedures.

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# Detail Report

CR Number: 2024007003		Implementation Date: 11-Jan-24	Related CR: 2024007003	
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Rauch-Steindl syndrome</i>	Approved Not as Requested	Proposed PT	
HLT primary	<i>Autosomal chromosomal abnormalities</i>		<i>Rauch-Steindl syndrome</i>	10090741
SOC primary	<i>Congenital, familial and genetic disorders</i>		HLT primary	
			<i>Musculoskeletal disorders congenital NEC</i>	10029513
			SOC primary	
			<i>Congenital, familial and genetic disorders</i>	10010331
			HLT secondary	
			<i>Musculoskeletal disorders congenital NEC</i>	10029513
			SOC secondary	
			<i>Musculoskeletal and connective tissue disorders</i>	10028395

MSSO Comment: The proposal to add a new PT Rauch-Steindl syndrome to primary HLT Autosomal chromosomal abnormalities in SOC Congenital, familial and genetic disorders is approved but not as requested. Rauch-Steindl syndrome is characterized by poor pre- and postnatal growth, sometimes with short stature and small head circumference, characteristic dysmorphic facial features, and variable developmental delay with delayed motor and speech acquisition and impaired intellectual function that can be mild. Other features may include hypotonia and behavioral abnormalities. Rauch-Steindl syndrome will be added as the clinically more severe form Wolf-Hirschhorn syndrome as a PT to bi-axial primary HLT Musculoskeletal disorders congenital NEC (primary SOC Congenital, familial and genetic disorders and secondary SOC Musculoskeletal and connective tissue disorders), and to secondary HLT Intellectual disabilities. In a related change, PT Wolf-Hirschhorn syndrome will be unlinked from HLT Musculoskeletal and connective tissue deformities of skull, face and buccal cavity. Then primary HLT for PT Wolf-Hirschhorn syndrome will be re-assigned from HLT Autosomal chromosomal abnormalities to HLT Musculoskeletal disorders congenital NEC.

CR Number: 2024011008		Implementation Date: 11-Jan-24	Related CR: 2024007003	
<a href="#">Change Requested</a>	Link a PT to a HLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Rauch-Steindl syndrome</i>	Approved as Requested	Proposed PT	
To HLT	<i>Intellectual disabilities</i>		<i>Rauch-Steindl syndrome</i>	10090741
			To HLT	
			<i>Intellectual disabilities</i>	10077548

MSSO Comment:

# Detail Report

CR Number: 2024011009		Implementation Date: 11-Jan-24	Related CR: 2024007003	
<a href="#">Change Requested</a>	Link (move) a PT to another HLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Wolf-Hirschhorn syndrome	Approved as Requested	Proposed PT	
From HLT	Autosomal chromosomal abnormalities		Wolf-Hirschhorn syndrome	10050361
To HLT	Musculoskeletal disorders congenital NEC		From HLT	
			Autosomal chromosomal abnormalities	10003842
			To HLT	
			Musculoskeletal disorders congenital NEC	10029513
MSSO Comment:				

<b>CR Number:</b> 2024011010		<b>Implementation Date:</b> 11-Jan-24	<b>Related CR:</b> 2024007003	
<a href="#">Change Requested</a>	Unlink a PT from a HLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Wolf-Hirschhorn syndrome</i>	Approved as Requested	Proposed PT	
From HLT	<i>Musculoskeletal and connective tissue deformities of skull, face and buccal cavity</i>		<i>Wolf-Hirschhorn syndrome</i>	10050361
			From HLT	
			<i>Musculoskeletal and connective tissue deformities of skull, face and buccal cavity</i>	10028378
MSSO Comment:				

# Detail Report

CR Number: 2024007004		Implementation Date: 15-Jan-24	Related CR: 2024007004	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Residual volume increased</i>	Approved Not as Requested	Proposed PT	
			<i>Pulmonary residual volume increased</i>	10090748
			HLT primary	
			<i>Respiratory and pulmonary function diagnostic procedures</i>	10037385
			SOC primary	
			<i>Investigations</i>	10022891

**MSSO Comment:** The proposal to add a new term Residual volume increased is approved but not as requested. Pulmonary residual volume refers to the volume of gas remaining in the lung after maximal exhalation. In obstructive lung disease, inflammation and decreased elastic recoil cause increased airway resistance and lead to premature small airway closure during expiration. As a result, excess air is trapped and left in the lung after you breathe, leading to an increase in residual volume. The proposed term will be modified for clarity and added as PT Pulmonary residual volume increased to HLT Respiratory and pulmonary function diagnostic procedures.

CR Number: 2024008000		Implementation Date: 15-Jan-24	Related CR: 2024008000	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Lines of Blaschko</i>	Approved Not as Requested	Proposed PT	
To PT	<i>Skin hypopigmentation</i>		<i>Visible Blaschko lines</i>	10090749
			HLT primary	
			<i>Pigmentation changes NEC</i>	10035021
			SOC primary	
			<i>Skin and subcutaneous tissue disorders</i>	10040785

**MSSO Comment:** The proposal to add a new LLT Lines of Blaschko to PT Skin hypopigmentation is approved but not as requested. The Lines of Blaschko are normally invisible but may present like patterns of lines or patches showing both hypo or hyperpigmentation in some skin conditions. Blaschko lines are thought to represent pathways of epidermal cell migration and proliferation during the development of the fetus. The proposed term will be modified to the more usual syntax and added as PT Visible Blaschko lines to HLT Pigmentation changes NEC.

# Detail Report

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<b>CR Number:</b> 2024008001		<b>Implementation Date:</b> 31-May-24	<b>Related CR:</b> 2024008001		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed LLT	<i>Epididymis inflammation</i>	Rejected After Suspension			
To PT	<i>noninfective Epididymitis</i>				

**MSSO Comment:** The proposal to add a new LLT Epididymis inflammation to PT noninfective Epididymitis is not approved after suspension. Based on the MedDRA Introductory guide section 6.11.2:Terms ending with “-itis” are linked to SOC Infections and infestations only if they most frequently represent infectious conditions. Those terms that most frequently represent inflammatory conditions are linked to their corresponding site of manifestation SOC without a primary link to SOC Infections and infestations. Epididymitis is generally often caused by a bacterial or sexually transmitted infection and therefore the unqualified PT Epididymitis is linked to SOC Infections and infestations. For scenarios, when there is no associated infection in epididymitis, there is the option to use PT Noninfective epididymitis.

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<b>CR Number:</b> 2024009000		<b>Implementation Date:</b> 15-Jan-24	<b>Related CR:</b> 2024009000		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed Term	<i>Utilization behavior</i>	Approved as Requested	Proposed LLT		
			<i>Utilization behavior</i>	10090751	Current
			To PT		
			<i>Utilisation behaviour</i>	10090750	

**MSSO Comment:** The proposal to add a new term Utilization behavior is approved as requested. Utilization behavior is a type of neurobehavioral phenomena that involves someone grabbing objects in view and starting the 'appropriate' behavior associated with it at an 'inappropriate' time. Patients exhibiting utilization behavior have difficulty resisting the impulse to operate or manipulate objects which are in their visual field and within reach. Utilization behavior will be added as an LLT under the British English spelled PT Utilisation behaviour under primary HLT Cortical dysfunction NEC and secondary HLT Specific cognitive ability disturbances.

# Detail Report

CR Number: 2024015005		Implementation Date: 15-Jan-24	Related CR: 2024009000	
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Utilisation behaviour	Approved as Requested	Proposed PT	
HLT primary	Cortical dysfunction NEC		Utilisation behaviour	10090750
SOC primary	Nervous system disorders		HLT primary	
			Cortical dysfunction NEC	10011168
			SOC primary	
			Nervous system disorders	10029205
			HLT secondary	
			Specific cognitive ability disturbances	10041427
			SOC secondary	
			Psychiatric disorders	10037175

MSSO  
Comment:

CR Number: 2024009004		Implementation Date: 15-Jan-24	Related CR: 2024009004	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	Nail bed redness	Rejected		

MSSO  
Comment: The proposal to add a new term Nail bed redness is not approved. To avoid overpopulation of MedDRA it is not possible to have a redness term for every possible anatomic location.

CR Number: 2024010000		Implementation Date: 15-Jan-24	Related CR: 2024010000	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	Abelchia	Rejected		

MSSO  
Comment: The proposal to add a new term Abelchia is not approved. The proposed concept may be represented with existing term LLT Retrograde cricopharyngeal dysfunction defined as the abnormal retrograde function of the upper esophageal sphincter, which does not relax to permit eructation, recently added in changer request 2023275002.

# Detail Report

CR Number: 2024010013		Implementation Date: 15-Jan-24	Related CR: 2024010013	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Chlamydial bronchitis</i>	Approved as Requested	Proposed PT <i>Chlamydial bronchitis</i>	10090752
			HLT primary <i>Chlamydial infections</i>	10008561
			SOC primary <i>Infections and infestations</i>	10021881
			HLT secondary <i>Bacterial lower respiratory tract infections</i>	10004048
			SOC secondary <i>Respiratory, thoracic and mediastinal disorders</i>	10038738
MSSO Comment:	The proposal to add a new term Chlamydial bronchitis is approved as requested. Chlamydia pneumoniae is involved in a wide spectrum of respiratory infections of the lower respiratory tract, such as acute bronchitis, exacerbations of chronic bronchitis, asthma and community acquired pneumonia, in both immunocompetent and immunocompromised hosts. Chlamydial bronchitis will be added as PT with a primary link to HLT Chlamydial infections and a secondary link to HLT Bacterial lower respiratory tract infections.			

CR Number: 2024010014		Implementation Date: 15-Jan-24	Related CR: 2024010014	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Left ventricular wall motion abnormality</i>	Rejected		
MSSO Comment:	The proposal to add a new LLT Left ventricular wall motion abnormality is not approved. The proposed term represents a grouping term. Cardiac wall motion abnormalities describe kinetic alterations in the cardiac wall motion during the cardiac cycle and have an effect on cardiac function. Normal heart contraction involves coordinated movement of the heart muscle, ensuring effective blood ejection with each heartbeat. Please consider related concepts as LLT/PT Ventricular dyskinesia.			

# Detail Report

<b>CR Number:</b> 2024011000		<b>Implementation Date:</b> 21-Jan-24	<b>Related CR:</b> 2024011000	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Pleural empyema</i>	Approved as Requested	Proposed LLT <i>Pleural empyema</i>	10090758 Current
			To PT <i>Infectious pleural effusion</i>	10071699
<b>MSSO Comment:</b> The proposal to add a new term Pleural empyema is approved as requested. Pleural empyema is defined as a collection of pus in the pleural cavity or culture from the pleural fluid. Pleural empyema will be added as LLT under PT Infectious pleural effusion.				

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<b>CR Number:</b> 2024012000		<b>Implementation Date:</b> 22-Jan-24	<b>Related CR:</b> 2024012000	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Corneal Punctate epitheliopathy</i>	Approved Not as Requested	Proposed LLT <i>Corneal punctate epitheliopathy</i>	10090753 Current
			To PT <i>Punctate keratitis</i>	10037508
<b>MSSO Comment:</b> The proposal to add a new term Corneal Punctate epitheliopathy is approved but not as requested. Corneal punctate epitheliopathy is corneal inflammation of diverse causes characterized by scattered, fine, punctate corneal epithelial loss or damage. Symptoms are redness, lacrimation, photophobia, and slightly decreased vision. The proposed term is a synonym of LLT Superficial punctate keratitis and, once modified in accordance with MedDRA capitalization conventions, will be added as LLT Corneal punctate epitheliopathy to PT Punctate keratitis.				

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<b>CR Number:</b> 2024012001		<b>Implementation Date:</b> 22-Jan-24	<b>Related CR:</b> 2024012001	
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Morphological change in corneal endothelial cell</i>	Approved Not as Requested	Proposed LLT <i>Pleomorphism of corneal endothelium</i>	10090759 Current
HLT primary	<i>Corneal disorders NEC</i>		To PT <i>Corneal endothelial disorder</i>	10066970
SOC primary	<i>Eye disorders</i>			
<b>MSSO Comment:</b> The proposal to add a new PT Morphological change in corneal endothelial cell to primary HLT Corneal disorders NEC in SOC Eye disorders is approved but not as requested. The endothelial monolayer comprises of cells that are hexagonal. Six-sided cellular arrangement of the cells is the most energy-efficient polygonal geometric shape. The human corneal endothelium does not regenerate. The endothelial health is interpreted with parameters such as percentage of hexagonal endothelial cells, coefficient of variation of cell area, and endothelial cell density. An increase in the variability of cell area is termed as polymegathism. A deviation from hexagonality is referred to as pleomorphism. The proposed term will be modified to the more specific Pleomorphism of corneal endothelium and will be added as an LLT to new PT Corneal endothelial disorder. In a related change LLT Corneal endothelial disorder will be promoted from PT Corneal disorder to PT level and placed under HLT Corneal structural change, deposit and degeneration. In addition, the related LLT Corneal endothelial polymegathism will be moved from PT Corneal disorder to new PT Corneal endothelial disorder for better alignment.				

# Detail Report

CR Number: 2024022012		Implementation Date: 22-Jan-24	Related CR: 2024012001	
<a href="#">Change Requested</a>	Link (move) an LLT to another PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Corneal endothelial polymegathism	Approved as Requested	Proposed LLT	10085736 Current
From PT	Corneal disorder		Corneal endothelial polymegathism	
To PT	Corneal endothelial disorder		From PT	10061453
			Corneal disorder	
			To PT	10066970
			Corneal endothelial disorder	
MSSO Comment:				

CR Number: 2024022011		Implementation Date: 22-Jan-24	Related CR: 2024012001	
<a href="#">Change Requested</a>	Promote an LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Corneal endothelial disorder</i>	Approved as Requested	Proposed LLT	10066970
From PT	<i>Corneal disorder</i>		<i>Corneal endothelial disorder</i>	
HLT primary	<i>Corneal structural change, deposit and degeneration</i>		From PT	10061453
			<i>Corneal disorder</i>	
			HLT primary	10011049
			<i>Corneal structural change, deposit and degeneration</i>	
		SOC primary	10015919	
		<i>Eye disorders</i>		
MSSO Comment:				



# Detail Report

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<b>CR Number:</b> 2024012002		<b>Implementation Date:</b> 22-Jan-24	<b>Related CR:</b> 2024012002	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	NSE	Approved as Requested	Proposed LLT NSE To PT Neurone-specific enolase	10090754 Current  10071927
<b>MSSO Comment:</b> The proposal to add a new LLT NSE is approved as requested. NSE is the acronym for Neurone-specific enolase and will be added as an LLT to PT Neurone-specific enolase.				

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<b>CR Number:</b> 2024012003		<b>Implementation Date:</b> 22-Jan-24	<b>Related CR:</b> 2024012003	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	Transcoronary ablation of septal hypertrophy	Approved as Requested	Proposed LLT Transcoronary ablation of septal hypertrophy To PT Percutaneous transluminal septal myocardial ablation	10090755 Current  10090704
<b>MSSO Comment:</b> The proposal to add a new term Transcoronary ablation of septal hypertrophy is approved as requested. Transcoronary ablation of septal hypertrophy is based on the conventional PTCA technique with the aim of inducing an artificial myocardial infarction by instillation of 96% ethanol into a coronary artery branch to treat hypertrophic obstructive cardiomyopathy. Transcoronary ablation of septal hypertrophy will be added as LLT to PT Percutaneous transluminal septal myocardial ablation added in change request 2023347005.				

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<b>CR Number:</b> 2024012004		<b>Implementation Date:</b> 21-Jan-24	<b>Related CR:</b> 2024012004	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	Cerebral microvascular ischemic disease	Approved as Requested	Proposed LLT Cerebral microvascular ischemic disease To PT Cerebral small vessel ischaemic disease	10090756 Current  10070878
<b>MSSO Comment:</b> The proposal to add a new term Cerebral microvascular ischemic disease is approved as requested. Cerebral microvascular ischemic disease (CMID) is a condition that affects the small blood vessels in the brain, leading to reduced blood flow to certain areas. It is a type of small vessel disease (SVD) and is often associated with aging and other vascular risk factors. Cerebral microvascular ischemic disease and its British spelled counterpart Cerebral microvascular ischaemic disease will both be added as LLTs to PT Cerebral small vessel ischaemic disease.				

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# Detail Report

<b>CR Number:</b> 2024022010		<b>Implementation Date:</b> 22-Jan-24	<b>Related CR:</b> 2024012004	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Cerebral microvascular ischaemic disease	Approved as Requested	Proposed LLT	
To PT	Cerebral small vessel ischaemic disease		Cerebral microvascular ischaemic disease	10090757 Current
			To PT	
			Cerebral small vessel ischaemic disease	10070878

MSSO  
Comment:

<b>CR Number:</b> 2024012005		<b>Implementation Date:</b> 22-Jan-24	<b>Related CR:</b> 2024012005	
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Magnetic resonance corrected T1 measurement'	Approved Not as Requested	Proposed PT	
HLT primary	Hepatobiliary imaging procedures		Hepatic magnetic resonance corrected T1 value	10090760
SOC primary	Investigations		HLT primary	
			Hepatobiliary imaging procedures	10019808
			SOC primary	
			Investigations	10022891

MSSO  
Comment: The proposal to add a new PT Magnetic resonance corrected T1 measurement' to primary HLT Hepatobiliary imaging procedures in SOC Investigations is approved but not as requested. Corrected T1 value is a novel MRI-based quantitative metric for assessing a composite of liver inflammation and fibrosis, which has been shown to distinguish between non-alcoholic fatty liver disease and non-alcoholic steatohepatitis. The proposed term will be modified to its most frequent reference in medical literature and added as PT Hepatic magnetic resonance corrected T1 value to HLT Hepatobiliary imaging procedures.

<b>CR Number:</b> 2024015000		<b>Implementation Date:</b> 22-Jan-24	<b>Related CR:</b> 2024015000	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	CANALICULAR ADENOMA	Approved Not as Requested	Proposed LLT	
			Salivary canalicular adenoma	10090761 Current
			To PT	
			Salivary gland adenoma	10051636

MSSO  
Comment: The proposal to add a new LLT CANALICULAR ADENOMA is approved but not as requested. Canalicular adenoma is a benign salivary gland neoplasm of monomorphous epithelial cells arranged in anastomosing cords within a loose, vascularized stroma. It is the third most common benign tumor of minor salivary glands, representing less than 1% of all salivary neoplasms. Proposed term will be modified in accordance with MedDRA capitalization conventions and specificity and added as subconcept LLT Salivary canalicular adenoma under PT Salivary gland adenoma.

# Detail Report

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<b>CR Number:</b> 2024015001	<b>Implementation Date:</b> 21-Jan-24	<b>Related CR:</b> 2024015001	<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>
Proposed LLT	<i>Rhinopharyngocele</i>	Rejected	

**MSSO Comment:** The proposal to add a new LLT Rhinopharyngocele is not approved. Proposed concept is rarely found in medical literature and as there is no context in the justification, it will not be added to MedDRA. For reconsideration, please provide the context and specify whether it refers to a congenital diverticulum of pharynx or other type.

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<b>CR Number:</b> 2024016000	<b>Implementation Date:</b> 22-Jan-24	<b>Related CR:</b> 2024016000	<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>
Proposed LLT	<i>Enthesoarthritis</i>	Rejected	

**MSSO Comment:** The proposal to add a new LLT Enthesoarthritis is not approved. This term is ambiguous and may refer to an extensive arthritis (involving muscular or tendinous structures) of any joint or as a more specific concept in relation with seronegative spondyloarthritis.

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<b>CR Number:</b> 2024016001	<b>Implementation Date:</b> 22-Jan-24	<b>Related CR:</b> 2024016001	<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>
Proposed LLT	<i>Erosive gastroesophageal reflux disease.</i>	Approved Not as Requested	Proposed LLT <i>Erosive gastroesophageal reflux disease</i> 10090764 Current To PT <i>Gastroesophageal reflux disease</i> 10017885

**MSSO Comment:** The proposal to add a new LLT Erosive gastroesophageal reflux disease. is approved but not as requested. Erosive gastroesophageal reflux disease is characterized by visible damage to the lining of the esophagus, which can be observed through endoscopy. The lining of the esophagus may show erosions, ulcers, or other signs of damage caused by the repeated exposure to stomach acid. The proposed term will be modified by removing errant period and added as LLT Erosive gastroesophageal reflux disease aligned with LLT Non-erosive reflux disease to PT Gastroesophageal reflux disease. The British English spelled counterpart LLT Erosive gastroesophageal reflux disease will also be added to PT Gastroesophageal reflux disease.

# Detail Report

CR Number: 2024022014		Implementation Date: 22-Jan-24	Related CR: 2024016001		
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed LLT	Erosive gastrooesophageal reflux disease	Approved as Requested	Proposed LLT		
To PT	Gastrooesophageal reflux disease		Erosive gastrooesophageal reflux disease	10090765	Current
			To PT		
			Gastrooesophageal reflux disease	10017885	

MSSO  
Comment:

CR Number: 2024016002		Implementation Date: 22-Jan-24	Related CR: 2024016002		
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed LLT	Lymphocyte subsets panel	Approved Not as Requested	Proposed PT		
			Lymphocyte subset panel	10090762	
			HLT primary		
			White blood cell analyses	10047938	
			SOC primary		
			Investigations	10022891	

MSSO  
Comment: The proposal to add a new LLT Lymphocyte subsets panel is approved but not as requested. A lymphocyte subsets panel is a laboratory test that measures the absolute and relative counts of different lymphocyte populations in a person's blood. Abnormalities in lymphocyte subsets may indicate immune system disorders, autoimmune diseases, or certain infections. The proposed term will be modified for MedDRA conventions and added in singular as new PT Lymphocyte subset panel linked to HLT White blood cell analyses.

# Detail Report

CR Number: 2024016003		Implementation Date: 22-Jan-24	Related CR: 2024016003	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Post pulmonary embolism syndrome	Approved Not as Requested	Proposed PT	
			Post pulmonary embolism syndrome	10090763
			HLT primary	
			Pulmonary thrombotic and embolic conditions	10037439
			SOC primary	
			Respiratory, thoracic and mediastinal disorders	10038738
			HLT secondary	
			Pulmonary embolism and thrombosis	10037379
			SOC secondary	
			Vascular disorders	10047065

MSSO Comment: The proposal to add a new LLT Post pulmonary embolism syndrome is approved but not as requested. Post-pulmonary embolism syndrome refers to a collection of symptoms and complications that can occur in some individuals after they have experienced a pulmonary embolism. These include chronic thromboembolic pulmonary disease with or without pulmonary hypertension, or post-pulmonary embolism functional impairment. Post pulmonary embolism syndrome will be added as PT to primary HLT Pulmonary thrombotic and embolic conditions, to secondary HLT Pulmonary embolism and thrombosis and to secondary HLT Right ventricular failures.

CR Number: 2024022015		Implementation Date: 22-Jan-24	Related CR: 2024016003	
<a href="#">Change Requested</a>	Link a PT to a HLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Post pulmonary embolism syndrome	Approved as Requested	Proposed PT	
To HLT	Right ventricular failures		Post pulmonary embolism syndrome	10090763
			To HLT	
			Right ventricular failures	10039164

MSSO Comment:

# Detail Report

CR Number: 2024016004		Implementation Date: 22-Jan-24	Related CR: 2024016004	
<a href="#">Change Requested</a>	Rename PT/LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Term to modify	Intestinal infection due to clostridium difficile	Rejected		
Replacement term	Clostridium difficile enteritis			
<div>MSSO</div> <div>Comment: The proposal to rename PT/LLT Intestinal infection due to clostridium difficile to Clostridium difficile enteritis is not approved. For this pathogen, intestinal infection occurs always in the colon, and current subordination is acceptable. "Intestinal", although anatomically broader, in this medical context always refers to the colon. MedDRA terms will generally not be renamed as this might impact legacy data, this term has been in MedDRA since version 2.1.</div>				

CR Number: 2024016005		Implementation Date: 22-Jan-24	Related CR: 2024016005	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Pollen food allergy syndrome	Approved as Requested	Proposed LLT	
To PT	Oral allergy syndrome		Pollen food allergy syndrome	10090767 Current
			To PT	
			Oral allergy syndrome	10068355
<div>MSSO</div> <div>Comment: The proposal to add a new LLT Pollen food allergy syndrome to PT Oral allergy syndrome is approved as requested. Pollen-food allergy syndrome (also called oral allergy syndrome) is a relatively common form of food allergy, which occurs in people who have pollen allergy and presents with itching and/or mild swelling of the mouth and throat immediately following ingestion of certain uncooked fruits (including nuts) or raw vegetables.</div>				

# Detail Report

CR Number: 2024016006		Implementation Date: 22-Jan-24	Related CR: 2024016006	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Radial scar breast	Approved Not as Requested	Proposed PT Breast radial scar	10090766
			HLT primary Breast and nipple neoplasms benign	10006287
			SOC primary Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10029104
			HLT secondary Benign and malignant breast neoplasms	10006289
			SOC secondary Reproductive system and breast disorders	10038604

**MSSO Comment:** The proposal to add a new LLT Radial scar breast is approved but not as requested. Radial scar / complex sclerosing lesion is a benign lesion with fibroelastosis and entrapped glandular structures, with or without proliferative epithelial lesions. Radial scars are small lesions, typically with a stellate configuration, whereas complex sclerosing lesions are larger and more disorganized. The proposed term will be modified to its natural word order and added as PT Breast radial scar with a primary link to HLT Breast and nipple neoplasms benign and a secondary link to HLT Benign and malignant breast neoplasms. In a related change, the related LLT Adenosis sclerosing will be promoted from PT Fibrocystic breast disease to PT level with a primary link to HLT Breast and nipple neoplasms benign and a secondary link to HLT Benign and malignant breast neoplasms.

# Detail Report

CR Number: 2024022016		Implementation Date: 22-Jan-24	Related CR: 2024016006	
<u>Change Requested</u>	Promote an LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Adenosis sclerosing</i>	Approved as Requested	Proposed LLT	
From PT	<i>Fibrocystic breast disease</i>		<i>Adenosis sclerosing</i>	10001243
HLT primary	<i>Breast and nipple neoplasms benign</i>		From PT	
			<i>Fibrocystic breast disease</i>	10016621
			HLT primary	
			<i>Breast and nipple neoplasms benign</i>	10006287
			SOC primary	
			<i>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</i>	10029104
			HLT secondary	
			<i>Benign and malignant breast neoplasms</i>	10006289
			SOC secondary	
			<i>Reproductive system and breast disorders</i>	10038604

MSSO  
Comment:

CR Number: 2024016007		Implementation Date: 22-Jan-24	Related CR: 2024016007	
<u>Change Requested</u>	Add a New Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	<i>Doctor shopping</i>	Approved Not as Requested	Proposed PT	
			<i>Illicit prescription attainment</i>	10090768
			HLT primary	
			<i>Criminal activity</i>	10011391
			SOC primary	
			<i>Social circumstances</i>	10041244

MSSO  
Comment: The proposal to add a new term Doctor shopping is approved but not as requested. The definition of doctor shopping is seeking by patients of illicit prescription medications, especially controlled substances by visiting multiple doctors. Since the proposed term may pose difficulty in translation and may be referred to differently in various regions, the proposed concept will be renamed as Illicit prescription attainment and added as new PT under HLT Criminal activity. In a related change, LLT Fraudulent prescription attainment from multiple physicians will be added to new PT Illicit prescription attainment.



# Detail Report

CR Number: 2024022017		Implementation Date: 22-Jan-24	Related CR: 2024016007		
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed LLT	<i>Fraudulent prescription attainment from multiple physicians</i>	Approved as Requested	Proposed LLT	<i>Fraudulent prescription attainment from multiple physicians</i>	10090769 Current
To PT	<i>Illicit prescription attainment</i>		To PT	<i>Illicit prescription attainment</i>	10090768
MSSO Comment:					

CR Number: 2024017000		Implementation Date: 24-Jan-24	Related CR: 2024017000		
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed LLT	<i>Non-filarial lymphoedema</i>	Rejected			
To PT	<i>Podoconiosis</i>				
MSSO Comment:	The proposal to add a new LLT Non-filarial lymphoedema to PT Podoconiosis is not approved. Even if the proposed term is sometimes used as a synonym of podoconiosis, conceptually it may be understood as any cause of lymphedema other than filarial lymphedema.				

CR Number: 2024017001		Implementation Date: 22-Jan-24		Related CR: 2024017001		
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>		
Proposed LLT	<i>Uroscopy</i>	Rejected				
<div>MSSO Comment: The proposal to add a new LLT Uroscopy is not approved. While uroscopy was once a common diagnostic tool, it has largely been replaced by more modern and scientifically rigorous methods in contemporary medicine. Today, urine analysis is still used in clinical settings, but it is conducted using advanced laboratory techniques and equipment to provide accurate and reliable information about a person's health. Please refer to existing LLT/PT Urine analysis.</div>						

# Detail Report

<b>CR Number:</b> 2024017002		<b>Implementation Date:</b> 24-Jan-24	<b>Related CR:</b> 2024017002	
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Gastric neuroendocrine tumors	Approved Not as Requested	Proposed LLT Gastric neuroendocrine tumor	10090774 Current
			To PT Gastrointestinal neuroendocrine tumour	10090770
<b>MSSO Comment:</b> The proposal to add a new LLT Gastric neuroendocrine tumors is approved but not as requested. A gastric neuroendocrine tumor is a type of neoplasm that develops in the neuroendocrine cells of the stomach. Neuroendocrine cells are specialized cells that have both nerve and endocrine features. These tumors can be benign or malignant. The proposed term modified to its singular form as LLT Gastric neuroendocrine tumor and its British English spelled counterpart LLT Gastric neuroendocrine tumour will be both be added to new PT Gastrointestinal neuroendocrine tumour added in change request 2024017003.				

<b>CR Number:</b> 2024024001		<b>Implementation Date:</b> 24-Jan-24	<b>Related CR:</b> 2024017002	
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Gastric neuroendocrine tumour	Approved as Requested	Proposed LLT Gastric neuroendocrine tumour	10090772 Current
To PT	Gastrointestinal neuroendocrine tumour		To PT Gastrointestinal neuroendocrine tumour	10090770

**MSSO Comment:**

<b>CR Number:</b> 2024017003		<b>Implementation Date:</b> 24-Jan-24	<b>Related CR:</b> 2024017003	
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Gastrointestinal neuroendocrine tumors	Approved Not as Requested	Proposed LLT Gastrointestinal neuroendocrine tumor	10090773 Current
			To PT Gastrointestinal neuroendocrine tumour	10090770

**MSSO Comment:** The proposal to add a new LLT Gastrointestinal neuroendocrine tumors is approved but not as requested. A gastrointestinal neuroendocrine tumor is a neoplasm that develops in the neuroendocrine cells of the gastrointestinal tract. Neuroendocrine cells are specialized cells that have both nerve and endocrine features. These tumors can be benign or malignant. The proposed term will be modified to its singular form and added as LLT Gastrointestinal neuroendocrine tumor to a new British spelled PT Gastrointestinal neuroendocrine tumour linked to primary HLT Islet cell neoplasms and APUDoma NEC, secondary HLT Endocrine neoplasms NEC and secondary HLT Gastrointestinal neoplasms NEC.

# Detail Report

CR Number: 2024024002		Implementation Date: 24-Jan-24	Related CR: 2024017003	
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Gastrointestinal neuroendocrine tumour	Approved as Requested	Proposed PT	
HLT primary	Islet cell neoplasms and APUDoma NEC		Gastrointestinal neuroendocrine tumour	10090770
SOC primary	Neoplasms benign, malignant and unspecified (incl cysts and polyps)		HLT primary	
			Islet cell neoplasms and APUDoma NEC	10023051
			SOC primary	
			Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10029104
			HLT secondary	
			Endocrine neoplasms NEC	10014714
			SOC secondary	
			Endocrine disorders	10014698

MSSO  
Comment:

CR Number: 2024024003		Implementation Date: 24-Jan-24	Related CR: 2024017003	
<a href="#">Change Requested</a>	Link a PT to a HLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Gastrointestinal neuroendocrine tumour	Approved as Requested	Proposed PT	
To HLT	Gastrointestinal neoplasms NEC		Gastrointestinal neuroendocrine tumour	10090770
			To HLT	
			Gastrointestinal neoplasms NEC	10017993

MSSO  
Comment:

# Detail Report

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<b>CR Number:</b> 2024017004		<b>Implementation Date:</b> 24-Jan-24	<b>Related CR:</b> 2024017004		
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed LLT	Scar tissue obstruction	Rejected			

**MSSO Comment:** The proposal to add a new LLT Scar tissue obstruction is not approved. Scar tissue can cause the narrowing of tubes or passages in the body, referred to as strictures. Scar tissue obstruction is an unspecific combination of obstruction and the pathophysiologic cause. In general, the MSSO does not add new combination terms including additional "induced" or "due to" terms.

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<b>CR Number:</b> 2024017005		<b>Implementation Date:</b> 24-Jan-24	<b>Related CR:</b> 2024017005		
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed LLT	Cutaneous necrotizing vasculitis	Approved as Requested	Proposed LLT Cutaneous necrotizing vasculitis	10090775	Current
			To PT Cutaneous vasculitis	10011686	

**MSSO Comment:** The proposal to add a new LLT Cutaneous necrotizing vasculitis is approved as requested. Cutaneous vasculitis refers to a vasculitis affecting small- or medium-sized vessels in the skin and subcutaneous tissue but not the internal organs. Cutaneous vasculitis may be limited to the skin, or may be a component of a systemic primary or secondary vasculitic disorder. Cutaneous necrotizing vasculitis along with its British English spelled counterpart Cutaneous necrotising vasculitis will both be added as LLTs to PT Cutaneous vasculitis.

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<b>CR Number:</b> 2024024004		<b>Implementation Date:</b> 24-Jan-24	<b>Related CR:</b> 2024017005		
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed LLT	Cutaneous necrotising vasculitis	Approved as Requested	Proposed LLT Cutaneous necrotising vasculitis	10090771	Current
To PT	Cutaneous vasculitis		To PT Cutaneous vasculitis	10011686	

**MSSO Comment:**

# Detail Report

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<b>CR Number:</b> 2024017006		<b>Implementation Date:</b> 24-Jan-24	<b>Related CR:</b> 2024017006		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed LLT	<i>Cutaneous small-vessel vasculitis</i>	Rejected			

MSSO Comment: The proposal to add a new LLT Cutaneous small-vessel vasculitis is not approved. The proposed term is available as LLT Cutaneous small vessel vasculitis.

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<b>CR Number:</b> 2024017007		<b>Implementation Date:</b> 24-Jan-24	<b>Related CR:</b> 2024017007		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed LLT	<i>Cutaneous leukocytoclastic angiitis</i>	Rejected			

MSSO Comment: The proposal to add a new LLT Cutaneous leukocytoclastic angiitis is not approved. The proposed term may be represented by existing LLT Leucocytoclastic vasculitis under PT Cutaneous vasculitis.

# Detail Report

CR Number: 2024018000		Implementation Date: 24-Jan-24	Related CR: 2024018000	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Seckel syndrome 5	Approved Not as Requested	Proposed PT Seckel syndrome	10090776
			HLT primary Non-site specific bone disorders congenital	10029509
			SOC primary Congenital, familial and genetic disorders	10010331
			HLT secondary Non-site specific bone disorders congenital	10029509
			SOC secondary Musculoskeletal and connective tissue disorders	10028395

MSSO  
Comment: The proposal to add a new LLT Seckel syndrome 5 is approved but not as requested. Seckel syndrome 5 is an autosomal recessive disorder characterized by proportionate short stature, severe microcephaly, mental retardation, and a typical 'bird-head' facial appearance. There are multiple types of Seckel syndrome caused by harmful changes in genes with similar phenotypes. The proposed term will be modified and added as the general syndrome PT Seckel syndrome to primary HLT Non-site specific bone disorders congenital (primary SOC Congenital, familial and genetic disorders and to secondary SOC Musculoskeletal and connective tissue disorders), and to secondary HLT Intellectual disabilities.

CR Number: 2024024005		Implementation Date: 24-Jan-24	Related CR: 2024018000	
<a href="#">Change Requested</a>	Link a PT to a HLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Seckel syndrome	Approved as Requested	Proposed PT Seckel syndrome	10090776
To HLT	Intellectual disabilities		To HLT Intellectual disabilities	10077548

MSSO  
Comment:

# Detail Report

CR Number: 2024019000		Implementation Date: 24-Jan-24	Related CR: 2024019000	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	Low weight for height	Approved as Requested	Proposed LLT Low weight for height To PT Underweight	10090777 Current  10048828
MSSO Comment:	The proposal to add a new term Low weight for height is approved as requested. Height and weight are correlated using height and weight charts, which act as a diagnostic tool to enable to gauge ideal body weight. A low weight for height may indicate undernutrition and wasting in children, usually as a consequence of insufficient food intake, which comports impairs the functioning of the immune system resulting in a high incidence of infectious diseases, especially diarrhea. Low weight for height will be added as an LLT to PT Underweight.			

CR Number: 2024019001		Implementation Date: 24-Jan-24	Related CR: 2024019001	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Pseudoclaudication	Approved as Requested	Proposed LLT Pseudoclaudication To PT Spinal claudication	10090778 Current  10041539
MSSO Comment:	The proposal to add a new LLT Pseudoclaudication is approved as requested. Spinal claudication, also known as neurogenic claudication or pseudoclaudication, is a condition characterized by symptoms such as pain, cramping, weakness, or numbness in the legs that occur during physical activity, particularly walking, with relieve by rest. The term "claudication" typically refers to pain that arises during exercise due to inadequate blood flow to the muscles. In the case of spinal claudication, the symptoms are not primarily caused by vascular issues but rather by compression or irritation of nerves in the spinal canal. Pseudoclaudication will be added as synonym LLT to PT Spinal claudication.			

# Detail Report

CR Number: 2024019002		Implementation Date: 04-Mar-24	Related CR: 2024019002	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Abdominal wall oedema	Approved as Requested	Proposed PT	
To SMQ	Haemodynamic oedema, effusions and fluid overload (SMQ)		Abdominal wall oedema	10082609
Term scope	Narrow		To SMQ	
			Haemodynamic oedema, effusions and fluid overload (SMQ)	20000145
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	

**MSSO Comment:** The proposal to add PT Abdominal wall oedema to Haemodynamic oedema, effusions and fluid overload (SMQ) as a narrow term is approved as requested. This term fits the inclusion criteria of this SMQ for terms consistent with definition of oedema, including terms for specific cavities and body sites. All terms are narrow scope. Similar terms such as PT Gastrointestinal oedema and PT Retroperitoneal oedema are already included.

CR Number: 2024019003		Implementation Date: 29-Jan-24	Related CR: 2024019003	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	Transduodenal ampullectomy	Approved Not as Requested	Proposed PT	
			Transduodenal ampullectomy	10090779
			HLT primary	
			Abdominal therapeutic procedures NEC	10027653
			SOC primary	
			Surgical and medical procedures	10042613

**MSSO Comment:** The proposal to add a new term Transduodenal ampullectomy is approved but not as requested. Transduodenal ampullectomy is a feasible and effective surgical procedure for the treatment of selected patients with ampullary tumors. It is an alternative treatment option in cases of ampullary tumors not amenable to endoscopic papillectomy or pancreaticoduodenectomy. Proposed term will be modified for the most commonly referenced spelling in literature and added as new PT Transduodenal ampullectomy under HLT Abdominal therapeutic procedures NEC.



# Detail Report

CR Number: 2024021001		Implementation Date: 29-Jan-24	Related CR: 2024021001		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed LLT	Mesenteric inflammatory veno-occlusive disease	Approved as Requested	Proposed LLT		
To PT	Enterocolic lymphocytic phlebitis		Mesenteric inflammatory veno-occlusive disease	10090780	Current
			To PT		
			Enterocolic lymphocytic phlebitis	10090691	Current

MSSO  
Comment: The proposal to add a new LLT Mesenteric inflammatory veno-occlusive disease to PT Enterocolic lymphocytic phlebitis is approved as requested. Enterocolic lymphocytic phlebitis (EP), mesenteric inflammatory veno-occlusive disease (MIVOD) as well as idiopathic myointimal hyperplasia of mesenteric veins (IMHMY) are described as different subcategories of isolated enterocolic phlebitis. EP and MIVOD may be considered the same disease and could be summarized under the descriptive term enterocolic phlebitis. Mesenteric inflammatory veno-occlusive disease will be added as LLT to PT Enterocolic lymphocytic phlebitis. In a related change, Enterocolic phlebitis will also be added as LLT to PT Enterocolic lymphocytic phlebitis and in a further change, LLT Enterocolic phlebitis will be swapped with PT Enterocolic lymphocytic phlebitis.

CR Number: 2024029007		Implementation Date: 29-Jan-24	Related CR: 2024021001		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Swap a PT with an LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed PT	Enterocolic lymphocytic phlebitis	Approved as Requested	Proposed PT		
With LLT	Enterocolic phlebitis		Enterocolic lymphocytic phlebitis	10090691	Current
			With LLT		
			Enterocolic phlebitis	10090781	

MSSO  
Comment:

CR Number: 2024029006		Implementation Date: 29-Jan-24	Related CR: 2024021001		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed LLT	Enterocolic phlebitis	Approved as Requested	Proposed LLT		
To PT	Enterocolic lymphocytic phlebitis		Enterocolic phlebitis	10090781	
			To PT		
			Enterocolic lymphocytic phlebitis	10090691	Current

MSSO  
Comment:

# Detail Report

<b>CR Number:</b> 2024022000		<b>Implementation Date:</b> 28-Jan-24	<b>Related CR:</b> 2024022000	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Maggot infestation of scalp</i>	Approved as Requested	Proposed LLT <i>Maggot infestation of scalp</i>	10090787 Current
			To PT <i>Myiasis</i>	10028586
<b>MSSO Comment:</b> The proposal to add a new LLT Maggot infestation of scalp is approved as requested. Larval (maggot) infestation (myiasis) is a condition in which fly larvae feed off and develop in the tissues of a living organism. Myiasis usually occurs at the location of pre-existing wounds. Infestations on the scalp can also occur in individuals with poor hygiene. Maggot infestation of scalp will be added as LLT to PT Myiasis.				

<b>CR Number:</b> 2024022001		<b>Implementation Date:</b> 28-Jan-24	<b>Related CR:</b> 2024022001	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Candida parapsilosis infection</i>	Approved as Requested	Proposed LLT <i>Candida parapsilosis infection</i>	10090784 Current
			To PT <i>Candida infection</i>	10074170

**MSSO Comment:** The proposal to add a new LLT Candida parapsilosis infection is approved as requested. Candida parapsilosis is part of the Candida species, which also includes Candida albicans, Candida glabrata, and others. Candida parapsilosis is one of the more common species responsible for candidiasis. Risk factors for Candida parapsilosis infections include immunocompromised states, prolonged hospitalization, surgery, broad-spectrum antibiotic use, and the presence of central venous catheters or other indwelling devices. Candida parapsilosis infection will be added as LLT to PT Candida infection.

<b>CR Number:</b> 2024022002		<b>Implementation Date:</b> 28-Jan-24	<b>Related CR:</b> 2024022002	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Legionella longbeachae infection</i>	Approved as Requested	Proposed LLT <i>Legionella longbeachae infection</i>	10090785 Current
			To PT <i>Legionella infection</i>	10061266

**MSSO Comment:** The proposal to add a new LLT Legionella longbeachae infection is approved as requested. Legionella longbeachae is one of the many species within the Legionella genus which cause Legionnaires' disease, which refers to pneumonia caused by Legionella spp. Legionella longbeachae is the second most common cause of human disease after Legionella pneumophila. Legionella longbeachae infection will be added as LLT to PT Legionella infection.

# Detail Report

<b>CR Number:</b> 2024022003		<b>Implementation Date:</b> 28-Jan-24	<b>Related CR:</b> 2024022003	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Legionella pneumophila antibody</i>	Approved as Requested	Proposed LLT <i>Legionella pneumophila antibody</i>	10090783 Current
			To PT <i>Legionella test</i>	10070410
<b>MSSO Comment:</b> The proposal to add a new LLT Legionella pneumophila antibody is approved as requested. The main testing options for Legionella infection include nucleic acid detection (eg, polymerase chain reaction), urine antigen tests, and culture. Antibody testing is possible and valuable in specific settings. Legionella pneumophila antibody will be added as LLT to PT Legionella test.				
<b>CR Number:</b> 2024022004		<b>Implementation Date:</b> 29-Jan-24	<b>Related CR:</b> 2024022004	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Legionella longbeachae antibody</i>	Approved as Requested	Proposed LLT <i>Legionella longbeachae antibody</i>	10090786 Current
			To PT <i>Legionella test</i>	10070410
<b>MSSO Comment:</b> The proposal to add a new LLT Legionella longbeachae antibody is approved as requested. The main testing options for Legionella infection include nucleic acid detection (eg, polymerase chain reaction), urine antigen tests, and culture. Antibody testing is possible and valuable in specific settings. Legionella longbeachae antibody will be added as LLT to PT Legionella test.				
<b>CR Number:</b> 2024022005		<b>Implementation Date:</b> 29-Jan-24	<b>Related CR:</b> 2024022005	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Bocavirus test</i>	Approved Not as Requested	Proposed PT <i>Human bocavirus test</i>	10090782
			HLT primary <i>Virus identification and serology</i>	10047490
			SOC primary <i>Investigations</i>	10022891
<b>MSSO Comment:</b> The proposal to add a new LLT Bocavirus test is approved but not as requested. While most HBoV1 infections are self-limited, they sometimes lead to life-threatening conditions. The availability of a rapid and accurate test for HBoV1 is likely to be useful in differential diagnoses and development of therapy, and will increase our understanding of the epidemiology and clinical impact of HBoV1 infections. Proposed term will be modified for specificity and added as new PT Human bocavirus test under HLT Virus identification and serology.				

# Detail Report

CR Number: 2024022006		Implementation Date: 28-Jan-24	Related CR: 2024022006		MedDRA Code #
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed LLT	Nodule on tendon sheat	Rejected			

MSSO Comment: The proposal to add a new LLT Nodule on tendon sheat is not approved. As per the MedDRA Introductory Guide, in general, new terms containing “nodule” are not added to MedDRA, except when a nodule represents a full diagnostic expression.

CR Number: 2024022007		Implementation Date: 28-Jan-24	Related CR: 2024022007		MedDRA Code #
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed LLT	Feeling rush	Rejected			

MSSO Comment: The proposal to add a new LLT Feeling rush is not approved. Proposed concept is not an internationally accepted valid concept. In addition, it may not be easily translated in all the available language translations of MedDRA. The more universally acceptable concept is LLT Adrenaline rush, added in change request 2023321010.

CR Number: 2024022008		Implementation Date: 28-Jan-24	Related CR: 2024022008		MedDRA Code #
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed LLT	Hurry sickness	Rejected			

MSSO Comment: The proposal to add a new LLT Hurry sickness is not approved. Hurry sickness is a behavior pattern (not a diagnosable condition) characterized by chronic rushing and anxiousness and an overwhelming, persistent sense of urgency. Proposed concept is not an internationally accepted valid concept. In addition, it may not be easily translated in all the available language translations of MedDRA.

# Detail Report

<b>CR Number:</b> 2024022009		<b>Implementation Date:</b> 29-Jan-24	<b>Related CR:</b> 2024022009	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	Urethrovaginal fistula	Approved as Requested	Proposed LLT Urethrovaginal fistula	10090788 Current
			To PT Urogenital fistula	10046696
<b>MSSO Comment:</b> The proposal to add a new term Urethrovaginal fistula is approved as requested. An urethrovaginal fistula is an abnormal passageway that may occur the urethra and the vagina. It is a sub-set of vaginal fistulas. It results in urinary incontinence as urine continually leaves the vagina. It can occur as an obstetrical complication, catheter insertion injury or a surgical injury. Urethrovaginal fistula will be added as an LLT to PT Urogenital fistula.				
<b>CR Number:</b> 2024022013		<b>Implementation Date:</b> 29-Jan-24	<b>Related CR:</b> 2024022013	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	Pericallosal lipoma	Approved as Requested	Proposed LLT Pericallosal lipoma	10090789 Current
			To PT Intracranial lipoma	10072288
<b>MSSO Comment:</b> The proposal to add a new term Pericallosal lipoma is approved as requested. Intracranial lipomas are rare, fat-containing asymptomatic lesions that are generally considered as congenital malformations. The most common location is the close vicinity of the corpus callosum, hence the name pericallosal lipomas. Pericallosal lipoma will be added as a sub-element LLT to PT Intracranial lipoma.				
<b>CR Number:</b> 2024022019		<b>Implementation Date:</b> 28-Jan-24	<b>Related CR:</b> 2024022019	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	Vascular leak syndrome	Rejected		
<b>MSSO Comment:</b> The proposal to add a new term Vascular leak syndrome is not approved. The term is represented in MedDRA by LLT Acute vascular leak syndrome and its synonym LLT/PT Capillary leak syndrome.				

# Detail Report

CR Number: 2024023000		Implementation Date: 29-Jan-24	Related CR: 2024023000	
<a href="#">Change Requested</a>	Promote an LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Diverticulosis</i>	Approved Not as Requested	Proposed LLT	
From PT	<i>Diverticulum</i>		<i>Diverticulosis</i>	10013549 Current
			From PT	
			<i>Diverticulum</i>	10013554
			To PT	
			<i>Diverticulum intestinal</i>	10013559
MSSO Comment:	The proposal to promote the LLT Diverticulosis from PT Diverticulum is approved but not as requested. Diverticulum is the anatomic site unspecified term. Diverticula can occur in many locations within the gastrointestinal tract. Not all locations are prone to multiple diverticula, like e.g. stomach or esophagus. Diverticulosis is often present in the colon/intestine with specific LLTs in MedDRA. Diverticulosis is defined as the presence of diverticula, particularly of colonic diverticula. LLT Diverticulosis will be moved from PT Diverticulum to PT Diverticulum intestinal for better alignment.			

CR Number: 2024023001		Implementation Date: 29-Jan-24	Related CR: 2024023001	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Ceftriaxone-Calcium precipitation</i>	Rejected		
MSSO Comment:	The proposal to add a new LLT Ceftriaxone-Calcium precipitation is not approved. It is not possible to accommodate every possible drug class/substance precipitation combination in MedDRA as well as drug names are usually not included in MedDRA, unless they give further clarification to the parent PT. Based on your scenario, please consider LLTs under PT Product deposit or PT Labelled drug-drug interaction issue or PT Labelled drug-drug interaction error, or LLT Contraindicated drug combination administered.			

# Detail Report

<b>CR Number:</b> 2024023002		<b>Implementation Date:</b> 28-Jan-24	<b>Related CR:</b> 2024023002	
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Pericardial perforation</i>	Approved Not as Requested	Proposed PT	
HLT primary	<i>Cardiac disorders NEC</i>		<i>Pericardial perforation</i>	10090793
SOC primary	<i>Cardiac disorders</i>		HLT primary	
			<i>Pericardial disorders NEC</i>	10034469
			SOC primary	
			<i>Cardiac disorders</i>	10007541
			HLT secondary	
			<i>Cardiac and vascular procedural complications</i>	10007602
			SOC secondary	
			<i>Injury, poisoning and procedural complications</i>	10022117
<b>MSSO Comment:</b>	The proposal to add a new PT Pericardial perforation to primary HLT Cardiac disorders NEC in SOC Cardiac disorders is approved but not as requested. Pericardial perforation may occur as result of trauma or as a procedural complication. Pericardial perforation will be added as PT with a primary link to HLT Pericardial disorders NEC and a secondary link to HLT Cardiac and vascular procedural complications.			

<b>CR Number:</b> 2024023571		<b>Implementation Date:</b> 29-Jan-24	<b>Related CR:</b> 2024023571	
<u>Change Requested</u>	Promote an LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Amyloid related imaging abnormality-microhaemorrhages</i>	Rejected		
From PT	<i>Amyloid related imaging abnormality-microhaemorrhages and haemosiderin deposits</i>			
<b>MSSO Comment:</b>	The proposal to promote the LLT Amyloid related imaging abnormality-microhaemorrhages from PT Amyloid related imaging abnormality-microhaemorrhages and haemosiderin deposits is not approved. Amyloid related imaging abnormality with hemosiderin deposition is almost always associated with microhemorrhages. The separated concepts for microhemorrhages or hemosiderin deposits alone can be found at the LLT level and used when appropriate. As such the LLT Amyloid related imaging abnormality-microhaemorrhages is currently appropriately placed under PT Amyloid related imaging abnormality-microhaemorrhages and haemosiderin deposits.			

# Detail Report

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<b>CR Number:</b> 2024023572	<b>Implementation Date:</b> 29-Jan-24	<b>Related CR:</b> 2024023572	<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Promote an LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>

Proposed LLT	<i>Amyloid related imaging abnormality-haemosiderin deposits</i>	Rejected
From PT	<i>Amyloid related imaging abnormality-microhaemorrhages and haemosiderin deposits</i>	

**MSSO Comment:** The proposal to promote the LLT Amyloid related imaging abnormality-haemosiderin deposits from PT Amyloid related imaging abnormality-microhaemorrhages and haemosiderin deposits is not approved. Amyloid related imaging abnormality with hemosiderin deposition is almost always associated with microhemorrhages. The separated concepts for microhemorrhages or hemosiderin deposits alone can be found at the LLT level and used when appropriate. As such the LLT Amyloid related imaging abnormality-haemosiderin deposits is currently appropriately placed under PT Amyloid related imaging abnormality-microhaemorrhages and haemosiderin deposits.

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<b>CR Number:</b> 2024023573	<b>Implementation Date:</b> 29-Jan-24	<b>Related CR:</b> 2024023573	<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>

Proposed LLT	<i>Endoscopic Ultrasound (EUS)</i>	Rejected
To PT	<i>Endoscopic ultrasound</i>	

**MSSO Comment:** The proposal to add a new LLT Endoscopic Ultrasound (EUS) to PT Endoscopic ultrasound is not approved. The proposed acronym is ambiguous and could also refer to Endorectal, Endoluminal, Esophageal Ultrasound or Emergency Ultrasound as a medical abbreviation.

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<b>CR Number:</b> 2024023574	<b>Implementation Date:</b> 29-Jan-24	<b>Related CR:</b> 2024023574	<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>

Proposed LLT	<i>Echo-endoscopy</i>	Approved Not as Requested	Proposed LLT	
To PT	<i>Endoscopic Ultrasound</i>		<i>Echoendoscopy</i>	10090791 Current
			To PT	
			<i>Endoscopic ultrasound</i>	10067016

**MSSO Comment:** The proposal to add a new LLT Echo-endoscopy to PT Endoscopic Ultrasound is approved but not as requested. Echoendoscopes differ from the standard endoscopes as they contain an ultrasound transducer at the tip, which allows for endoscopic ultrasound examination of the gastrointestinal wall, as well as extra-luminal structures. Proposed term will be modified and added without hyphen as subconcept LLT Echoendoscopy under PT Endoscopic ultrasound.



# Detail Report

<b>CR Number:</b> 2024023575		<b>Implementation Date:</b> 29-Jan-24	<b>Related CR:</b> 2024023575		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed PT	<i>Involuntary vocalization</i>	Approved Not as Requested	Proposed LLT <i>Involuntary vocalization</i>	10090792	Current
			To PT <i>Involuntary vocalisation</i>	10090790	

**MSSO Comment:** The proposal to add a new PT Involuntary vocalization is approved but not as requested. Involuntary vocalization may be encountered throughout the entire tenor of neuropsychiatry, movement disorders, and neurodevelopmental syndromes. Importantly, involuntary vocalizing behaviors may often constitute a predominant clinical sign, and, therefore, their early recognition and appropriate classification are necessary to guide diagnosis and treatment. Involuntary vocalization will be added as an LLT to the British English spelled PT Involuntary vocalisation, which will be added, in a related change to primary HLT Neurological signs and symptoms NEC and to secondary HLT Abnormal behaviour NEC.

<b>CR Number:</b> 2024029016		<b>Implementation Date:</b> 29-Jan-24	<b>Related CR:</b> 2024023575		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed PT	<i>Involuntary vocalisation</i>	Approved as Requested	Proposed PT <i>Involuntary vocalisation</i>	10090790	
HLT primary	<i>Neurological signs and symptoms NEC</i>		HLT primary <i>Neurological signs and symptoms NEC</i>	10029306	
SOC primary	<i>Nervous system disorders</i>		SOC primary <i>Nervous system disorders</i>	10029205	
			HLT secondary <i>Abnormal behaviour NEC</i>	10000117	
			SOC secondary <i>Psychiatric disorders</i>	10037175	

**MSSO Comment:**

# Detail Report

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<b>CR Number:</b> 2024023576	<b>Implementation Date:</b> 29-Jan-24	<b>Related CR:</b> 2024023576	<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>
Proposed PT	Post-COVID symptom	Rejected	

**MSSO Comment:** The proposal to add a new PT Post-COVID symptom is not approved. The proposed term implies a causal relationship between two concepts, and therefore represents a combination term. The MSSO refrains from adding such terms as to avoid overpopulation of MedDRA. Please note that Section 3.8.2 of the MedDRA Term Selection: Points to Consider document provides coding options for combinations e.g. both microorganisms and related pathological conditions. As well, the proposed term is ambiguous.

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<b>CR Number:</b> 2024023577	<b>Implementation Date:</b> 29-Jan-24	<b>Related CR:</b> 2024023577	<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>
Proposed LLT	Infusion-related headache	Rejected	
To PT	Infusion related reaction		

**MSSO Comment:** The proposal to add a new LLT Infusion-related headache to PT Infusion related reaction is not approved. In order to avoid the overpopulation of terms in MedDRA, the MSSO generally refrains from adding all possible infusion related event terms or concepts which can be represented by combination coding. As well, the MSSO considers this proposed term to be of a “due to” nature. Terms that state or imply a “due to” concept are generally not added to MedDRA because causality is not inherent in the coded term, but is instead determined by the reporter/investigator or by the sponsor.

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<b>CR Number:</b> 2024023578	<b>Implementation Date:</b> 31-Jan-24	<b>Related CR:</b> 2024023578	<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>
Proposed LLT	Mixed arteriovenous type ulcer	Approved Not as Requested	Proposed LLT Mixed arteriovenous ulcer 10090794 Current
			To PT Skin ulcer 10040943

**MSSO Comment:** The proposal to add a new LLT Mixed arteriovenous type ulcer is approved but not as requested. A mixed arteriovenous ulcer is that in which there is participation of both insufficient arterial blood supply and deficient venous drainage in the ulcer formation. The proposed term will be modified for simplification and added as the LLT Mixed arteriovenous ulcer under PT Skin ulcer.

# Detail Report

<b>CR Number:</b> 2024024006		<b>Implementation Date:</b> 31-Jan-24	<b>Related CR:</b> 2024024006	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Skin and soft tissue infections</i>	Approved Not as Requested	Proposed LLT <i>Skin and soft tissue infection</i>	10090795 Current
			To PT <i>Skin infection</i>	10040872
<b>MSSO Comment:</b> The proposal to add a new term Skin and soft tissue infections is approved but not as requested. Skin and soft-tissue infections encompass a variety of pathological conditions that involve the skin and underlying subcutaneous tissue, fascia, or muscle, ranging from simple superficial infections to severe necrotizing infections. The proposed term will be modified to its singular form and added as an LLT Skin and soft tissue infection to PT Skin infection.				
<b>CR Number:</b> 2024024007		<b>Implementation Date:</b> 31-Jan-24	<b>Related CR:</b> 2024024007	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Ulcerative colitis associated arthritis</i>	Approved as Requested	Proposed LLT <i>Ulcerative colitis associated arthritis</i>	10090796 Current
			To PT <i>Arthritis enteropathic</i>	10003253
<b>MSSO Comment:</b> The proposal to add a new term Ulcerative colitis associated arthritis is approved as requested. Ulcerative colitis associated arthritis is a sub-type of the so called enteropathic arthropathy, which is a type of arthritis linked to Crohn's disease, ulcerative colitis, and chronic inflammatory bowel diseases. Ulcerative colitis associated arthritis will be added as LLT to PT Arthritis enteropathic.				
<b>CR Number:</b> 2024025000		<b>Implementation Date:</b> 31-Jan-24	<b>Related CR:</b> 2024025000	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Cardiopulmonary cerebral resuscitation</i>	Approved Not as Requested	Proposed LLT <i>Cardiocerebral resuscitation</i>	10090797 Current
			To PT <i>Resuscitation</i>	10038749
<b>MSSO Comment:</b> The proposal to add a new term Cardiopulmonary cerebral resuscitation is approved but not as requested. Instituting the new cardiocerebral resuscitation protocol for managing prehospital cardiac arrest improved survival of adult patients with witnessed cardiac arrest and an initially shockable rhythm. The proposed term will be modified to Cardiocerebral resuscitation as the commonly referenced recent human resuscitation measure and added as an LLT to PT Resuscitation.				

# Detail Report

CR Number: 2024025001		Implementation Date: 19-Mar-24	Related CR: 2024025001	
<u>Change Requested</u>	Add term to SMQ	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Injection site discomfort	Approved Not as Requested	Proposed PT	
To SMQ	Extravasation events (injections, infusions and implants) (SMQ)		Vessel puncture site induration	10073156
Term scope	Broad		To SMQ	
			Extravasation events (injections, infusions and implants) (SMQ)	20000136
			Term scope	
			Broad	
			Term_category	
			A	
			Term_weight	
			0	

**MSSO** The proposal to add PT Injection site discomfort to Extravasation events (injections, infusions and implants) (SMQ) as a broad term is approved but not as requested.

**Comment:** Based on the inclusion and exclusion criteria of this SMQ, the following PTs of the submitted list will be added to the broad scope of the Extravasation events (injections, infusions and implants) (SMQ): PT Vessel puncture site induration, PT Vessel puncture site pain and PT Vessel puncture site swelling. The addition of puncture site PTs are potentially vague and might add noise due to high numbers of legacy terms. All further proposed additions were considered as not meeting the inclusion and exclusion criteria of the SMQ or to be potentially adding noise. Please consider, based on the description in the SMQ introductory guide, that "in general, 'application site' terms are considered not appropriate for the scope of this SMQ, even though they did retrieve a few cases of interest during pre-production testing. MedDRA users should consider – based on their own data – if 'application site' terms may have been used when coding cases related to extravasation and include relevant terms as needed." In line with this please, consider whether your coding practices/guidelines require the addition of more terms in your customized search strategy in addition to the terms in SMQ Extravasation events (injections, infusions and implants).

# Detail Report

CR Number: 2024080003		Implementation Date: 20-Mar-24	Related CR: 2024025001	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Vessel puncture site swelling	Approved as Requested	Proposed PT	
To SMQ	Extravasation events (injections, infusions and implants) (SMQ)		Vessel puncture site swelling	10070648
Term scope	Broad		To SMQ	
			Extravasation events (injections, infusions and implants) (SMQ)	20000136
			Term scope	
			Broad	
			Term_category	
			A	
			Term_weight	
			0	

MSSO  
Comment:

CR Number: 2024080002		Implementation Date: 20-Mar-24	Related CR: 2024025001	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Vessel puncture site pain	Approved as Requested	Proposed PT	
To SMQ	Extravasation events (injections, infusions and implants) (SMQ)		Vessel puncture site pain	10066951
Term scope	Broad		To SMQ	
			Extravasation events (injections, infusions and implants) (SMQ)	20000136
			Term scope	
			Broad	
			Term_category	
			A	
			Term_weight	
			0	

MSSO  
Comment:

# Detail Report

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<b>CR Number:</b> 2024025002		<b>Implementation Date:</b> 31-Jan-24	<b>Related CR:</b> 2024025002		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Demote a PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
PT to merge	Blood urine	Rejected			
To PT	Blood urine present				

**MSSO Comment:** The proposal to demote the PT Blood urine under PT Blood urine present is not approved. Blood urine has been in MedDRA since version 2.1 and thus any changes will greatly impact legacy data. As well the term exists in Haemorrhages (SMQ).

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<b>CR Number:</b> 2024026000		<b>Implementation Date:</b> 31-Jan-24	<b>Related CR:</b> 2024026000		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed Term	Fascicutaneous flap operation	Approved as Requested	Proposed PT		
			Fascicutaneous flap operation		10090798
			HLT primary		
			Soft tissue therapeutic procedures NEC		10052876
			SOC primary		
			Surgical and medical procedures		10042613

**MSSO Comment:** The proposal to add a new term Fasciutaneous flap operation is approved as requested. Fasciutaneous flaps are commonly based on vessels arising in fascial planes in between muscles and do not intrinsically include any muscle in the design. These flaps are less bulky than musculocutaneous flaps and are used to cover large superficial defects when skin alone would not provide adequate coverage. Fasciutaneous flap operation will be added as PT to the HLT Soft tissue therapeutic procedures NEC. In a related change, the PT Fasciutaneous rotation flap will be demoted under the new PT Fasciutaneous flap operation for better alignment.

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<b>CR Number:</b> 2024031004		<b>Implementation Date:</b> 31-Jan-24	<b>Related CR:</b> 2024026000		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Demote a PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
PT to merge	Fasciutaneous rotation flap	Approved as Requested	PT to merge		
To PT	Fasciutaneous flap operation		Fasciutaneous rotation flap		10088632 Current
			To PT		
			Fasciutaneous flap operation		10090798

**MSSO Comment:**

# Detail Report

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<b>CR Number:</b> 2024026001		<b>Implementation Date:</b> 31-Jan-24	<b>Related CR:</b> 2024026001		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed Term	Microvascular free flap reconstruction	Rejected			

**MSSO Comment:** The proposal to add a new term Microvascular free flap reconstruction is not approved. The requested concept already exists in LLT Free microvascular flap surgery under PT Microvascular reconstruction.

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<b>CR Number:</b> 2024026002		<b>Implementation Date:</b> 31-Jan-24	<b>Related CR:</b> 2024026002		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed Term	Electromagnetic navigation bronchoscopy	Approved as Requested	Proposed LLT Electromagnetic navigation bronchoscopy To PT Bronchoscopy	10090799 Current  10006479	

**MSSO Comment:** The proposal to add a new term Electromagnetic navigation bronchoscopy is approved as requested. Electromagnetic navigation bronchoscopy (ENB) allows an accurate location of peripheral pulmonary target lesions, using technology similar to this of a global positioning system unit. Potential uses for ENB include biopsy of peripheral lung lesions, pleural dye marking of nodules for surgical wedge resection, placement of fiducial markers for stereotactic radiotherapy, and therapeutic insertion of brachytherapy catheters into malignant tissue. Electromagnetic navigation bronchoscopy will be added as LLT to PT Bronchoscopy.

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<b>CR Number:</b> 2024026003		<b>Implementation Date:</b> 31-Jan-24	<b>Related CR:</b> 2024026003		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed Term	Post prostatectomy erectile dysfunction	Rejected			

**MSSO Comment:** The proposal to add a new term Post prostatectomy erectile dysfunction is not approved. The proposed term combines a medical concept with additional medical wording related to etiology and/or pathophysiology. Section 3.5 of the MedDRA Term Selection Points to Consider (MTS:PTC) document defines these as "combination terms". When considering the addition of such combination terms, MedDRA generally attempts to limit inclusion to those terms which describe important, distinct and robust medical concepts which are internationally recognized diagnostic entities. Examples include terms such as diabetic retinopathy, hypertensive cardiomegaly and eosinophilic pneumonia.

# Detail Report

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<b>CR Number:</b> 2024026004		<b>Implementation Date:</b> 31-Jan-24	<b>Related CR:</b> 2024026004	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Gastrojejunostomy tube placement</i>	Approved as Requested	Proposed LLT <i>Gastrojejunostomy tube placement</i> To PT <i>Gastrointestinal tube insertion</i>	10090801 Current  10053050
<b>MSSO Comment:</b>	The proposal to add a new term Gastrojejunostomy tube placement is approved as requested. A Gastrojejunostomy tube is a soft, narrow tube that enters the stomach in the upper part of the abdomen and is threaded into the small intestine. The tube has two ports: a gastric port sits in the stomach and is used to vent air, drain fluids and give medicines, if needed, whereas the the jejunal port sits in the small intestine and is used for feeding. Gastrojejunostomy tube placement will be added as an LLT to PT Gastrointestinal tube insertion.			

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<b>CR Number:</b> 2024026005		<b>Implementation Date:</b> 31-Jan-24	<b>Related CR:</b> 2024026005	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Gastrojejunostomy tube removal</i>	Approved as Requested	Proposed LLT <i>Gastrojejunostomy tube removal</i> To PT <i>Gastrostomy tube removal</i>	10090800 Current  10072964
<b>MSSO Comment:</b>	The proposal to add a new term Gastrojejunostomy tube removal is approved as requested. A Gastrojejunostomy tube is a soft, narrow tube that enters the stomach in the upper part of the abdomen and is threaded into the small intestine. The tube has two ports: a gastric port sits in the stomach and is used to vent air, drain fluids and give medicines, if needed, whereas the jejunal port sits in the small intestine and is used for feeding. Gastrojejunostomy tube removal will be added as an LLT to PT Gastrostomy tube removal.			

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<b>CR Number:</b> 2024026006		<b>Implementation Date:</b> 31-Jan-24	<b>Related CR:</b> 2024026006	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Hyperinflammatory syndrome</i>	Rejected		
<b>MSSO Comment:</b>	The proposal to add a new LLT Hyperinflammatory syndrome is not approved. Hyperinflammatory syndrome(s) refer to a basket of inflammatory syndromes often associated with multisystem involvement and aberrant cytokine release and should be differentiated from autoinflammatory, autoimmune and hyperimmune syndromes. The major subtypes of hyperinflammatory syndromes, including macrophage activation syndrome, haemophagocytic lymphohistiocytosis, cytokine release syndrome and cytokine storm are available in MedDRA and depending on specific scenario, may be used. Multisystem inflammatory syndrome in children and Multisystem inflammatory syndrome in adults associated with SARS-CoV-2 represent the latest additions-added in version 24.1.			

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# Detail Report

<b>CR Number:</b> 2024026007		<b>Implementation Date:</b> 31-Jan-24	<b>Related CR:</b> 2024026007	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Zoster sine herpete</i>	Approved as Requested	Proposed PT <i>Zoster sine herpete</i>	10090802
			HLT primary <i>Herpes viral infections</i>	10019972
			SOC primary <i>Infections and infestations</i>	10021881
			HLT secondary <i>Peripheral neuropathies NEC</i>	10034607
			SOC secondary <i>Nervous system disorders</i>	10029205

**MSSO Comment:** The proposal to add a new term Zoster sine herpete is approved as requested. Zoster sine herpete (ZSH) is one of the atypical clinical manifestations of herpes zoster. Varicella-zoster virus(VZV) reactivation does not always cause shingles, and can occur in the enteric nervous system, such as the viscera or autonomic nerves, which do not project to the skin. This kind of reactivation with no shingles after the initial VZV infection is called Zoster sine herpete. Zoster sine herpete will be added as a new PT under primary HLT Herpes viral infections and secondary HLT Peripheral neuropathies NEC.

<b>CR Number:</b> 2024028008		<b>Implementation Date:</b> 31-Jan-24	<b>Related CR:</b> 2024028008	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Ultrasound guided tongue biopsy</i>	Approved as Requested	Proposed LLT <i>Ultrasound guided tongue biopsy</i>	10090804 Current
			To PT <i>Biopsy tongue</i>	10004891

**MSSO Comment:** The proposal to add a new term Ultrasound guided tongue biopsy is approved as requested. An ultrasound-guided tongue biopsy is a medical procedure in which a biopsy of the tongue is performed with the assistance of ultrasound imaging. Ultrasound guided tongue biopsy will be added as LLT to PT Biopsy tongue.

# Detail Report

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<b>CR Number:</b> 2024028009		<b>Implementation Date:</b> 31-Jan-24	<b>Related CR:</b> 2024028009	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Ultrasound guided lymph node biopsy</i>	Approved as Requested	Proposed LLT <i>Ultrasound guided lymph node biopsy</i>	10090803 Current
			To PT <i>Biopsy lymph gland</i>	10004797
<b>MSSO Comment:</b> The proposal to add a new term Ultrasound guided lymph node biopsy is approved as requested. An ultrasound guided lymph node biopsy is a medical procedure in which a biopsy of a lymph node is performed with the assistance of ultrasound imaging. Ultrasound guided lymph node biopsy will be added as LLT to PT Biopsy lymph gland.				

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<b>CR Number:</b> 2024029000		<b>Implementation Date:</b> 05-Feb-24	<b>Related CR:</b> 2024029000	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Eosinophilic cryptitis</i>	Approved as Requested	Proposed LLT <i>Eosinophilic cryptitis</i>	10090808 Current
			To PT <i>Cryptitis</i>	10079893
<b>MSSO Comment:</b> The proposal to add a new term Eosinophilic cryptitis is approved as requested. Eosinophilic cryptitis specifically refers to the presence of inflammation with a high concentration of eosinophils in the crypts of the small or large intestine when viewed under a microscope. It may be present in conditions like eosinophilic colitis, Crohn's disease or ulcerative colitis. Eosinophilic cryptitis will be added as LLT to the PT Cryptitis.				

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<b>CR Number:</b> 2024029001		<b>Implementation Date:</b> 31-Jan-24	<b>Related CR:</b> 2024029001	
<a href="#">Change Requested</a>	Rename PT/LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Term to modify	<i>Post-anaphylaxis mast cell anergy</i>	Rejected		
Replacement term	<i>Post-anaphylaxis mast cell allergy</i>			
<b>MSSO Comment:</b> The proposal to rename PT/LLT Post-anaphylaxis mast cell anergy to Post-anaphylaxis mast cell allergy is not approved. Post-anaphylaxis mast cell anergy (PAMA), commonly referred to as 'empty mast cell (MC) syndrome', is a state of temporary loss of cutaneous MC reactivity in the immediate aftermath of anaphylaxis. As such PT/LLT Post-anaphylaxis mast cell anergy is correctly spelled and was added in change request 2020328015 in MedDRA version 24.0.				

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# Detail Report

<b>CR Number:</b> 2024029002		<b>Implementation Date:</b> 31-Jan-24	<b>Related CR:</b> 2024029002	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Miles' operation	Approved Not as Requested	Proposed LLT Miles operation	10090805 Current
			To PT Proctocolectomy	10059848
<b>MSSO Comment:</b> The proposal to add a new LLT Miles' operation is approved but not as requested. Abdominoperineal resection is predominantly used to treat low-lying rectal carcinoma by removing the sigmoid colon, rectum, and anus, leaving behind a permanent colostomy. The procedure was first described by Sir William Ernest Miles in 1908. Proposed term will be modified by removal of apostrophe and added as LLT Miles operation under PT Proctocolectomy.				

<b>CR Number:</b> 2024029003		<b>Implementation Date:</b> 05-Feb-24	<b>Related CR:</b> 2024029003	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Thoracic endovascular aortic repair	Approved Not as Requested	Proposed PT Thoracic endovascular aortic repair	10090810
To PT	Aortic aneurysm repair		HLT primary Aortic therapeutic procedures	10002903
			SOC primary Surgical and medical procedures	10042613

**MSSO Comment:** The proposal to add a new LLT Thoracic endovascular aortic repair to PT Aortic aneurysm repair is approved but not as requested. Thoracic endovascular aortic repair is a minimally invasive alternative to traditional open surgery for thoracic aortic diseases, such as thoracic aortic aneurysms and aortic dissections. Thoracic endovascular aortic repair involves the insertion of a stent graft into the diseased or damaged portion of the thoracic aorta. The requested term Thoracic endovascular aortic repair will be added as a PT to HLT Aortic therapeutic procedures.

<b>CR Number:</b> 2024029004		<b>Implementation Date:</b> 05-Feb-24	<b>Related CR:</b> 2024029004	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	TEVAR	Approved Not as Requested	Proposed LLT TEVAR	10090811 Current
To PT	Aortic aneurysm repair		To PT Thoracic endovascular aortic repair	10090810

**MSSO Comment:** The proposal to add a new LLT TEVAR to PT Aortic aneurysm repair is approved but not as requested. TEVAR is the acronym for Thoracic endovascular aortic repair. TEVAR will be added as LLT to new PT Thoracic endovascular aortic repair added in change request 2024029003.

# Detail Report

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<b>CR Number:</b> 2024029005		<b>Implementation Date:</b> 05-Feb-24	<b>Related CR:</b> 2024029005		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed LLT	Thoracic endovascular aortic aneurysm repair	Rejected			
To PT	Aortic aneurysm repair				

**MSSO** The proposal to add a new LLT Thoracic endovascular aortic aneurysm repair to PT Aortic aneurysm repair is not approved. The proposed term can be represented by  
**Comment:** new LLT/PT Thoracic endovascular aortic repair added in change request 2024029003 and other existing MedDRA codes based on scenario.

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<b>CR Number:</b> 2024029008		<b>Implementation Date:</b> 05-Feb-24	<b>Related CR:</b> 2024029008		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed Term	Basal joint arthritis	Rejected			

**MSSO** The proposal to add a new term Basal joint arthritis is not approved. Osteoarthritis of the thumb occurs in the vast majority of cases in the trapeziometacarpal joint.  
**Comment:** Therefore, the "basal" locator is redundant. Please see existing LLT Thumb osteoarthritis.

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<b>CR Number:</b> 2024029009		<b>Implementation Date:</b> 05-Feb-24	<b>Related CR:</b> 2024029009		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed Term	Multiple sclerosis worsening	Rejected			

**MSSO** The proposal to add a new term Multiple sclerosis worsening is not approved. Based on the concept description; and for the purposes of term placement in MedDRA, the  
**Comment:** use of modifiers exacerbated, aggravated and worsened is interchangeable. As such, the concept LLT Multiple sclerosis aggravated may be used. The approach, based on specifics of clinical scenario, may be memorialized and addressed in coding conventions

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# Detail Report

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<b>CR Number:</b> 2024029010		<b>Implementation Date:</b> 05-Feb-24	<b>Related CR:</b> 2024029010	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Autoimmune vasculitis</i>	Approved as Requested	Proposed PT	
			<i>Autoimmune vasculitis</i>	10090809
			HLT primary	
			<i>Vasculitides NEC</i>	10047113
			SOC primary	
			<i>Vascular disorders</i>	10047065
			HLT secondary	
			<i>Autoimmune disorders NEC</i>	10027657
			SOC secondary	
			<i>Immune system disorders</i>	10021428

**MSSO** The proposal to add a new term Autoimmune vasculitis is approved as requested. Vasculitis may be primary (has no known cause) or secondary, which may be triggered  
**Comment:** by an infection, a drug, or a toxin or may occur as part of another inflammatory disorder or cancer. Vasculitis can present an autoimmune pathogenesis and may also be secondary to other autoimmune diseases. Autoimmune vasculitis will be added as PT with a primary link to HLT Vasculitides NEC and a secondary link to HLT Autoimmune disorders NEC.

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<b>CR Number:</b> 2024029011		<b>Implementation Date:</b> 05-Feb-24	<b>Related CR:</b> 2024029011	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Biliary polypectomy</i>	Rejected		

**MSSO** The proposal to add a new term Biliary polypectomy is not approved. Polyps in the biliary system are generally located in the gallbladder and therefore existing PT  
**Comment:** Gallbladder polypectomy can be used to code the requested concept.

# Detail Report

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<b>CR Number:</b> 2024029012		<b>Implementation Date:</b> 05-Feb-24	<b>Related CR:</b> 2024029012	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	Shoulder reconstruction	Approved as Requested	Proposed LLT Shoulder reconstruction	10090812 Current
			To PT Shoulder operation	10062242
<b>MSSO Comment:</b> The proposal to add a new term Shoulder reconstruction is approved as requested. Shoulder reconstruction surgery is an operative procedure in which stretched or torn soft-tissue structures that surround the shoulder joint such as the capsule, ligaments, and cartilage, are repaired to secure the shoulder joint in place. The procedure is mainly employed for the treatment of individuals with shoulder instability. Shoulder reconstruction will be added as sub-concept LLT under PT Shoulder operation aligned with LLT Bankart repair.				

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<b>CR Number:</b> 2024029083		<b>Implementation Date:</b> 05-Feb-24	<b>Related CR:</b> 2024029083	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Worsening malaise	Rejected		
To PT	Malaise			
<b>MSSO Comment:</b> The proposal to add a new LLT Worsening malaise to PT Malaise is not approved. The MSSO refrains from adding new terms with a qualifier of aggravation / worsening / exacerbation unless such a term represents an internationally accepted unique medical concept.				

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<b>CR Number:</b> 2024029084		<b>Implementation Date:</b> 05-Feb-24	<b>Related CR:</b> 2024029084	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Nephroureterolithiasis	Approved as Requested	Proposed LLT Nephroureterolithiasis	10090813 Current
			To PT Nephrolithiasis	10029148
<b>MSSO Comment:</b> The proposal to add a new LLT Nephroureterolithiasis is approved as requested. While nephrolithiasis specifically refers to calculi in the kidneys, renal calculi and ureteral calculi (ureterolithiasis) are often discussed in conjunction. Ureteral calculi almost always originate in the kidneys, although they may continue to grow once they lodge in the ureter. Thus, the proposed term Nephroureterolithiasis will be added as LLT to PT Nephrolithiasis.				

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# Detail Report

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<b>CR Number:</b> 2024029085		<b>Implementation Date:</b> 05-Feb-24	<b>Related CR:</b> 2024029085	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Dixon operation	Approved as Requested	Proposed LLT Dixon operation	10090814 Current
			To PT Proctectomy	10077252
<b>MSSO Comment:</b> The proposal to add a new LLT Dixon operation is approved as requested. Dixon operation is a continence-preserving anterior rectum resection. Although the term is not used frequently anymore, it will be added as LLT Dixon operation to PT Proctectomy aligned with LLT Anterior rectum resection.				

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<b>CR Number:</b> 2024030005		<b>Implementation Date:</b> 05-Feb-24	<b>Related CR:</b> 2024030005	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	Cecal adenocarcinoma	Approved as Requested	Proposed LLT Cecal adenocarcinoma	10090806 Current
			To PT Adenocarcinoma of colon	10001167
<b>MSSO Comment:</b> The proposal to add a new term Cecal adenocarcinoma is approved as requested. Adenocarcinomas of the cecum, together with those of the ascending colon, are both considered right-sided colon carcinomas, which exhibit exophytic pathological behavior and a poorer overall survival than left-sided colon carcinomas. Cecal adenocarcinoma will be added as a sub-concept LLT to PT Adenocarcinoma of colon. In a related change, its British English spelled counterpart Caecal adenocarcinoma, will also be added as LLT to the PT Adenocarcinoma of colon.				

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<b>CR Number:</b> 2024036004		<b>Implementation Date:</b> 05-Feb-24	<b>Related CR:</b> 2024030005	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Caecal adenocarcinoma	Approved as Requested	Proposed LLT Caecal adenocarcinoma	10090807 Current
To PT	Adenocarcinoma of colon		To PT Adenocarcinoma of colon	10001167
<b>MSSO Comment:</b>				

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# Detail Report

<b>CR Number:</b> 2024030006		<b>Implementation Date:</b> 05-Feb-24	<b>Related CR:</b> 2024030006	
<u>Change Requested</u>	Promote an LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Vitreous haze</i>	Approved as Requested	Proposed LLT	
From PT	<i>Vitreous opacities</i>		<i>Vitreous haze</i>	10077514
			From PT	
			<i>Vitreous opacities</i>	10047658
			HLT primary	
			<i>Choroid and vitreous structural change, deposit and degeneration</i>	10008776
			SOC primary	
			<i>Eye disorders</i>	10015919

**MSSO Comment:** The proposal to promote the LLT Vitreous haze from PT Vitreous opacities is approved as requested. Haze is a uniform densification all over the vitreous whereas opacity is rather used when opacification is localized to certain obstacles like floaters. Grading of intraocular inflammation using cell counts in the aqueous humor and anterior vitreous was a subjective assessment of anterior chamber flare which has recently have been standardized by the Nussenblatt vitreous haze scale. The LLT Vitreous haze will be promoted from PT Vitreous opacities to a PT level and added to HLT Choroid and vitreous structural change, deposit and degeneration.

<b>CR Number:</b> 2024031000		<b>Implementation Date:</b> 05-Feb-24	<b>Related CR:</b> 2024031000	
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Glioma related epilepsy</i>	Rejected		
To PT	<i>Epilepsy</i>			

**MSSO Comment:** The proposal to add a new LLT Glioma related epilepsy to PT Epilepsy is not approved. Glioma related epilepsy is defined as symptomatic epileptic seizures secondary to gliomas, occurring in nearly 50% in high-grade glioma patients and up to 90% in patients with low-grade glioma. The proposed term implies a causal relationship between two concepts, and therefore represents a combination term. The MSSO refrains from adding such terms as to avoid overpopulation of MedDRA.

<b>CR Number:</b> 2024031001		<b>Implementation Date:</b> 05-Feb-24	<b>Related CR:</b> 2024031001	
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>IDDTV</i>	Approved Not as Requested	Proposed LLT	
To PT	<i>Deep vein thrombosis</i>		<i>Isolated distal deep vein thrombosis</i>	10090815 Current
			To PT	
			<i>Deep vein thrombosis</i>	10051055

**MSSO Comment:** The proposal to add a new LLT IDDTV to PT Deep vein thrombosis is approved but not as requested. Isolated distal deep vein thrombosis (IDDTV) (also known as calf vein DVT) has no proximal component, is located below the knee, and is confined to the calf veins. The popliteal vein is not involved. IDDTV will be modified to its spelled-out version and added as LLT Isolated distal deep vein thrombosis to PT Deep vein thrombosis.



# Detail Report

<b>CR Number:</b> 2024031002		<b>Implementation Date:</b> 05-Feb-24	<b>Related CR:</b> 2024031002	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Thymidine kinase 2 deficiency (TK2d)	Approved Not as Requested	Proposed LLT	
To PT	Mitochondrial DNA depletion		Thymidine kinase 2 deficiency	10090816 Current
			To PT	
			Mitochondrial DNA depletion	10059396
<b>MSSO Comment:</b> The proposal to add a new LLT Thymidine kinase 2 deficiency (TK2d) to PT Mitochondrial DNA depletion is approved but not as requested. Thymidine kinase 2 deficiency (TK2d) is a rare genetic disorder that affects mitochondrial DNA maintenance and replication. As a result, affected individuals may experience a wide range of symptoms, including muscle weakness, respiratory problems, developmental delay, and other issues related to mitochondrial dysfunction. The proposed term will be modified for MedDRA term conventions to Thymidine kinase 2 deficiency and added as LLT to PT Mitochondrial DNA depletion.				

<b>CR Number:</b> 2024031005		<b>Implementation Date:</b> 07-Feb-24	<b>Related CR:</b> 2024031005	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	Vascularized fibula graft	Approved as Requested	Proposed LLT	
			Vascularized fibula graft	10090819 Current
			To PT	
			Bone graft	10005971
<b>MSSO Comment:</b> The proposal to add a new term Vascularized fibula graft is approved as requested. A vascularized fibula graft is a surgical procedure in which a segment of the fibula bone, along with its blood supply, is transplanted to another site. Vascularized fibula grafts are commonly used in reconstructive surgery, particularly in cases where traditional bone grafts may not be sufficient or when the blood supply to the affected area is compromised. Vascularized fibula graft and its British English spelled counterpart Vascularised fibula graft will both be added as LLTs to PT Bone graft.				

<b>CR Number:</b> 2024038002		<b>Implementation Date:</b> 07-Feb-24	<b>Related CR:</b> 2024031005	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Vascularised fibula graft	Approved as Requested	Proposed LLT	
To PT	Bone graft		Vascularised fibula graft	10090821 Current
			To PT	
			Bone graft	10005971
<b>MSSO Comment:</b>				

# Detail Report

<b>CR Number:</b> 2024031006		<b>Implementation Date:</b> 07-Feb-24	<b>Related CR:</b> 2024031006	
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Anti-Jo-1 antibody negative</i>	Approved Not as Requested	Proposed LLT <i>Anti-Jo-1 antibody negative</i>	10090820 Current
			To PT <i>Antinuclear antibody negative</i>	10002809
<b>MSSO Comment:</b> The proposal to add a new PT Anti-Jo-1 antibody negative is approved but not as requested. Anti-Jo-1 antibody negative will be added as an LLT to PT Antinuclear antibody negative, as synonym of existing of Jo-1 antibody negative. In a related change, PT Anti-Jo-1 antibody will be demoted under PT Antinuclear antibody for better alignment.				

<b>CR Number:</b> 2024038003		<b>Implementation Date:</b> 07-Feb-24	<b>Related CR:</b> 2024031006	
<a href="#">Change Requested</a>	Demote a PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
PT to merge	<i>Anti-Jo-1 antibody</i>	Approved as Requested	PT to merge <i>Anti-Jo-1 antibody</i>	10089581 Current
To PT	<i>Antinuclear antibody</i>		To PT <i>Antinuclear antibody</i>	10002807

**MSSO Comment:**

<b>CR Number:</b> 2024031007		<b>Implementation Date:</b> 07-Feb-24	<b>Related CR:</b> 2024031007	
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Anti-Jo-1 antibody positive</i>	Approved Not as Requested	Proposed LLT <i>Anti-Jo-1 antibody positive</i>	10090818 Current
			To PT <i>Antinuclear antibody positive</i>	10060055

**MSSO Comment:** The proposal to add a new PT Anti-Jo-1 antibody positive is approved but not as requested. Anti-Jo-1 antibody positive will be added as an LLT to PT Antinuclear antibody positive, as a synonym of existing LLT Jo-1 antibody positive.

# Detail Report

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<b>CR Number:</b> 2024031008	<b>Implementation Date:</b> 07-Feb-24	<b>Related CR:</b> 2024031008	<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>
Proposed Term	<i>For test terms with qualifiers</i>	Rejected	

**MSSO Comment:** The proposal to add a new term For test terms with qualifiers is not approved. The MSSO generally only adds investigation terms if a specific need for a term is provided by the subscriber, but not pro-actively. In case you have proactivity requests, kindly submit them to the MSSO through an email to the helpdesk. For more detailed information on proactivity requests, please refer to: <https://www.meddra.org/how-to-use/change-requests>.

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<b>CR Number:</b> 2024032000	<b>Implementation Date:</b> 05-Feb-24	<b>Related CR:</b> 2024032000	<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>
Proposed LLT	<i>Atrial septal aneurysm</i>	Rejected	

**MSSO Comment:** The proposal to add a new LLT Atrial septal aneurysm is not approved. The proposed concept exists in the LLT Interatrial septal aneurysm.

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<b>CR Number:</b> 2024032001	<b>Implementation Date:</b> 07-Feb-24	<b>Related CR:</b> 2024032001	<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>
Proposed Term	<i>Nerve sparing robot assisted radical prostatectomy</i>	Approved as Requested	
		Proposed LLT	
		<i>Nerve sparing robot assisted radical prostatectomy</i>	10090822 Current
		To PT	
		<i>Radical prostatectomy</i>	10050756

**MSSO Comment:** The proposal to add a new term Nerve sparing robot assisted radical prostatectomy is approved as requested. Although technically demanding, nerve sparing robot assisted radical prostatectomy involves different techniques and approaches but is a critical step in improving the functional outcomes following surgery. The aim is to spare injury to the prostatic plexus of nerves along with vessels constituting the predominant neurovascular bundle. Nerve sparing robot assisted radical prostatectomy will be added as a subconcept LLT under PT Radical prostatectomy.

# Detail Report

<b>CR Number:</b> 2024032002		<b>Implementation Date:</b> 07-Feb-24		<b>Related CR:</b> 2024032002	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed Term	Robot assisted laparoscopic radical prostatectomy	Approved as Requested	Proposed LLT Robot assisted laparoscopic radical prostatectomy	10090823	Current
			To PT Radical prostatectomy	10050756	
<b>MSSO Comment:</b> The proposal to add a new term Robot assisted laparoscopic radical prostatectomy is approved as requested. Radical prostatectomy is considered the 'gold standard' treatment for patients with organ-confined prostate cancer and greater than 10 years life expectancy. There are now several surgical approaches available to the urologist: perineal, open retropubic, laparoscopic, and robotic-assisted laparoscopic. Robot assisted laparoscopic radical prostatectomy will be added as a sub-concept LLT under PT Radical prostatectomy.					

<b>CR Number:</b> 2024032003		<b>Implementation Date:</b> 07-Feb-24		<b>Related CR:</b> 2024032003	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed Term	Pneumocystis jirovecii sputum PCR positive	Approved as Requested	Proposed LLT Pneumocystis jirovecii sputum PCR positive	10090824	Current
			To PT Pneumocystis test positive	10070454	
<b>MSSO Comment:</b> The proposal to add a new term Pneumocystis jirovecii sputum PCR positive is approved as requested. Pneumocystis jirovecii is a fungus that can cause pneumonia, especially in individuals with weakened immune systems, such as those with HIV/AIDS or undergoing immunosuppressive therapy. PCR testing of respiratory specimens, such as sputum or broncho-alveolar lavage fluid, can detect the presence of Pneumocystis jirovecii DNA. Pneumocystis jirovecii sputum PCR positive will be added as LLT to PT Pneumocystis test positive.					

<b>CR Number:</b> 2024032004		<b>Implementation Date:</b> 07-Feb-24		<b>Related CR:</b> 2024032004	
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed PT	Hair hypopigmentation	Approved Not as Requested	Proposed LLT Hair hypopigmentation	10090825	Current
HLT primary	Hypopigmentation disorders		To PT Hair colour changes	10019030	
SOC primary	Skin and subcutaneous tissue disorders				
<b>MSSO Comment:</b> The proposal to add a new PT Hair hypopigmentation to primary HLT Hypopigmentation disorders in SOC Skin and subcutaneous tissue disorders is approved but not as requested. Hair colour modifications comprise lightening/greying, darkening, or even a complete hair colour change, which may involve the scalp and/or all body hair. Hair hypopigmentation will be added as an LLT to PT Hair colour changes as quasi synonyms of LLT Hair depigmented and LLT Hair lightened.					

# Detail Report

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<b>CR Number:</b> 2024032005		<b>Implementation Date:</b> 07-Feb-24	<b>Related CR:</b> 2024032005		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Link (move) an LLT to another PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed LLT	Hair depigmented	Rejected			
From PT	Hair colour changes				
To PT	Hair hypopigmentation				
<b>MSSO Comment:</b> The proposal to move the LLT Hair depigmented from PT Hair colour changes to PT Hair hypopigmentation is not approved. The proposed move is a technical rejection as Hair hypopigmentation was added as an LLT in change request 2024032004.					

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<b>CR Number:</b> 2024032006		<b>Implementation Date:</b> 07-Feb-24	<b>Related CR:</b> 2024032006		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Link (move) an LLT to another PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed LLT	Hair colour greying	Rejected			
From PT	Hair colour changes				
To PT	Hair hypopigmentation				
<b>MSSO Comment:</b> The proposal to move the LLT Hair colour greying from PT Hair colour changes to PT Hair hypopigmentation is not approved. The proposed move is a technical rejection as Hair hypopigmentation was added as an LLT in change request 2024032004.					

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<b>CR Number:</b> 2024032007		<b>Implementation Date:</b> 07-Feb-24	<b>Related CR:</b> 2024032007		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Link (move) an LLT to another PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed LLT	Hair lightened	Rejected			
From PT	Hair colour changes				
To PT	Hair hypopigmentation				
<b>MSSO Comment:</b> The proposal to move the LLT Hair lightened from PT Hair colour changes to PT Hair hypopigmentation is not approved. The proposed move is a technical rejection as Hair hypopigmentation was added as an LLT in change request 2024032004.					

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# Detail Report

<b>CR Number: 2024032008</b>		<b>Implementation Date:</b> 07-Feb-24		<b>Related CR:</b> 2024032008	
<a href="#">Change Requested</a>	Link (move) an LLT to another PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed LLT	<i>Hair color graying</i>	Rejected			
From PT	<i>Hair colour changes</i>				
To PT	<i>Hair hypopigmentation</i>				
<b>MSSO Comment:</b>	The proposal to move the LLT Hair color graying from PT Hair colour changes to PT Hair hypopigmentation is not approved. The proposed move is a technical rejection as Hair hypopigmentation was added as an LLT in change request 2024032004.				

<b>CR Number:</b> 2024032009		<b>Implementation Date:</b> 07-Feb-24		<b>Related CR:</b> 2024032009	
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed PT	Hair hyperpigmentation	Approved Not as Requested	Proposed LLT		
HLT primary	Hyperpigmentation disorders		Hair hyperpigmentation	10090826	Current
SOC primary	Skin and subcutaneous tissue disorders		To PT		
			Hair colour changes	10019030	
<b>MSSO Comment:</b>	The proposal to add a new PT Hair hyperpigmentation to primary HLT Hyperpigmentation disorders in SOC Skin and subcutaneous tissue disorders is approved but not as requested. Hair colour modifications comprise lightening/greying, darkening, or even a complete hair colour change, which may involve the scalp and/or all body hair. Hair hyperpigmentation will be added as an LLT to PT Hair colour changes as quasi synonyms of LLT Black pigmentation of hair roots and LLT Hair darkened.				

<b>CR Number:</b> 2024032010		<b>Implementation Date:</b> 07-Feb-24		<b>Related CR:</b> 2024032010	
<a href="#">Change Requested</a>	Link (move) an LLT to another PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed LLT	<i>Black pigmentation of hair roots</i>	Rejected			
From PT	<i>Hair colour changes</i>				
To PT	<i>Hair hyperpigmentation</i>				
<b>MSSO Comment:</b>	The proposal to move the LLT Black pigmentation of hair roots from PT Hair colour changes to PT Hair hyperpigmentation is not approved. The proposed move is a technical rejection as Hair hyperpigmentation was added as an LLT in change request 2024032009.				

# Detail Report

<b>CR Number:</b> 2024032011		<b>Implementation Date:</b> 07-Feb-24		<b>Related CR:</b> 2024032011	
<a href="#">Change Requested</a>	Link (move) an LLT to another PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed LLT	<i>Hair darkened</i>	Rejected			
From PT	<i>Hair colour changes</i>				
To PT	<i>Hair hyperpigmentation</i>				
<b>MSSO Comment:</b>	The proposal to move the LLT Hair darkened from PT Hair colour changes to PT Hair hyperpigmentation is not approved. The proposed move is a technical rejection as Hair hyperpigmentation was added as an LLT in change request 2024032009.				

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<b>CR Number:</b> 2024032012		<b>Implementation Date:</b> 07-Feb-24		<b>Related CR:</b> 2024032012	
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed PT	<i>Hair colour restored</i>	Rejected			
HLT primary	<i>Pilar disorders NEC</i>				
SOC primary	<i>Skin and subcutaneous tissue disorders</i>				
<b>MSSO Comment:</b>	The proposal to add a new PT Hair colour restored to primary HLT Pilar disorders NEC in SOC Skin and subcutaneous tissue disorders is not approved. Hair color changes can sometimes provide insights into a person's health. Some medications may cause changes in hair color as a side effect. Hair color restored is very similar to existing LLT Hair color renewed.				

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<b>CR Number:</b> 2024032013		<b>Implementation Date:</b> 07-Feb-24		<b>Related CR:</b> 2024032013	
<a href="#">Change Requested</a>	Link (move) an LLT to another PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed LLT	<i>Hair colour renewed</i>	Rejected			
From PT	<i>Hair colour changes</i>				
To PT	<i>Hair colour restored</i>				
<b>MSSO Comment:</b>	The proposal to move the LLT Hair colour renewed from PT Hair colour changes to PT Hair colour restored is not approved. This is a technical rejection as PT Hair colour restored was not added in change request 2024032012.				

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# Detail Report

<b>CR Number:</b> 2024032014		<b>Implementation Date:</b> 07-Feb-24		<b>Related CR:</b> 2024032014	
<a href="#">Change Requested</a>	Link (move) an LLT to another PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed LLT	<i>Hair color renewed</i>	Rejected			
From PT	<i>Hair colour changes</i>				
To PT	<i>Hair colour restored</i>				
<b>MSSO Comment:</b>	The proposal to move the LLT Hair color renewed from PT Hair colour changes to PT Hair colour restored is not approved. This is a technical rejection as PT Hair colour restored was not added in change request 2024032012.				

<b>CR Number:</b> 2024032015		<b>Implementation Date:</b> 07-Feb-24		<b>Related CR:</b> 2024032015	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed LLT	<i>Hair color restored</i>	Rejected			
To PT	<i>Hair colour restored</i>				
<b>MSSO Comment:</b>	The proposal to add a new LLT Hair color restored to PT Hair colour restored is not approved. This is a technical rejection as PT Hair colour restored was not added in change request 2024032012.				

<b>CR Number:</b> 2024032016		<b>Implementation Date:</b> 13-May-24		<b>Related CR:</b> 2024032016	
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed PT	Genetic focal segmental glomerulosclerosis	Approved Not as Requested After Suspension	Proposed LLT		
			Genetic focal segmental glomerulosclerosis	10091121	Current
			To PT		
			Congenital nephrotic syndrome	10060737	
<b>MSSO Comment:</b>	The proposal to add a new PT Genetic focal segmental glomerulosclerosis is approved but not as requested after suspension. A substantial percentage (up to 30%) of sporadic, steroid-resistant nephrotic syndrome patients carry the specific genetic mutation causally linked to focal segmental glomerulosclerosis, to the point that it may be advisable that all patients who have failed steroids should be offered genetic screening for mutations at the time of or prior to starting more aggressive treatments, as those patients have been shown to unfavorably respond to immunosuppressant therapy. Genetic focal segmental glomerulosclerosis will be added as LLT to PT Congenital nephrotic syndrome. In a related change LLT APOL1-mediated focal segmental glomerulosclerosis will be moved from PT Focal segmental glomerulosclerosis to PT Congenital nephrotic syndrome for better alignment.				



# Detail Report

CR Number: 2024134007		Implementation Date: 13-May-24	Related CR: 2024032016	
<a href="#">Change Requested</a>	Link (move) an LLT to another PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>APOL1-mediated focal segmental glomerulosclerosis</i>	Approved as Requested	Proposed LLT	10087691 Current
From PT	<i>Focal segmental glomerulosclerosis</i>		<i>APOL1-mediated focal segmental glomerulosclerosis</i>	
To PT	<i>Congenital nephrotic syndrome</i>		From PT	10067757
			<i>Focal segmental glomerulosclerosis</i>	
			To PT	10060737
			<i>Congenital nephrotic syndrome</i>	

MSSO  
Comment:

CR Number: 2024032017		Implementation Date: 07-Feb-24	Related CR: 2024032017	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Contrast Induced Nephropathy</i>	Rejected		

MSSO  
Comment: The proposal to add a new term Contrast Induced Nephropathy is not approved. The proposed concept exists as LLT Radiocontrast nephropathy.

CR Number: 2024032018		Implementation Date: 07-Feb-24	Related CR: 2024032018	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Pulp Polyp</i>	Approved Not as Requested	Proposed LLT	10090832 Current
			<i>Pulp polyp</i>	
			To PT	10090828
			<i>Chronic hyperplastic pulpitis</i>	

MSSO  
Comment: The proposal to add a new term Pulp Polyp is approved but not as requested. The proposed term will be modified for MedDRA capitalization conventions and added as a synonym LLT Pulp polyp to PT Chronic hyperplastic pulpitis, which will be added in change request 2024032019.

# Detail Report

<b>CR Number:</b> 2024032019		<b>Implementation Date:</b> 07-Feb-24	<b>Related CR:</b> 2024032019	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Chronic hyperplastic pulpitis</i>	Approved as Requested	Proposed PT	
			<i>Chronic hyperplastic pulpitis</i>	10090828
			HLT primary	
			<i>Dental pulp disorders</i>	10044050
			SOC primary	
			<i>Gastrointestinal disorders</i>	10017947

**MSSO Comment:** The proposal to add a new term Chronic hyperplastic pulpitis is approved as requested. Chronic hyperplastic pulpitis is a "productive" inflammation of dental pulp in which the development of granulation tissue is seen in response to persistent, low-grade mechanical irritation and bacterial invasion of the pulp. Chronic hyperplastic pulpitis will be added as a PT to HLT Dental pulp disorders.

<b>CR Number:</b> 2024032020		<b>Implementation Date:</b> 07-Feb-24	<b>Related CR:</b> 2024032020	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Atrial infarction</i>	Approved as Requested	Proposed LLT	
			<i>Atrial infarction</i>	10090837 Current
			To PT	
			<i>Myocardial infarction</i>	10028596

**MSSO Comment:** The proposal to add a new term Atrial infarction is approved as requested. Atrial infarction has been a relatively understudied entity. The right atrium is involved five times as often as the left, with the auricle the predominant site in either atria. Clinical atrial infarction may present with supraventricular arrhythmias, atrial rupture, hemodynamic compromise and thromboembolic phenomena. Atrial infarction will be added as an LLT to PT Myocardial infarction.

<b>CR Number:</b> 2024032021		<b>Implementation Date:</b> 07-Feb-24	<b>Related CR:</b> 2024032021	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Ureteroscopic Lithotripsy (URSL)</i>	Rejected		

**MSSO Comment:** The proposal to add a new term Ureteroscopic Lithotripsy (URSL) is not approved. This concept was recently added in change request 2023268013, and will be available with the MedDRA version 27.0 release in March.

# Detail Report

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<b>CR Number:</b> 2024032022		<b>Implementation Date:</b> 07-Feb-24	<b>Related CR:</b> 2024032022	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Subependymomas</i>	Approved Not as Requested	Proposed LLT <i>Subependymoma</i>	10090830 Current
			To PT <i>Ependymoma benign</i>	10014969
<b>MSSO Comment:</b> The proposal to add a new term Subependymomas is approved but not as requested. Subependymomas are benign slow-growing tumors of ependymal origin that account for less than 10% of ependymal neoplasms. Subependymomas are often asymptomatic and discovered only incidentally on neuroimaging for unrelated reasons or at autopsy. Symptomatic intracranial examples are typically associated with manifestations of ventricular obstruction and intracranial hypertension. The proposed term will be modified to its singular form and added as the LLT Subependymoma to the PT Ependymoma benign.				

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<b>CR Number:</b> 2024032023		<b>Implementation Date:</b> 07-Feb-24	<b>Related CR:</b> 2024032023	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Belly Button Bleeding</i>	Rejected		

**MSSO Comment:** The proposal to add a new term Belly Button Bleeding is not approved. The more specific medical term LLT Umbilical bleeding already exists.

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<b>CR Number:</b> 2024032024		<b>Implementation Date:</b> 07-Feb-24	<b>Related CR:</b> 2024032024	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Umbilical Endometriosis</i>	Approved Not as Requested	Proposed LLT <i>Umbilical endometriosis</i>	10090835 Current
			To PT <i>Endometriosis</i>	10014778

**MSSO Comment:** The proposal to add a new term Umbilical Endometriosis is approved but not as requested. Umbilical endometriosis is defined as the presence of ectopic endometrial glands and stroma within umbilicus. Umbilical Endometriosis will be modified according to MedDRA capitalization rules to Umbilical endometriosis and will be added as LLT to PT Endometriosis.

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# Detail Report

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<b>CR Number:</b> 2024032025		<b>Implementation Date:</b> 07-Feb-24	<b>Related CR:</b> 2024032025	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Tubal re-anastomosis surgery</i>	Approved as Requested	Proposed LLT <i>Tubal re-anastomosis surgery</i>	10090831 Current
			To PT <i>Salpingoplasty</i>	10056426
<b>MSSO Comment:</b> The proposal to add a new term Tubal re-anastomosis surgery is approved as requested. Tubal re-anastomosis surgery, also known as tubal ligation reversal, is a procedure performed to reconnect the fallopian tubes in women who have previously undergone tubal ligation. Tubal re-anastomosis surgery will be added as LLT to PT Salpingoplasty.				

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<b>CR Number:</b> 2024032026		<b>Implementation Date:</b> 07-Feb-24	<b>Related CR:</b> 2024032026	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Tuboplasty</i>	Rejected		
<b>MSSO Comment:</b> The proposal to add a new term Tuboplasty is not approved. Tuboplasty can refer to a number of surgical operations that attempt to restore patency and functioning of the fallopian tubes or repair of any type of tube-like structure, including the Eustachian tube in the head and neck. The term is thus considered ambiguous.				

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<b>CR Number:</b> 2024032027		<b>Implementation Date:</b> 07-Feb-24	<b>Related CR:</b> 2024032027	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>TUBAL LIGATION REVERSAL</i>	Approved Not as Requested	Proposed LLT <i>Tubal ligation reversal</i>	10090833 Current
			To PT <i>Salpingoplasty</i>	10056426
<b>MSSO Comment:</b> The proposal to add a new term TUBAL LIGATION REVERSAL is approved but not as requested. Tubal re-anastomosis surgery, also known as tubal ligation reversal, is a procedure performed to reconnect the fallopian tubes in women who have previously undergone tubal ligation. Tubal ligation is a surgical procedure in which the fallopian tubes are blocked or cut to prevent eggs from reaching the uterus and sperm from reaching the eggs, thus preventing pregnancy. The proposed term will be modified according to MedDRA capitalization rules and will be added as LLT Tubal ligation reversal to PT Salpingoplasty.				

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# Detail Report

<b>CR Number:</b> 2024032028		<b>Implementation Date:</b> 07-Feb-24	<b>Related CR:</b> 2024032028	
<u>Change Requested</u>	Add a New Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	TONSIL ASYMMETRY	Approved Not as Requested	Proposed PT Tonsil asymmetry	10090827
			HLT primary Respiratory tract disorders NEC	10057184
			SOC primary Respiratory, thoracic and mediastinal disorders	10038738

**MSSO Comment:** The proposal to add a new term TONSIL ASYMMETRY is approved but not as requested. Tonsil asymmetry refers to a condition in which one tonsil appears different in size or shape compared to the other tonsil. Tonsil asymmetry can be indicative of various underlying medical conditions, including infections, tumors, abscesses, inflammatory conditions, trauma, congenital anomalies, or systemic diseases. The proposed term will be modified for MedDRA capitalization conventions and added as PT Tonsil asymmetry under HLT Respiratory tract disorders NEC.

<b>CR Number:</b> 2024032029		<b>Implementation Date:</b> 07-Feb-24	<b>Related CR:</b> 2024032029	
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Saddle Anesthetic Block	Approved Not as Requested	Proposed LLT Saddle block anesthesia	10090836 Current
To PT	Spinal anaesthesia		To PT Spinal anaesthesia	10041536

**MSSO Comment:** The proposal to add a new LLT Saddle Anesthetic Block to PT Spinal anaesthesia is approved but not as requested. Saddle block anesthesia is a kind of low spinal block that manifests anesthesia over the saddle area, i.e., perineum, perianal area, medial aspect of legs and thigh. Proposed term will be modified according to MedDRA capitalization conventions and in the most commonly referenced word order and added as subconcept LLT Saddle block anesthesia under PT Spinal anaesthesia. In a related change, the British English spelled counterpart LLT Saddle block anaesthesia will also be added under PT Spinal anaesthesia.

<b>CR Number:</b> 2024038004		<b>Implementation Date:</b> 07-Feb-24	<b>Related CR:</b> 2024032029	
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Saddle block anaesthesia	Approved as Requested	Proposed LLT Saddle block anaesthesia	10090838 Current
To PT	Spinal anaesthesia		To PT Spinal anaesthesia	10041536

**MSSO Comment:**

# Detail Report

<b>CR Number:</b> 2024032030		<b>Implementation Date:</b> 07-Feb-24	<b>Related CR:</b> 2024032030	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Pancreatic Necrosectomy</i>	Approved Not as Requested	Proposed PT <i>Pancreatic necrosectomy</i>	10090829
			HLT primary <i>Pancreatic therapeutic procedures</i>	10033634
			SOC primary <i>Surgical and medical procedures</i>	10042613

**MSSO Comment:** The proposal to add a new term Pancreatic Necrosectomy is approved but not as requested. Pancreatic necrosectomy consists of debridement of the necrotic pancreatic tissue and may be done by several approaches including: Open necrosectomy, percutaneous drainage or by endoscopic pancreatic necrosectomy. The proposed term will be modified for MedDRA capitalization conventions and added as PT Pancreatic necrosectomy under HLT Pancreatic therapeutic procedures.

<b>CR Number:</b> 2024032031		<b>Implementation Date:</b> 07-Feb-24	<b>Related CR:</b> 2024032031	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Periampullary diverticulum</i>	Approved as Requested	Proposed LLT <i>Periampullary diverticulum</i>	10090834 Current
To PT	<i>Diverticulum intestinal</i>		To PT <i>Diverticulum intestinal</i>	10013559

**MSSO Comment:** The proposal to add a new LLT Periampullary diverticulum to PT Diverticulum intestinal is approved as requested. A periampullary diverticulum is a location-specific type of duodenal diverticulum.

<b>CR Number:</b> 2024032032		<b>Implementation Date:</b> 05-Feb-24	<b>Related CR:</b> 2024032032	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Endemic non-filarial elephantiasis</i>	Approved as Requested	Proposed LLT <i>Endemic non-filarial elephantiasis</i>	10090817 Current
To PT	<i>Podoconiosis</i>		To PT <i>Podoconiosis</i>	10090382

**MSSO Comment:** The proposal to add a new LLT Endemic non-filarial elephantiasis to PT Podoconiosis is approved as requested. Endemic non-filarial elephantiasis is a frequently used synonym of PT Podoconiosis.

# Detail Report

<b>CR Number:</b> 2024032033		<b>Implementation Date:</b> 07-Feb-24	<b>Related CR:</b> 2024032033	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	Total glosso-laryngectomy	Approved Not as Requested	Proposed LLT Total glossolaryngectomy To PT Laryngectomy	10090839 Current  10023872

**MSSO Comment:** The proposal to add a new term Total glosso-laryngectomy is approved but not as requested. A glossolaryngectomy is a surgical procedure involving the removal of the tongue and the larynx. This procedure is typically performed in cases where there is advanced cancer affecting both the tongue and the larynx, and the removal of these structures is necessary to treat the cancer. The proposed term will be modified for consistency and added as LLT Total glossolaryngectomy to PT Laryngectomy.

<b>CR Number:</b> 2024033000		<b>Implementation Date:</b> 07-Feb-24	<b>Related CR:</b> 2024033000	
<a href="#">Change Requested</a>	Link (move) an LLT to another PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Shoulder injury	Rejected		
From PT	Limb injury			
To PT	joint injury			

**MSSO Comment:** The proposal to move the LLT Shoulder injury from PT Limb injury to PT joint injury is not approved. Shoulder injury is most often uses as a location descriptor in reference to an injury in the region of the shoulder, rather than to anyone of the shoulder structural components, and thus it is not considered to be a code referring specifically to the shoulder joint.

<b>CR Number:</b> 2024033001		<b>Implementation Date:</b> 07-Feb-24	<b>Related CR:</b> 2024033001	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	Intraoperative increased blood pressure	Rejected		

**MSSO Comment:** The proposal to add a new term Intraoperative increased blood pressure is not approved. The proposed term implies a temporal relationship between two concepts, and therefore represents a combination concept or a 'due to' relationship. The MSSO generally refrains from adding any new 'post procedural,' 'procedural,' or 'intraoperative' types of terms. For this particular proposal, please consider whether the existing LLT Intraoperative hypertension can satisfy your needs. Otherwise, please refer to Section 3.5 of the MedDRA Term Selection: Points to Consider Document regarding coding approaches/considerations.

# Detail Report

CR Number: 2024035000		Implementation Date: 07-Feb-24	Related CR: 2024035000	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	EBV-positive diffuse large B-cell lymphoma	Approved as Requested	Proposed LLT	
			EBV-positive diffuse large B-cell lymphoma	10090842 Current
			To PT	
			Diffuse large B-cell lymphoma	10012818
MSSO Comment:	The proposal to add a new LLT EBV-positive diffuse large B-cell lymphoma is approved as requested. Epstein-Barr virus (EBV)-positive diffuse large B cell lymphoma (DLBCL) is known for distinct clinical features. EBV+ DLBCL is characterized by the presence of EBV in the tumor cells, and it often has distinct clinical and pathological features compared to EBV-negative DLBCL. EBV-positive diffuse large B-cell lymphoma will be added as a new LLT to PT Diffuse large B-cell lymphoma.			

CR Number: 2024035001		Implementation Date: 07-Feb-24	Related CR: 2024035001	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Caseous necrosis	Approved as Requested	Proposed LLT	
			Caseous necrosis	10090843 Current
			To PT	
			Necrosis	10028851
MSSO Comment:	The proposal to add a new LLT Caseous necrosis is approved as requested. Caseous necrosis is a necrosis in which the tissue becomes a soft, dry, crumbly mass resembling cheese, usually caused by mycobacterial infection. Caseous necrosis will be added as LLT to PT Necrosis.			



# Detail Report

CR Number: 2024035002		Implementation Date: 07-Feb-24	Related CR: 2024035002	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>iatrogenic (transplant-related) Kaposi sarcoma</i>	Approved Not as Requested	Proposed PT <i>iatrogenic Kaposi sarcoma</i>	10090840
			HLT primary <i>Kaposi's sarcomas</i>	10023285
			SOC primary <i>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</i>	10029104
			HLT secondary <i>Non-site specific procedural complications</i>	10029559
			SOC secondary <i>Injury, poisoning and procedural complications</i>	10022117
<div>MSSO</div> <div>Comment: The proposal to add a new LLT iatrogenic (transplant-related) Kaposi sarcoma is approved but not as requested. Iatrogenic Kaposi sarcoma refers to Kaposi sarcoma that develops as a result of medical interventions, particularly immunosuppressive therapy following organ transplantation. The proposed term will be modified following MedDRA naming conventions to iatrogenic Kaposi sarcoma and added as a new PT to primary HLT Kaposi's sarcomas and to secondary HLT Non-site specific procedural complications.</div>				

# Detail Report

CR Number: 2024035003		Implementation Date: 07-Feb-24	Related CR: 2024035003	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Marden-Walker syndrome	Approved Not as Requested	Proposed PT Marden-Walker syndrome	10090841
			HLT primary Musculoskeletal disorders congenital NEC	10029513
			SOC primary Congenital, familial and genetic disorders	10010331
			HLT secondary Musculoskeletal disorders congenital NEC	10029513
			SOC secondary Musculoskeletal and connective tissue disorders	10028395

MSSO Comment: The proposal to add a new LLT Marden-Walker syndrome is approved but not as requested. Marden-Walker syndrome is a rare developmental defect during embryogenesis characterized by multiple joint contractures (arthrogryposis), a mask-like face with blepharophimosis, micrognathia, high-arched or cleft palate, low-set ears, decreased muscular bulk, kyphoscoliosis and arachnodactyly. Inheritance is autosomal recessive. Marden-Walker syndrome will be added as PT under bi-axial HLT Musculoskeletal disorders congenital NEC to (primary SOC Congenital, familial and genetic disorders and secondary SOC Musculoskeletal and connective tissue disorders).

CR Number: 2024035004		Implementation Date: 07-Feb-24	Related CR: 2024035004	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Flail leg syndrome	Approved as Requested	Proposed LLT Flail leg syndrome	10090844 Current
			To PT Amyotrophic lateral sclerosis	10002026

MSSO Comment: The proposal to add a new LLT Flail leg syndrome is approved as requested. The flail leg syndrome (also called the pseudo-polyneuritic variant of ALS/motor neuron disease) is characterized by progressive lower motor neuron weakness and wasting with onset in the distal leg. Patients presenting with the flail leg syndrome have a lower rate of comorbid dementia, a longer survival time, and a slower rate of progression to involvement of other body segments and of the development of respiratory muscle weakness. Flail leg syndrome will be added as sub-concept LLT to PT Amyotrophic lateral sclerosis.

# Detail Report

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<b>CR Number:</b> 2024036000	<b>Implementation Date:</b> 07-Feb-24	<b>Related CR:</b> 2024036000	<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>
Proposed LLT	<i>Non-obstructive coronary artery disease</i>	Rejected	

**MSSO** The proposal to add a new LLT Non-obstructive coronary artery disease is not approved. Proposed term has been added already in change request 2023219026 as LLT  
**Comment:** Nonobstructive coronary artery disease under PT Coronary artery disease.

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<b>CR Number:</b> 2024036001	<b>Implementation Date:</b> 07-Feb-24	<b>Related CR:</b> 2024036001	<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>
Proposed LLT	<i>Consolidation radiotherapy</i>	Approved as Requested	Proposed LLT <i>Consolidation radiotherapy</i> 10090845 Current To PT <i>Radiotherapy</i> 10037794

**MSSO** The proposal to add a new LLT Consolidation radiotherapy is approved as requested. Treatment that is given after cancer has disappeared following the initial therapy is called consolidation therapy (may include radiation therapy, stem cell transplant, or treatment with anti-neoplastic drugs) and is used to kill any cancer cells that may be left in the body. Consolidation radiotherapy will be added as sub-concept LLT under PT Radiotherapy.  
**Comment:**

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<b>CR Number:</b> 2024036002	<b>Implementation Date:</b> 07-Feb-24	<b>Related CR:</b> 2024036002	<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>
Proposed LLT	<i>Alcohol misuse disorder</i>	Rejected	

**MSSO** The proposal to add a new LLT Alcohol misuse disorder is not approved. The proposed term is commonly also referred in literature as alcohol use disorder which exists as  
**Comment:** LLT/PT Alcohol use disorder.

# Detail Report

CR Number: 2024036003		Implementation Date: 08-Feb-24	Related CR: 2024036003		
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed LLT	Acquired aural fistula	Rejected			

MSSO Comment: The proposal to add a new LLT Acquired aural fistula is not approved. Aural fistula is almost always a congenital deformity of the external ear and as such is in MedDRA as LLT/PT Congenital aural fistula. Please provide further references around an acquired aural fistula.

CR Number: 2024037000		Implementation Date: 08-Feb-24	Related CR: 2024037000		
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed Term	Drug-induced erythema multiforme	Rejected			

MSSO Comment: The proposal to add a new term Drug-induced erythema multiforme is not approved. The MSSO generally refrains from adding new drug-induced terms. Causality relationship between a drug and an adverse event are not to be determined by a term itself, but from several other parameters and judgments made over a report.

CR Number: 2024037001		Implementation Date: 08-Feb-24	Related CR: 2024037001		
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed Term	Subacute hepatitis	Approved as Requested	Proposed LLT Subacute hepatitis	10090846	Current
			To PT Hepatitis acute	10019727	

MSSO Comment: The proposal to add a new term Subacute hepatitis is approved as requested. In subacute hepatitis, signs, symptoms, and laboratory values appear with an intensity between acute and chronic. Subacute hepatitis will be added as an LLT to PT Hepatitis acute.

# Detail Report

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<b>CR Number:</b> 2024037002		<b>Implementation Date:</b> 08-Feb-24	<b>Related CR:</b> 2024037002	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Partially blocked fallopian tube</i>	Approved as Requested	Proposed LLT <i>Partially blocked fallopian tube</i>	10090847 Current
			To PT <i>Fallopian tube stenosis</i>	10065791
<b>MSSO Comment:</b> The proposal to add a new term Partially blocked fallopian tube is approved as requested. In cases where a fallopian tube is partially blocked, there is still the possibility of oocyte fertilization. Partially blocked fallopian tube will be added as an LLT to PT Fallopian tube stenosis.				

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<b>CR Number:</b> 2024037003		<b>Implementation Date:</b> 08-Feb-24	<b>Related CR:</b> 2024037003	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Ventricular septal thickening</i>	Rejected		
<b>MSSO Comment:</b> The proposal to add a new term Ventricular septal thickening is not approved. The proposed term concept has been added as LLT Ventricular septum thickening to PT Cardiac septal hypertrophy in change request 2023342004 and will be available with the MedDRA 27.1 version release in September 2024.				

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<b>CR Number:</b> 2024038000		<b>Implementation Date:</b> 08-Feb-24	<b>Related CR:</b> 2024038000	
<a href="#">Change Requested</a>	Change Status of LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
LLT to change	<i>Endometriosis of uterus</i>	Rejected		
Status	<i>non-current</i>			
<b>MSSO Comment:</b> The proposal to change status of LLT Endometriosis of uterus to non-current is not approved. Endometriosis of uterus is a synonym of PT Adenomyosis. Adenomyosis occurs when the tissue that normally lines the internal cavity of the uterus (endometrial tissue) develops into the muscular wall of the uterus, thus being sometimes called "endometriosis of the uterus".				

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# Detail Report

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<b>CR Number:</b> 2024038001	<b>Implementation Date:</b> 08-Feb-24	<b>Related CR:</b> 2024038001	<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>
Proposed Term	Subacute severe viral hepatitis	Rejected	

**MSSO Comment:** The proposal to add a new term Subacute severe viral hepatitis is not approved. Based on the reference provided, the concept may be represented by existing LLT Subacute fulminant hepatitis and LLT Viral hepatitis. The proposed term combines a medical concept with additional medical wording related to etiology and/or pathophysiology. Section 3.5 of the MedDRA Term Selection Points to Consider (MTS:PTC) document defines these as "combination terms". When considering the addition of such combination terms, MedDRA generally attempts to limit inclusion to those terms which describe important, distinct and robust medical concepts which are internationally recognized diagnostic entities. Furthermore, the MSSO refrains from adding new terms with a severity qualifier unless such a term represents an internationally accepted unique medical concept.

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<b>CR Number:</b> 2024039000	<b>Implementation Date:</b> 18-Feb-24	<b>Related CR:</b> 2024039000	<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>
Proposed LLT	Dislike of product smell	Approved as Requested	Proposed LLT Dislike of product smell To PT Product use complaint
			10090850 Current 10079400

**MSSO Comment:** The proposal to add a new LLT Dislike of product smell is approved as requested. Taste and smell aversion is a common problem with drugs and other therapies and may sometimes present symptoms associated with the consumption of the drug, such as nausea. Dislike of product smell may be considered a safety concern since it increases the risk for noncompliance. Dislike of product smell will be added as LLT to PT Product use complaint in line with LLT Dislike of product taste.

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<b>CR Number:</b> 2024039001	<b>Implementation Date:</b> 20-Feb-24	<b>Related CR:</b> 2024039001	<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>
Proposed Term	Toxoplasmosis pregnancy	Rejected	

**MSSO Comment:** The proposal to add a new term Toxoplasmosis pregnancy is not approved. The requested concept is a combination of two concurrent events, pregnancy and a toxoplasmosis infection, both of which count on existing MedDRA terms. For the likelihood of fetal damage outcome, PT Congenital toxoplasmosis can be considered. Please refer to Section 3.5 of the MedDRA Term Selection: Points to Consider Document regarding the coding of combination terms.

# Detail Report

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<b>CR Number:</b> 2024039002		<b>Implementation Date:</b> 20-Feb-24	<b>Related CR:</b> 2024039002		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed LLT	<i>Chikungunya virus disease immunisation</i>	Rejected			

**MSSO Comment:** The proposal to add a new LLT Chikungunya virus disease immunisation is not approved. The requested concept already exists in the PT/LLT Chikungunya immunisation added in change request 2023334170. It will be available with the MedDRA version 27.0 release in March 2024.

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<b>CR Number:</b> 2024039003		<b>Implementation Date:</b> 18-Feb-24	<b>Related CR:</b> 2024039003		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed LLT	<i>Watchman device insertion</i>	Rejected			

**MSSO Comment:** The proposal to add a new LLT Watchman device insertion is not approved. The proposed concept already exists as LLT/PT Left atrial appendage closure implant. Please also note that trade names for medical devices, equipment and diagnostic products are out of scope and, therefore, not included in MedDRA.

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<b>CR Number:</b> 2024039004		<b>Implementation Date:</b> 20-Feb-24	<b>Related CR:</b> 2024039004		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed LLT	<i>Gottron's sign</i>	Approved Not as Requested	Proposed LLT		
To PT	<i>Dermatomyositis</i>		<i>Gottron's sign</i>	10090851	Current
			To PT		
			<i>Gottron's papules</i>	10056954	

**MSSO Comment:** The proposal to add a new LLT Gottron's sign to PT Dermatomyositis is approved but not as requested. Gottron's sign, also known as Gottron's papules, is a dermatological characteristic commonly associated with dermatomyositis. Gottron's sign is characterized by flat or slightly raised, violaceous, erythematous patches or papules that develop over the knuckles, elbows, or knees. These patches often have a scaly or rough texture and can be accompanied by inflammation or irritation. Gottron's sign will be added as an LLT to the newly promoted PT Gottron's papules. In a related change, LLT Gottron's papules will be promoted from PT Dermatomyositis to a PT level and placed under primary HLT Connective tissue disorders and secondary HLT Autoimmune disorders NEC.

# Detail Report

CR Number: 2024051006		Implementation Date: 20-Feb-24	Related CR: 2024039004	
<u>Change Requested</u>	Promote an LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Gottron's papules</i>	Approved as Requested	Proposed LLT	
From PT	<i>Dermatomyositis</i>		<i>Gottron's papules</i>	10056954
HLT primary	<i>Connective tissue disorders</i>		From PT	
			<i>Dermatomyositis</i>	10012503
			HLT primary	
			<i>Connective tissue disorders</i>	10010760
			SOC primary	
			<i>Skin and subcutaneous tissue disorders</i>	10040785
			HLT secondary	
			<i>Autoimmune disorders NEC</i>	10027657
			SOC secondary	
			<i>Immune system disorders</i>	10021428

MSSO  
Comment:

CR Number: 2024039005		Implementation Date: 20-Feb-24	Related CR: 2024039005	
<u>Change Requested</u>	Add a New PT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Thoracic cavity drainage normal</i>	Approved Not as Requested	Proposed PT	
HLT primary	<i>Respiratory tract and thoracic histopathology procedures</i>		<i>Thoracic cavity drainage test normal</i>	10090852
SOC primary	<i>Investigations</i>		HLT primary	
			<i>Respiratory tract and thoracic histopathology procedures</i>	10006472
			SOC primary	
			<i>Investigations</i>	10022891

MSSO  
Comment: The proposal to add a new PT Thoracic cavity drainage normal to primary HLT Respiratory tract and thoracic histopathology procedures in SOC Investigations is approved but not as requested. Normal drainage from a thoracic cavity drainage system depends on several factors, including the underlying condition, the size and type of chest tube used, and the patient's response to treatment, so that "normal" can vary significantly depending on the circumstances. A thoracic cavity drainage test is a procedure to assess the functionality of a chest tube and the patency of the drainage system. The proposed term will be modified for specificity to Thoracic cavity drainage test normal and added as a new PT to HLT Respiratory tract and thoracic histopathology procedures as a "normal" counterpart to existing PT Thoracic cavity drainage test abnormal.



# Detail Report

<b>CR Number:</b> 2024040000		<b>Implementation Date:</b> 20-Feb-24	<b>Related CR:</b> 2024040000		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed LLT	<i>Movement and neurocognitive toxicity</i>	Rejected			

**MSSO Comment:** The proposal to add a new LLT Movement and neurocognitive toxicity is not approved. Movement and neurocognitive toxicity (NMT) is a recently detected neurotoxicity derived of of treatment with chimeric (CAR-T cell) antigen receptor therapies, which comprise a cluster of movement (e.g., micrographia, tremors), cognitive (e.g., memory loss, disturbance in attention), and personality changes (e.g. reduced facial expression, flat affect). Although some symptoms overlap with immune effector cell-associated neurotoxicity syndrome (ICANS) symptomatology (i.e., altered mental status, somnolence), MNT symptoms occur after a period of recovery from cytokine release syndrome and/or ICANS and may present in a unique pattern, including insidious onset. Limitations of the small study should be noted as the concept is not yet medically established; we prefer to wait until findings around this concept are more consolidated.

<b>CR Number:</b> 2024043000		<b>Implementation Date:</b> 20-Feb-24	<b>Related CR:</b> 2024043000		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed Term	<i>Gibbus deformity</i>	Approved as Requested	Proposed LLT <i>Gibbus deformity</i>		10090853 Current
			To PT <i>Kyphosis</i>		10023509

**MSSO Comment:** The proposal to add a new term Gibbus deformity is approved as requested. Gibbus deformity, also known as kyphotic deformity or angular kyphosis, is a spinal deformity characterized by a sharp angular prominence of the vertebrae. It often occurs due to structural abnormalities such as compression fractures of the vertebrae, tuberculosis of the spine (Pott's disease), or other pathological conditions affecting the spine. Gibbus deformity will be added as an LLT to PT Kyphosis.

<b>CR Number:</b> 2024043001		<b>Implementation Date:</b> 20-Feb-24	<b>Related CR:</b> 2024043001		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed LLT	<i>Talc pleurodesis</i>	Approved as Requested	Proposed LLT <i>Talc pleurodesis</i>		10090854 Current
			To PT <i>Pleurodesis</i>		10035625

**MSSO Comment:** The proposal to add a new LLT Talc pleurodesis is approved as requested. Chemical pleurodesis is a therapeutic procedure applied to create the symphysis between the parietal and visceral pleura by intrapleural administration of various chemical agents (e.g. talc, tetracycline, iodopovidone, etc.). Talc pleurodesis will be added as an LLT to PT Pleurodesis, as a synonym of LLT Thoracoscopic talcage.

# Detail Report

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CR Number: 2024043002		Implementation Date: 20-Feb-24	Related CR: 2024043002		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed LLT	Radiation related hearing disorder	Rejected			

MSSO Comment: The proposal to add a new LLT Radiation related hearing disorder is not approved. MedDRA cannot provide a term for all possible complications after radiotherapy exposure. The proposed term combines a medical concept with additional medical wording related to etiology and/or pathophysiology. Section 3.5 of the MedDRA Term Selection Points to Consider (MTS:PTC) document defines these as "combination terms". When considering the addition of such combination terms, MedDRA generally attempts to limit inclusion to those terms which describe important, distinct and robust medical concepts which are internationally recognized diagnostic entities. Please also refer to section 3.5.4 When to "split" into more than one MedDRA term.

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CR Number: 2024043003		Implementation Date: 18-Feb-24	Related CR: 2024043003		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed LLT	Radiation induced ocular photosensitivity	Rejected			

MSSO Comment: The proposal to add a new LLT Radiation induced ocular photosensitivity is not approved. MedDRA cannot provide a term for all possible complications after radiotherapy exposure. The proposed term combines a medical concept with additional medical wording related to etiology and/or pathophysiology. Section 3.5 of the MedDRA Term Selection Points to MedDRA generally attempts to limit inclusion of such combination terms to important, distinct and robust medical concepts which are internationally recognized diagnostic entities, such as PTs Radiation cataract, Radiation corneal injury and Radiation retinopathy. Please refer to MedDRA Term Selection: Points to Consider document Section 3.5 for a description of "combination terms" and section 3.5.4 When to "split" into more than one MedDRA term.

# Detail Report

CR Number: 2024043004		Implementation Date: 20-Feb-24	Related CR: 2024043004	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Ewing's Sarcoma of the Adrenal Gland	Approved Not as Requested	Proposed PT	
			Ewing's sarcoma of adrenal gland	10090855
			HLT primary	
			Extraskeletal Ewing's sarcomas	10015760
			SOC primary	
			Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10029104
			HLT secondary	
			Adrenal neoplasms	10001376
			SOC secondary	
			Endocrine disorders	10014698

MSSO Comment: The proposal to add a new LLT Ewing's Sarcoma of the Adrenal Gland is approved but not as requested. Ewing's sarcoma or primitive neuro-ectodermal tumor typically occurs in long or flat bones, the chest wall, extra-skeletal soft tissue, and rarely in solid organs. Incidence of adrenal Ewing's sarcoma is very rare. Proposed term will be modified for MedDRA capitalization conventions and added as new PT Ewing's sarcoma of adrenal gland under primary HLT Extraskeletal Ewing's sarcomas and secondary HLT Adrenal neoplasms.

# Detail Report

CR Number: 2024043055		Implementation Date: 20-Feb-24	Related CR: 2024043055	
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Metabolic dysfunction-associated steatohepatitis</i>	Approved as Requested	Proposed PT	
			<i>Metabolic dysfunction-associated steatohepatitis</i>	10090856
			HLT primary	
			<i>Hepatocellular damage and hepatitis NEC</i>	10019833
			SOC primary	
			<i>Hepatobiliary disorders</i>	10019805
			HLT secondary	
			<i>Lipid metabolism and deposit disorders NEC</i>	10024581
			SOC secondary	
			<i>Metabolism and nutrition disorders</i>	10027433

MSSO Comment: The proposal to add a new PT Metabolic dysfunction-associated steatohepatitis is approved as requested. Metabolic dysfunction-associated steatohepatitis is the most updated designation of the current PT Non-alcoholic steatohepatitis, and therefore will be added as PT with a primary link to HLT to Hepatocellular damage and hepatitis NEC and a secondary link to HLT Lipid metabolism and deposit disorders NEC. In a related change, the representing the former outdated expression PT Non-alcoholic steatohepatitis will be demoted under the new PT Metabolic dysfunction-associated steatohepatitis. Furthermore, and with the same rationale, a new LLT Metabolic dysfunction-associated liver disease will be added under PT Non-alcoholic fatty liver. Then PT Non-alcoholic fatty liver will be swapped with the new LLT Metabolic dysfunction-associated liver disease.

CR Number: 2024051034		Implementation Date: 20-Feb-24	Related CR: 2024043055	
<a href="#">Change Requested</a>	Demote a PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
PT to merge	<i>Non-alcoholic steatohepatitis</i>	Approved as Requested	PT to merge	
To PT	<i>Metabolic dysfunction-associated steatohepatitis</i>		<i>Non-alcoholic steatohepatitis</i>	10053219 Current
			To PT	
			<i>Metabolic dysfunction-associated steatohepatitis</i>	10090856

MSSO Comment:

# Detail Report

CR Number: 2024051035		Implementation Date: 20-Feb-24	Related CR: 2024043055	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Metabolic dysfunction-associated liver disease	Approved as Requested	Proposed LLT	
To PT	Non-alcoholic fatty liver		Metabolic dysfunction-associated liver disease	10090857
			To PT	
			Non-alcoholic fatty liver	10029530 Current
MSSO Comment:				

CR Number: 2024051036		Implementation Date: 20-Feb-24	Related CR: 2024043055	
<a href="#">Change Requested</a>	Swap a PT with an LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Non-alcoholic fatty liver	Approved as Requested	Proposed PT	
With LLT	Metabolic dysfunction-associated liver disease		Non-alcoholic fatty liver	10029530 Current
			With LLT	
			Metabolic dysfunction-associated liver disease	10090857
MSSO Comment:				

CR Number: 2024044000		Implementation Date: 20-Feb-24	Related CR: 2024044000	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	Radiotherapy to tonsil	Approved Not as Requested	Proposed LLT	
			Radiotherapy to tonsillar region	10090849 Current
			To PT	
			Radiotherapy to pharynx	10082859
MSSO Comment: The proposal to add a new term Radiotherapy to tonsil is approved but not as requested. Radiotherapy to tonsillar region is an established treatment paradigm for patients with early-stage and locally advanced squamous cell carcinoma of the tonsil in both the definitive and postoperative settings. The proposed term will be modified to represent the technically correct procedure and added as an LLT Radiotherapy to tonsillar region to PT Radiotherapy to pharynx.				

# Detail Report

<b>CR Number:</b> 2024044001		<b>Implementation Date:</b> 20-Feb-24	<b>Related CR:</b> 2024044001	
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Immunotherapy mediated sarcoidosis</i>	Approved Not as Requested	Proposed LLT <i>Sarcoidosis reactivation</i>	10090848 Current
			To PT <i>Sarcoidosis</i>	10039486

**MSSO Comment:** The proposal to add a new LLT Immunotherapy mediated sarcoidosis is approved but not as requested. Sarcoidosis may occur de novo or be a reactivation of a pre-existing sarcoidosis after use of some types of immunotherapy. In general, the MSSO does not add combination terms including additional terms which associate causality because causality should not be inherent in the coded term but rather determined by the reporter/investigator or by the sponsor. The proposed term will be modified to describe the medical condition and added as LLT Sarcoidosis reactivation to PT Sarcoidosis.

<b>CR Number:</b> 2024044002		<b>Implementation Date:</b> 18-Feb-24	<b>Related CR:</b> 2024044002	
<u>Change Requested</u>	Add a New PT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Exacerbation of hereditary angioedema</i>	Rejected		
HLT primary	<i>Angioedemas</i>			
SOC primary	<i>Immune system disorders</i>			

**MSSO Comment:** The proposal to add a new PT Exacerbation of hereditary angioedema to primary HLT Angioedemas in SOC Immune system disorders is not approved. The MSSO refrains from adding new terms with a qualifier of aggravation / worsening / exacerbation unless such a term represents an internationally accepted unique medical concept. Please reference section 3.5 of the MedDRA Term Selection Points to Consider (MTS:PTC) document.

<b>CR Number:</b> 2024044003		<b>Implementation Date:</b> 20-Feb-24	<b>Related CR:</b> 2024044003	
<u>Change Requested</u>	Add a New Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	<i>Primary warm autoimmune haemolytic anaemia</i>	Approved as Requested	Proposed LLT <i>Primary warm autoimmune haemolytic anaemia</i>	10090862 Current
			To PT <i>Warm autoimmune haemolytic anaemia</i>	10087091

**MSSO Comment:** The proposal to add a new term Primary warm autoimmune haemolytic anaemia is approved as requested. Autoimmune hemolytic anemia is caused by autoantibodies that react with self red blood cells and cause them to be destroyed. Warm autoimmune hemolytic anemia, due to antibodies that are active at body temperature, is the most common type of autoimmune hemolytic anemia. Primary warm autoimmune hemolytic anemia refers to warm autoimmune hemolytic anemia with no underlying condition. Primary warm autoimmune haemolytic anaemia and its American English spelled counterpart Primary warm autoimmune hemolytic anemia will both be added to PT Warm autoimmune haemolytic anaemia.

# Detail Report

<b>CR Number:</b> 2024051037		<b>Implementation Date:</b> 20-Feb-24	<b>Related CR:</b> 2024044003		
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed LLT	Primary warm autoimmune hemolytic anemia	Approved as Requested	Proposed LLT		
To PT	Warm autoimmune haemolytic anaemia		Primary warm autoimmune hemolytic anemia	10090863	Current
			To PT		
			Warm autoimmune haemolytic anaemia	10087091	

MSSO  
Comment:

<b>CR Number:</b> 2024044004		<b>Implementation Date:</b> 20-Feb-24	<b>Related CR:</b> 2024044004		
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed Term	Secondary warm autoimmune haemolytic anaemia	Approved as Requested	Proposed LLT		
			Secondary warm autoimmune haemolytic anaemia	10090861	Current
			To PT		
			Warm autoimmune haemolytic anaemia	10087091	

MSSO  
Comment: The proposal to add a new term Secondary warm autoimmune haemolytic anaemia is approved as requested. Autoimmune hemolytic anemia is caused by autoantibodies that react with self red blood cells and cause them to be destroyed. Warm autoimmune hemolytic anemia, due to antibodies that are active at body temperature, is the most common type of autoimmune hemolytic anemia. Secondary warm autoimmune haemolytic anaemia occurs in association with an underlying disorder such as systemic lupus erythematosus, lymphoma, or chronic lymphocytic leukemia or after use of certain drugs. Secondary warm autoimmune haemolytic anaemia and its American English spelled counterpart Secondary warm autoimmune hemolytic anemia will both be added to PT Warm autoimmune haemolytic anaemia.

<b>CR Number:</b> 2024051038		<b>Implementation Date:</b> 20-Feb-24	<b>Related CR:</b> 2024044004		
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed LLT	Secondary warm autoimmune hemolytic anemia	Approved as Requested	Proposed LLT		
To PT	Warm autoimmune haemolytic anaemia		Secondary warm autoimmune hemolytic anemia	10090864	Current
			To PT		
			Warm autoimmune haemolytic anaemia	10087091	

MSSO  
Comment:

# Detail Report

<b>CR Number: 2024046000</b>		<b>Implementation Date:</b> 20-Feb-24	<b>Related CR:</b> 2024046000		
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed LLT	Cataract extraction with IOL	Rejected			
MSSO Comment:	The proposal to add a new LLT Cataract extraction with IOL is not approved. The requested term is a combination term of two procedures, which are usually performed in the same operation. The MSSO typically refrains from adding such combination terms to the terminology. Please refer to Section 3.5 of the MedDRA Term Selection: Points to Consider Document regarding the coding of combination terms.				

<b>CR Number: 2024046001</b>		<b>Implementation Date:</b> 20-Feb-24	<b>Related CR:</b> 2024046001		
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed LLT	Intestinal resection with anastomosis	Rejected			
MSSO Comment:	The proposal to add a new LLT Intestinal resection with anastomosis is not approved. The requested term is a combination term of two procedures, which can be performed in the same operation. The MSSO typically refrains from adding such combination terms to the terminology. Please refer to Section 3.5 of the MedDRA Term Selection: Points to Consider Document regarding the coding of combination terms.				

<b>CR Number: 2024046002</b>		<b>Implementation Date:</b> 20-Feb-24	<b>Related CR:</b> 2024046002		
<a href="#">Change Requested</a>	Link (move) an LLT to another PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed LLT	Increase in seizure duration	Approved Not as Requested	PT to merge		
From PT	Change in seizure presentation		Change in seizure presentation	10075606	Current
To PT	Seizure		To PT		
			Seizure	10039906	
MSSO Comment:	The proposal to move the LLT Increase in seizure duration from PT Change in seizure presentation to PT Seizure is approved but not as requested. Many patients with epilepsy can experience changes in the pattern, frequency and nature of their seizures. Such changes might mean worsening of the disorder, improvement of the condition, or have no consequences. For better alignment of sub-concept LLTs, PT Change in seizure presentation will be demoted under PT Seizure.				



# Detail Report

<b>CR Number:</b> 2024046003		<b>Implementation Date:</b> 20-Feb-24	<b>Related CR:</b> 2024046003	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Facial pressure</i>	Approved Not as Requested	Proposed LLT <i>Facial pressure sensation</i>	10090865 Current
			To PT <i>Facial discomfort</i>	10083537

**MSSO Comment:** The proposal to add a new term Facial pressure is approved but not as requested. Many conditions such as sinus headaches, sinusitis, and deviated septum are the leading causes of facial pressure. The proposed term will be modified for more frequent expression and added as LLT Facial pressure sensation under PT Facial discomfort.

<b>CR Number:</b> 2024047001		<b>Implementation Date:</b> 20-Feb-24	<b>Related CR:</b> 2024047001	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Ulna impaction syndrome</i>	Approved Not as Requested	Proposed LLT <i>Ulnar impaction syndrome</i>	10090860 Current
			To PT <i>Ulnocarpal abutment syndrome</i>	10069429

**MSSO Comment:** The proposal to add a new LLT Ulna impaction syndrome is approved but not as requested. Ulnar impaction syndrome occurs when the ulna is relatively larger than it should be when compared to the radius. This forces the ulna to bear more of the weight and force to the wrist on that side of the arm. The proposed term will be modified and added as a synonym LLT Ulnar impaction syndrome to PT Ulnocarpal abutment syndrome.

<b>CR Number:</b> 2024047002		<b>Implementation Date:</b> 20-Feb-24	<b>Related CR:</b> 2024047002	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Multiple myeloma related lytic bone disease</i>	Approved Not as Requested	Proposed LLT <i>Lytic bone disease</i>	10090859 Current
			To PT <i>Osteolysis</i>	10031248

**MSSO Comment:** The proposal to add a new LLT Multiple myeloma related lytic bone disease is approved but not as requested. The proposed term will be modified to represent a single concept without causality association and added as a synonym LLT Lytic bone disease to PT Osteolysis. MedDRA generally attempts to limit inclusion of combination terms. Please reference Section 3.5 of the MedDRA Term Selection Points to Consider (MTS:PTC) document for guidance on coding of "combination terms".

# Detail Report

CR Number: 2024047003		Implementation Date: 20-Feb-24	Related CR: 2024047003	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Myelodysplastic syndrome/myeloproliferative neoplasm overlap syndrome	Approved Not as Requested	Proposed PT	
			Myelodysplastic syndrome/myeloproliferative neoplasm overlap syndrome	10090858
			HLT primary	
			Myelodysplastic syndromes	10028536
			SOC primary	
			Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10029104
			HLT secondary	
			Myelodysplastic syndromes	10028536
			SOC secondary	
			Blood and lymphatic system disorders	10005329

**MSSO Comment:** The proposal to add a new LLT Myelodysplastic syndrome/myeloproliferative neoplasm overlap syndrome is approved but not as requested. Myelodysplastic syndrome/myeloproliferative neoplasm (MDS/MPN) overlap syndrome represents a chronic clonal myeloid malignancy in which there are features of both MDS and MPN at the time of presentation. Myelodysplastic syndrome/myeloproliferative neoplasm overlap syndrome will be added as PT under bi-axial HLT Myelodysplastic syndromes (primary SOC Neoplasms benign, malignant and unspecified (incl cysts and polyps) and secondary SOC Blood and lymphatic system disorders).

CR Number: 2024051000		Implementation Date: 01-Mar-24	Related CR: 2024051000	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Patrikios syndrome	Rejected		

**MSSO Comment:** The proposal to add a new LLT Patrikios syndrome is not approved. Patrikios syndrome, Marie-Patrikios form, psuedopolyneuritic variant of amyotrophic lateral sclerosis (ALS) or peroneal form of ALS are other names for the recently added LLT Flail leg syndrome (change request 2024035004). MedDRA limits the inclusion of eponym terms to internationally recognized names.

# Detail Report

<b>CR Number:</b> 2024051001		<b>Implementation Date:</b> 01-Mar-24	<b>Related CR:</b> 2024051001	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Lou Gehrig's disease</i>	Approved as Requested	Proposed LLT <i>Lou Gehrig's disease</i>	10090869 Current
			To PT <i>Amyotrophic lateral sclerosis</i>	10002026
<b>MSSO Comment:</b> The proposal to add a new LLT Lou Gehrig's disease is approved as requested. Amyotrophic lateral sclerosis is also known as Lou Gehrig's disease, after the famous New York Yankee baseball player who was affected with the disorder. Lou Gehrig's disease is an eponym used frequently in literature and will be added as synonym LLT to PT Amyotrophic lateral sclerosis.				

<b>CR Number:</b> 2024051002		<b>Implementation Date:</b> 01-Mar-24	<b>Related CR:</b> 2024051002	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Intestinal Behcet's disease</i>	Rejected		
<b>MSSO Comment:</b> The proposal to add a new LLT Intestinal Behcet's disease is not approved. The proposed concept is represented by existing LLT Gastro-intestinal Behcet disease.				

<b>CR Number:</b> 2024051003		<b>Implementation Date:</b> 01-Mar-24	<b>Related CR:</b> 2024051003	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Pyocyanic septicemia</i>	Approved as Requested	Proposed LLT <i>Pyocyanic septicemia</i>	10090870 Current
			To PT <i>Pseudomonal sepsis</i>	10058877
<b>MSSO Comment:</b> The proposal to add a new LLT Pyocyanic septicemia is approved as requested. Pyocyanic septicemia, also known as pyocyanic bacteremia, is a severe bacterial infection caused by <i>Pseudomonas aeruginosa</i> . This bacterium is commonly found in soil, water, plants, and animals, and it can cause infections in humans, particularly in individuals with weakened immune systems or those with underlying health conditions. Pyocyanic septicemia will be added as LLT to PT Pseudomonal sepsis. In a related change, the British English spelled counterpart LLT Pyocyanic septicaemia will also be added under PT Pseudomonal sepsis.				

# Detail Report

CR Number: 2024061004		Implementation Date: 01-Mar-24	Related CR: 2024051003		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed LLT	Pyocyanic septicaemia	Approved as Requested	Proposed LLT		
To PT	Pseudomonal sepsis		Pyocyanic septicaemia	10090871	Current
			To PT		
			Pseudomonal sepsis	10058877	

MSSO  
Comment:

CR Number: 2024051004		Implementation Date: 01-Mar-24	Related CR: 2024051004		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed LLT	Pyocyanic Stomatitis	Approved Not as Requested	Proposed PT		
			Pseudomonas stomatitis	10090868	
			HLT primary		
			Pseudomonal infections	10037132	
			SOC primary		
			Infections and infestations	10021881	
			HLT secondary		
			Oral soft tissue infections	10031017	
			SOC secondary		
			Gastrointestinal disorders	10017947	

MSSO  
Comment: The proposal to add a new LLT Pyocyanic Stomatitis is approved but not as requested. Pyocyanin is an exuberant blue-coloured phenazine, produced exclusively by 90–95% of Pseudomonas aeruginosa strains. As the proposed term is not a currently internationally recognized medical term, it will be modified to the more accepted term and added as PT Pseudomonas stomatitis under primary HLT Pseudomonal infections and secondary HLT Oral soft tissue infections.

# Detail Report

CR Number: 2024052000		Implementation Date: 01-Mar-24	Related CR: 2024052000	
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Prostatic hypertrophy with calcification	Rejected		
HLT primary	Prostatic signs, symptoms and disorders NEC			
SOC primary	Reproductive system and breast disorders			
MSSO Comment:	The proposal to add a new PT Prostatic hypertrophy with calcification to primary HLT Prostatic signs, symptoms and disorders NEC in SOC Reproductive system and breast disorders is not approved. The proposed term is a combination of two concepts, benign prostate hyperplasia and prostate calcification, both of which are already represented in existing MedDRA terms. MedDRA refrains from adding combinations of a medical concept with additional medical wording related to etiology and/or pathophysiology. Section 3.5 of the MedDRA Term Selection Points to Consider (MTS:PTC) document defines these as "combination terms".			

CR Number: 2024052001		Implementation Date: 01-Mar-24	Related CR: 2024052001	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Cerebrospinal fluid seeding	Approved Not as Requested	Proposed LLT	
			Metastases by cerebrospinal fluid seeding	10090872 Current
			To PT	
			Metastases to spinal cord	10078267
MSSO Comment:	The proposal to add a new LLT Cerebrospinal fluid seeding is approved but not as requested. Both intracranial and spinal cord neoplasm may disseminate through CSF circulation, as can be demonstrated by analytical histochemical investigations, such as the presence of and elevated index of CSF protein or the presence of malignant cells. The proposed term will be modified for greater clarification and added as the sub-concept LLT Metastases by cerebrospinal fluid seeding to the PT Metastases to spinal cord.			

# Detail Report

CR Number: 2024054001		Implementation Date: 01-Mar-24	Related CR: 2024054001	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Glaucoma drainage device exposure</i>	Approved as Requested	Proposed PT <i>Glaucoma drainage device exposure</i>	10090878
			HLT primary <i>Eye and ear procedural complications</i>	10015908
			SOC primary <i>Injury, poisoning and procedural complications</i>	10022117
			HLT secondary <i>Ocular injuries NEC</i>	10030047
			SOC secondary <i>Eye disorders</i>	10015919

**MSSO Comment:** The proposal to add a new term Glaucoma drainage device exposure is approved as requested. During the implantation of most glaucoma drainage devices, the native sclera or a patch graft material is used to cover the anterior aspect of the device. One of the most serious complications of glaucoma drainage devices is exposure of the tube and/or plate that comprises the glaucoma drainage devices. Tube exposure can lead to vision-threatening endophthalmitis, as the exposed tube can serve as a pathway for organisms to enter the eye from the ocular surface. Glaucoma drainage device exposure will be added as PT to primary HLT Eye and ear procedural complications and secondary HLT Ocular injuries NEC.

CR Number: 2024054002		Implementation Date: 01-Mar-24	Related CR: 2024054002	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Circulating tumor DNA (ctDNA) test</i>	Rejected		

**MSSO Comment:** The proposal to add a new LLT Circulating tumor DNA (ctDNA) test is not approved. Proposed term has been added in change request 2023268008 as LLT/PT Circulating tumour DNA test and will be available with the MedDRA 27.0 version release in March 2024.

# Detail Report

<b>CR Number:</b> 2024054003		<b>Implementation Date:</b> 01-Mar-24	<b>Related CR:</b> 2024054003	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Congenital thenar hypoplasia</i>	Approved as Requested	Proposed LLT <i>Congenital thenar hypoplasia</i>	10090874 Current
			To PT <i>Congenital hand malformation</i>	10062335
<b>MSSO Comment:</b> The proposal to add a new LLT Congenital thenar hypoplasia is approved as requested. Thenar hypoplasia is a type 5 congenital hand anomaly, as classified by the International Federation of Societies for Surgery of the Hand. Congenital thenar hypoplasia can be an isolated defect as in Cavanagh syndrome or may be accompanied by other organ abnormalities such as in the heart or eye. Congenital thenar hypoplasia will be added as sub-concept LLT under PT Congenital hand malformation.				

<b>CR Number:</b> 2024054004		<b>Implementation Date:</b> 01-Mar-24	<b>Related CR:</b> 2024054004	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Anti-HU encephalitis</i>	Approved Not as Requested	Proposed LLT <i>Anti-Hu encephalitis</i>	10090875 Current
			To PT <i>Paraneoplastic encephalomyelitis</i>	10069587

**MSSO Comment:** The proposal to add a new LLT Anti-HU encephalitis is approved but not as requested. Anti-Hu encephalitis is a rare paraneoplastic manifestation most commonly seen in patients with small cell lung carcinoma. The anti-Hu paraneoplastic syndrome can be clinically diverse, presenting as encephalitis, myelitis, or combined encephalomyelitis. The proposed term will be modified for better alignment and added as LLT Anti-Hu encephalitis to PT Paraneoplastic encephalomyelitis.

<b>CR Number:</b> 2024054005		<b>Implementation Date:</b> 26-Apr-24	<b>Related CR:</b> 2024054005	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Serum oligoclonal banding</i>	Approved Not as Requested After Suspension	Proposed LLT <i>Serum oligoclonal band</i>	10091032 Current
			To PT <i>Oligoclonal band assay</i>	10091031

**MSSO Comment:** The proposal to add a new LLT Serum oligoclonal banding is approved but not as requested after suspension. The oligoclonal band assay requires paired cerebrospinal fluid (CSF) and serum samples. Oligoclonal bands (OCBs) are proteins called immunoglobulins. The presence of these proteins indicates inflammation of the central nervous system. Examining CSF and serum in parallel for OCBs of IgG provides more diagnostic information than examining CSF alone, and the latter is potentially misleading. The proposed term Serum oligoclonal band will be added as LLT to PT Oligoclonal band assay. In a related change a new PT Oligoclonal band assay will be added to HLT Cerebrospinal fluid tests (excl microbiology). Furthermore, the PT CSF oligoclonal band will be demoted to new PT Oligoclonal band assay.

# Detail Report

<b>CR Number:</b> 2024116011		<b>Implementation Date:</b> 25-Apr-24	<b>Related CR:</b> 2024054005	
<a href="#">Change Requested</a>	Demote a PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
PT to merge	CSF oligoclonal band	Approved as Requested	PT to merge	
To PT	Oligoclonal band assay		CSF oligoclonal band	10011558 Current
			To PT	
			Oligoclonal band assay	10091031

MSSO  
Comment:

<b>CR Number:</b> 2024116010		<b>Implementation Date:</b> 25-Apr-24	<b>Related CR:</b> 2024054005	
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Oligoclonal band assay	Approved as Requested	Proposed PT	
HLT primary	Cerebrospinal fluid tests (excl microbiology)		Oligoclonal band assay	10091031
SOC primary	Investigations		HLT primary	
			Cerebrospinal fluid tests (excl microbiology)	10008183
			SOC primary	
			Investigations	10022891

MSSO  
Comment:

<b>CR Number:</b> 2024054006		<b>Implementation Date:</b> 01-Mar-24	<b>Related CR:</b> 2024054006	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Chronic immune sensory polyradiculopathy (CISP)	Approved Not as Requested	Proposed LLT	
			Chronic immune sensory polyradiculopathy	10090876 Current
			To PT	
			Chronic inflammatory demyelinating polyradiculoneuropathy	10057645

MSSO  
Comment: The proposal to add a new LLT Chronic immune sensory polyradiculopathy (CISP) is approved but not as requested. Chronic immune sensory polyradiculopathy (CISP) is an uncommon and treatable inflammatory disorder of the proximal sensory nerve roots. Patients typically present with severe sensory ataxia, normal motor examination, unsteady gait, and normal nerve conduction studies. The condition is a rare variant of chronic inflammatory demyelinating polyradiculoneuropathy. Proposed term will be modified to remove the acronym and added as sub-concept LLT Chronic immune sensory polyradiculopathy under PT Chronic inflammatory demyelinating polyradiculoneuropathy.



# Detail Report

CR Number: 2024054007		Implementation Date: 01-Mar-24	Related CR: 2024054007	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	MET gene amplification	Approved as Requested	Proposed LLT MET gene amplification	10090866 Current
			To PT Transmembrane receptor tyrosine kinase overexpression	10071991
<div>MSSO</div> <div>The proposal to add a new LLT MET gene amplification is approved as requested. MET gene amplification can be considered an quasi-synonym of existing PT</div> <div>Comment: Transmembrane receptor tyrosine kinase overexpression and will be added as its LLT.</div>				

CR Number: 2024054008		Implementation Date: 01-Mar-24	Related CR: 2024054008	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	High myopia	Approved as Requested	Proposed LLT High myopia	10090867 Current
			To PT Pathologic myopia	10073286
<div>MSSO</div> <div>The proposal to add a new LLT High myopia is approved as requested. High myopia is generally defined as nearsightedness requiring a glasses correction of -6.00</div> <div>Comment: diopters or more and is sometimes referred to as degenerative myopia or pathological myopia. High myopia will be added as an LLT to PT Pathologic myopia.</div>				

# Detail Report

CR Number: 2024054009		Implementation Date: 07-Mar-24	Related CR: 2024054009	
<a href="#">Change Requested</a>		<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Ewart's sign	Approved as Requested	Proposed PT	
To SMQ	Haemodynamic oedema, effusions and fluid overload (SMQ)		Ewart's sign	10090743
Term scope	Narrow		To SMQ	
			Haemodynamic oedema, effusions and fluid overload (SMQ)	20000145
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	
MSSO Comment:	The proposal to add PT Ewart's sign to Haemodynamic oedema, effusions and fluid overload (SMQ) as a narrow term is approved as requested. Ewart's sign is dullness to percussion at the base of the left inferior scapular border in conjunction with tubular breath sounds and egophony. Ewart's sign is a set of findings on physical examination in people with large collections of fluid around their heart (pericardial effusions).			

CR Number: 2024054011		Implementation Date: 27-Feb-24	Related CR: 2024054011	
<a href="#">Change Requested</a>		<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Early branching of renal artery	Approved as Requested	Proposed PT	
To SMQ	Congenital, familial and genetic disorders (SMQ)		Early branching of renal artery	10090711
Term scope	Narrow		To SMQ	
			Congenital, familial and genetic disorders (SMQ)	20000077
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	
MSSO Comment:	The proposal to add PT Early branching of renal artery to Congenital, familial and genetic disorders (SMQ) as a narrow term is approved as requested. This term fits the inclusion criteria for this SMQ which includes all PTs in SOC Congenital, familial and genetic disorders. All terms in this SMQ are narrow in scope.			

# Detail Report

CR Number: 2024054012		Implementation Date: 27-Feb-24	Related CR: 2024054012	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	MUTYH-associated polyposis	Approved as Requested	Proposed PT	
To SMQ	Congenital, familial and genetic disorders (SMQ)		MUTYH-associated polyposis	10090739
Term scope	Narrow		To SMQ	
			Congenital, familial and genetic disorders (SMQ)	20000077
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	
MSSO Comment:	The proposal to add PT MUTYH-associated polyposis to Congenital, familial and genetic disorders (SMQ) as a narrow term is approved as requested. This term fits the inclusion criteria for this SMQ which includes all PTs in SOC Congenital, familial and genetic disorders. All terms in this SMQ are narrow in scope.			

CR Number: 2024054013		Implementation Date: 27-Feb-24	Related CR: 2024054013	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Marden-Walker syndrome	Approved as Requested	Proposed PT	
To SMQ	Congenital, familial and genetic disorders (SMQ)		Marden-Walker syndrome	10090841
Term scope	Narrow		To SMQ	
			Congenital, familial and genetic disorders (SMQ)	20000077
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	
MSSO Comment:	The proposal to add PT Marden-Walker syndrome to Congenital, familial and genetic disorders (SMQ) as a narrow term is approved as requested. This term fits the inclusion criteria for this SMQ which includes all PTs in SOC Congenital, familial and genetic disorders. All terms in this SMQ are narrow in scope.			

# Detail Report

CR Number: 2024054014		Implementation Date: 27-Feb-24	Related CR: 2024054014		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed PT	<i>Rauch-Steindl syndrome</i>	Approved as Requested	Proposed PT		
To SMQ	<i>Congenital, familial and genetic disorders (SMQ)</i>		<i>Rauch-Steindl syndrome</i>		10090741
Term scope	<i>Narrow</i>		To SMQ		
			<i>Congenital, familial and genetic disorders (SMQ)</i>		20000077
			Term scope		
			<i>Narrow</i>		
			Term_category		
			A		
			Term_weight		
			0		

MSSO Comment: The proposal to add PT Rauch-Steindl syndrome to Congenital, familial and genetic disorders (SMQ) as a narrow term is approved as requested. This term fits the inclusion criteria for this SMQ which includes all PTs in SOC Congenital, familial and genetic disorders. All terms in this SMQ are narrow in scope.

CR Number: 2024054015		Implementation Date: 27-Feb-24	Related CR: 2024054015		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed PT	<i>Seckel syndrome</i>	Approved as Requested	Proposed PT		
To SMQ	<i>Congenital, familial and genetic disorders (SMQ)</i>		<i>Seckel syndrome</i>		10090776
Term scope	<i>Narrow</i>		To SMQ		
			<i>Congenital, familial and genetic disorders (SMQ)</i>		20000077
			Term scope		
			<i>Narrow</i>		
			Term_category		
			A		
			Term_weight		
			0		

MSSO Comment: The proposal to add PT Seckel syndrome to Congenital, familial and genetic disorders (SMQ) as a narrow term is approved as requested. This term fits the inclusion criteria for this SMQ which includes all PTs in SOC Congenital, familial and genetic disorders. All terms in this SMQ are narrow in scope.

# Detail Report

CR Number: 2024054016		Implementation Date: 27-Feb-24	Related CR: 2024054016	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Gastrointestinal neuroendocrine tumour	Approved as Requested	Proposed PT	
To SMQ	Non-haematological tumours of unspecified malignancy (SMQ)		Gastrointestinal neuroendocrine tumour	10090770
Term scope	Narrow		To SMQ	
			Non-haematological tumours of unspecified malignancy (SMQ)	20000230
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	

**MSSO Comment:** The proposal to add PT Gastrointestinal neuroendocrine tumour to Non-haematological tumours of unspecified malignancy (SMQ) as a narrow term is approved as requested. A gastrointestinal neuroendocrine tumor is a neoplasm that develops in the neuroendocrine cells of the gastrointestinal tract. Neuroendocrine cells are specialized cells that have both nerve and endocrine features. These tumors can be benign or malignant. Meeting the inclusion criterion: All MedDRA terms for malignant or unspecified tumors. Similar PTs referring to unspecified neuroendocrine tumours at different sites are also included. Gastrointestinal neuroendocrine tumour will be added to Non-haematological tumours of unspecified malignancy (SMQ). This SMQ only has narrow scope terms.

CR Number: 2024054017		Implementation Date: 27-Feb-24	Related CR: 2024054017	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Iatrogenic Kaposi sarcoma	Approved as Requested	Proposed PT	
To SMQ	Non-haematological malignant tumours (SMQ)		Iatrogenic Kaposi sarcoma	10090840
Term scope	Narrow		To SMQ	
			Non-haematological malignant tumours (SMQ)	20000228
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	

**MSSO Comment:** The proposal to add PT Iatrogenic Kaposi sarcoma to Non-haematological malignant tumours (SMQ) as a narrow term is approved as requested. Kaposi sarcoma is typically considered a malignant condition. Iatrogenic Kaposi sarcoma meets the inclusion criterion: All MedDRA terms for malignant or unspecified tumors. Iatrogenic Kaposi sarcoma will be added to the Non-haematological malignant tumours (SMQ). This SMQ has only narrow search terms.

# Detail Report

CR Number: 2024054018		Implementation Date: 27-Feb-24	Related CR: 2024054018	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Vasoproliferative retinal tumour</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Retinal disorders (SMQ)</i>		<i>Vasoproliferative retinal tumour</i>	10090663
Term scope	<i>Narrow</i>		To SMQ	
			<i>Retinal disorders (SMQ)</i>	20000158
			Term scope	
			<i>Narrow</i>	
			Term_category	
			A	
			Term_weight	
			0	

**MSSO Comment:** The proposal to add PT Vasoproliferative retinal tumour to Retinal disorders (SMQ) as a narrow term is approved as requested. Vasoproliferative retinal tumor is characterized by one or more retinal nodules. The tumor in question consists mostly of glial cells, capillaries and hyalinized blood vessels. These lesions cause retinal exudates, macular edema, and epiretinal membranes. Vasoproliferative retinal tumour meets the inclusion criterion of the narrow scope of the SMQ: All terms that contain "retin," except those which represent retinal infections (see Exclusion criteria) and will be added to Retinal disorders (SMQ).

CR Number: 2024054019		Implementation Date: 27-Feb-24	Related CR: 2024054019	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Transduodenal ampullectomy</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Malignancy related therapeutic and diagnostic procedures (SMQ)</i>		<i>Transduodenal ampullectomy</i>	10090779
Term scope	<i>Narrow</i>		To SMQ	
			<i>Malignancy related therapeutic and diagnostic procedures (SMQ)</i>	20000093
			Term scope	
			<i>Narrow</i>	
			Term_category	
			A	
			Term_weight	
			0	

**MSSO Comment:** The proposal to add PT Transduodenal ampullectomy to Malignancy related therapeutic and diagnostic procedures (SMQ) as a narrow term is approved as requested. Transduodenal ampullectomy is a surgical procedure primarily performed to remove tumors located at the ampulla of Vater. Transduodenal ampullectomy will be added to Malignancy related therapeutic and diagnostic procedures (SMQ). The SMQ has only narrow search terms.

# Detail Report

CR Number: 2024054020		Implementation Date: 27-Feb-24	Related CR: 2024054020	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Kaleidoscope vision</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Retinal disorders (SMQ)</i>		<i>Kaleidoscope vision</i>	10090683
Term scope	<i>Broad</i>		To SMQ	
			<i>Retinal disorders (SMQ)</i>	20000158
			Term scope	
			<i>Broad</i>	
			Term_category	
			A	
			Term_weight	
			0	

**MSSO** The proposal to add PT Kaleidoscope vision to Retinal disorders (SMQ) as a broad term is approved as requested. Kaleidoscope vision is most often caused by migraine with aura. In some cases, kaleidoscope vision can be a symptom of more serious problems, including stroke, retinal damage, and serious brain injury. Kaleidoscope vision meets inclusion criterion: Terms for signs and symptoms of visual disturbance and will be added to the broad scope of Retinal disorders (SMQ).

CR Number: 2024054021		Implementation Date: 27-Feb-24	Related CR: 2024054021	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Photothermal therapy</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Malignancy related therapeutic and diagnostic procedures (SMQ)</i>		<i>Photothermal therapy</i>	10090662
Term scope	<i>Narrow</i>		To SMQ	
			<i>Malignancy related therapeutic and diagnostic procedures (SMQ)</i>	20000093
			Term scope	
			<i>Narrow</i>	
			Term_category	
			A	
			Term_weight	
			0	

**MSSO** The proposal to add PT Photothermal therapy to Malignancy related therapeutic and diagnostic procedures (SMQ) as a narrow term is approved as requested. Photothermal therapy refers to the use of electromagnetic radiation (most often in infrared wavelengths) for the treatment of various medical conditions, including cancer. Photothermal therapy meets inclusion criterion: Terms for therapeutic and diagnostic procedures used to treat malignancies (Some of these procedures are also used for the treatment of non-malignant conditions). Photothermal therapy will be added to Malignancy related therapeutic and diagnostic procedures (SMQ). This SMQ has only narrow search terms.

# Detail Report

CR Number: 2024054022		Implementation Date: 27-Feb-24	Related CR: 2024054022		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Change term status in a SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed PT	<i>Vitreous haze</i>	Approved as Requested	Proposed PT		
To SMQ	<i>Ocular infections (SMQ)</i>		<i>Vitreous haze</i>		10077514
Status	A		To SMQ		
			<i>Ocular infections (SMQ)</i>		20000183
			Status		
			A		

**MSSO Comment:** The proposal to change status of the term Vitreous haze in Ocular infections (SMQ) to Active is approved as requested. Vitreous haze usually designates a generalized, diffuse lack of opacity, or a cloudiness to the vitreous, as is seen with inflammatory conditions such as uveitis, endophthalmitis, and with neoplastic cell infiltration. Because Vitreous haze can be a sign of intraocular infection, PT Vitreous haze warrants addition as a broad scope term to Ocular infections (SMQ). Before being demoted, this term was a PT in the broad scope of Ocular infections (SMQ).

CR Number: 2024054023		Implementation Date: 27-Feb-24	Related CR: 2024054023		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed PT	<i>Commotio cordis</i>	Approved as Requested	Proposed PT		
To SMQ	<i>Shock-associated circulatory or cardiac conditions (excl torsade de pointes) (SMQ)</i>		<i>Commotio cordis</i>		10090682
Term scope	<i>Narrow</i>		To SMQ		
			<i>Shock-associated circulatory or cardiac conditions (excl torsade de pointes) (SMQ)</i>		20000067
			Term scope		
			<i>Narrow</i>		
			Term_category		
			A		
			Term_weight		
			0		

**MSSO Comment:** The proposal to add PT Commotio cordis to Shock-associated circulatory or cardiac conditions (excl torsade de pointes) (SMQ) as a narrow term is approved as requested. Commotio cordis is defined as sudden cardiac arrest or death secondary to a blunt, nonpenetrating precordial impact. It is provoked by the simultaneous occurrence of specific mechanistic elements (e.g., timing, location, and velocity of impact) that result in ventricular fibrillation. The term will be added to the narrow scope of Shock-associated circulatory or cardiac conditions (excl torsade de pointes) (SMQ) in line with other terms like PT Cardiac arrest.



# Detail Report

CR Number: 2024054024

Implementation Date: 27-Feb-24

Related CR: 2024054024

Change Requested

Add term to SMQ

Final Disposition

Final Placement

MedDRA  
Code #

Proposed PT *Hospital anxiety and depression scale abnormal*

Approved as Requested

Proposed PT

*Hospital anxiety and depression scale  
abnormal*

10090698

To SMQ *Depression (excl suicide and self injury) (SMQ)*

To SMQ

*Depression (excl suicide and self injury)  
(SMQ)*

20000167

Term scope *Narrow*

Term scope

*Narrow*

Term\_category

*A*

Term\_weight

*0*

**MSSO** The proposal to add PT Hospital anxiety and depression scale abnormal to Depression (excl suicide and self injury) (SMQ) as a narrow term is approved as requested.  
**Comment:** This term fits the inclusion criteria for this SMQ which includes terms related to depression or depression-related symptoms. A HADS score of 11-21 is considered abnormal and is considered a case. Similar term such as PT Depression rating scale score increased is already included as a narrow scope term.

CR Number: 2024054025

Implementation Date: 27-Feb-24

Related CR: 2024054025

Change Requested

Add term to SMQ

Final Disposition

Final Placement

MedDRA  
Code #

Proposed PT *Tonsil asymmetry*

Approved as Requested

Proposed PT

*Tonsil asymmetry*

10090827

To SMQ *Oropharyngeal conditions (excl neoplasms,  
infections and allergies) (SMQ)*

To SMQ

*Oropharyngeal conditions (excl neoplasms,  
infections and allergies) (SMQ)*

20000114

Term scope *Narrow*

Term scope

*Narrow*

Term\_category

*A*

Term\_weight

*0*

**MSSO** The proposal to add PT Tonsil asymmetry to Oropharyngeal conditions (excl neoplasms, infections and allergies) (SMQ) as a narrow term is approved as requested. PT  
**Comment:** Tonsil asymmetry will be added in version 27.1 and refers to a condition in which one tonsil appears different in size or shape compared to the other tonsil. Tonsil asymmetry can be indicative of various underlying medical conditions, including infections, tumors, abscesses, inflammatory conditions, trauma, congenital anomalies, or systemic diseases. It fits the inclusion criterion "Lesions not clearly related to specific infections, neoplasms or allergic reactions but due to the following etiology - Unspecified disorder". All PTs of this SMQ are narrow in scope.

# Detail Report

CR Number: 2024054026		Implementation Date: 27-Feb-24	Related CR: 2024054026		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed PT	Enterocolic phlebitis	Approved as Requested	Proposed PT		
To SMQ	Ischaemic colitis (SMQ)		Enterocolic phlebitis		10090781
Term scope	Broad		To SMQ		
			Ischaemic colitis (SMQ)		20000144
			Term scope		
			Broad		
			Term_category		
			A		
			Term_weight		
			0		

**MSSO Comment:** The proposal to add PT Enterocolic phlebitis to Ischaemic colitis (SMQ) as a broad term is approved as requested. Enterocolic phlebitis is a mesenteric inflammatory veno-occlusive disease which typically presents with either a tumor-like mass, gastrointestinal hemorrhage, or acute abdomen. Ischemia is a possible relatively frequent outcome of this disease. Since it is not present in all cases, it will be added in the broad scope.

CR Number: 2024054027		Implementation Date: 27-Feb-24	Related CR: 2024054027		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed PT	Gut derived infection	Approved as Requested	Proposed PT		
To SMQ	Opportunistic infections (SMQ)		Gut derived infection		10090701
Term scope	Broad		To SMQ		
			Opportunistic infections (SMQ)		20000235
			Term scope		
			Broad		
			Term_category		
			A		
			Term_weight		
			0		

**MSSO Comment:** The proposal to add PT Gut derived infection to Opportunistic infections (SMQ) as a broad term is approved as requested. Gut derived infection is among the most common complications in patients who underwent severe trauma, serious burn, major surgery, hemorrhagic shock or severe acute pancreatitis. It could cause sepsis and multiple organ dysfunction syndrome, which are regarded as a leading cause of mortality in these cases. Gut derived infection is commonly caused by pathological translocation of intestinal bacteria or endotoxins, resulting from the dysfunction of the gut barrier. It can be considered as characteristic of the immunocompromised state since it presents in patients who underwent severe trauma, serious burn, major surgery, hemorrhagic shock, etc. Since it is rather a pathogenic concept than an infection per-se, it will be added in the broad scope.

# Detail Report

CR Number: 2024054028		Implementation Date: 27-Feb-24	Related CR: 2024054028	
<a href="#">Change Requested</a>		<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Commotio cordis	Approved as Requested	Proposed PT	
To SMQ	Accidents and injuries (SMQ)		Commotio cordis	10090682
Term scope	Narrow		To SMQ	
			Accidents and injuries (SMQ)	20000135
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	

**MSSO**  
**Comment:** The proposal to add PT Commotio cordis to Accidents and injuries (SMQ) as a narrow term is approved as requested. Commotio cordis is defined as sudden cardiac arrest or death secondary to a blunt, non-penetrating precordial impact. It is provoked by the simultaneous occurrence of specific mechanistic elements (e.g., timing, location, and velocity of impact) that result in ventricular fibrillation. Because the term describes a clinical condition which is characteristically associated with trauma, it will be added to the narrow search terms of this SMQ.

CR Number: 2024054029		Implementation Date: 27-Feb-24	Related CR: 2024054029	
<a href="#">Change Requested</a>		<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Ewart's sign	Approved as Requested	Proposed PT	
To SMQ	Noninfectious myocarditis/pericarditis (SMQ)		Ewart's sign	10090743
Term scope	Broad		To SMQ	
			Noninfectious myocarditis/pericarditis (SMQ)	20000239
			Term scope	
			Broad	
			Term_category	
			A	
			Term_weight	
			0	

**MSSO**  
**Comment:** The proposal to add PT Ewart's sign to Noninfectious myocarditis/pericarditis (SMQ) as a broad term is approved as requested. Ewart's sign refers to the dullness to percussion in the left lower lung field from the atelectasis caused by a large pericardial effusion compressing the lung. This term describes a clinical finding which is associated with pericarditis and will be added to the broad search terms of this SMQ.

# Detail Report

CR Number: 2024054030		Implementation Date: 27-Feb-24	Related CR: 2024054030	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Fazekas scale abnormal</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Conditions associated with central nervous system haemorrhages and cerebrovascular accidents (SMQ)</i>		<i>Fazekas scale abnormal</i>	10090674
Term scope	<i>Broad</i>		To SMQ	
			<i>Conditions associated with central nervous system haemorrhages and cerebrovascular accidents (SMQ)</i>	20000166
			Term scope	
		<i>Broad</i>	Term_category	
			A	
			Term_weight	
			0	

**MSSO Comment:** The proposal to add PT Fazekas scale abnormal to Conditions associated with central nervous system haemorrhages and cerebrovascular accidents (SMQ) as a broad term is approved as requested. The Fazekas scale is used to simply quantify the amount of cerebral white matter T2 hyper-intense lesions usually attributed to chronic small vessel ischaemia. However, because abnormalities of this scale may be associated with conditions besides ischemic stroke, it will be added to the broad terms of this SMQ.

CR Number: 2024054031		Implementation Date: 27-Feb-24	Related CR: 2024054031	
<u>Change Requested</u>	Add term to SMQ	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Fazekas scale abnormal</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Dementia (SMQ)</i>		<i>Fazekas scale abnormal</i>	10090674
Term scope	<i>Broad</i>		To SMQ	
			<i>Dementia (SMQ)</i>	20000073
			Term scope	
		<i>Broad</i>		
			Term_category	
			<i>A</i>	
			Term_weight	
			<i>0</i>	

**MSSO Comment:** The proposal to add PT Fazekas scale abnormal to Dementia (SMQ) as a broad term is approved as requested. The Fazekas scale is used to simply quantify the amount of cerebral white matter T2 hyper-intense lesions usually attributed to chronic small vessel ischaemia. These lesions are common in the aging brain and are often associated with dementia. As this term describes a non-specific finding, it will be added to the broad search terms of this SMQ of dementia-related terms.

# Detail Report

CR Number: 2024054032		Implementation Date: 27-Feb-24	Related CR: 2024054032	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Myocarditis-myositis-myasthenia gravis overlap syndrome	Approved as Requested	Proposed PT	
To SMQ	Noninfectious myocarditis/pericarditis (SMQ)		Myocarditis-myositis-myasthenia gravis overlap syndrome	10090724
Term scope	Narrow		To SMQ	
			Noninfectious myocarditis/pericarditis (SMQ)	20000239
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	

**MSSO Comment:** The proposal to add PT Myocarditis-myositis-myasthenia gravis overlap syndrome to Noninfectious myocarditis/pericarditis (SMQ) as a narrow term is approved as requested. Myocarditis-myositis-myasthenia gravis overlap syndrome is an emerging syndrome of life-threatening immune-related adverse events. It is also called "triple M syndrome" and is seen in immune check-point inhibitor (ICI)- treated patients. Because this term describes a non-infectious etiology of myocarditis, it will be added to the narrow search terms of this SMQ.

CR Number: 2024054033		Implementation Date: 27-Feb-24	Related CR: 2024054033	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	MUTYH-associated polyposis	Approved as Requested	Proposed PT	
To SMQ	Gastrointestinal premalignant disorders (SMQ)		MUTYH-associated polyposis	10090739
Term scope	Narrow		To SMQ	
			Gastrointestinal premalignant disorders (SMQ)	20000087
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	

**MSSO Comment:** The proposal to add PT MUTYH-associated polyposis to Gastrointestinal premalignant disorders (SMQ) as a narrow term is approved as requested. MUTYH-associated polyposis is an autosomal recessive polyposis syndrome caused by biallelic pathogenic germline variants in the MUTYH gene. Affected patients have multiple colorectal adenomas with an increased risk for developing colorectal cancer.

# Detail Report

CR Number: 2024054034		Implementation Date: 27-Feb-24	Related CR: 2024054034	
<u>Change Requested</u>	Add term to SMQ	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Illicit prescription attainment</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Drug abuse and dependence (SMQ)</i>		<i>Illicit prescription attainment</i>	10090768
Term scope	<i>Broad</i>		To SMQ	
			<i>Drug abuse and dependence (SMQ)</i>	20000101
			Term scope	
			<i>Broad</i>	
			Term_category	
			A	
			Term_weight	
			0	

MSSO The proposal to add PT Illicit prescription attainment to Drug abuse and dependence (SMQ) as a broad term is approved as requested. This term fits the inclusion criteria  
Comment: for this SMQ. Similar terms such as PT Drug diversion and PT Prescription form tampering are already included as broad scope terms.

CR Number: 2024054035		Implementation Date: 27-Feb-24	Related CR: 2024054035	
<u>Change Requested</u>	Add term to SMQ	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Succenturiate placenta</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (SMQ)</i>		<i>Succenturiate placenta</i>	10090664
Term scope	<i>Narrow</i>		To SMQ	
			<i>Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (SMQ)</i>	20000186
			Term scope	
			<i>Narrow</i>	
			Term_category	
			A	
			Term_weight	
			0	

MSSO The proposal to add PT Succenturiate placenta to Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (SMQ) as a narrow term is  
Comment: approved as requested. This term fits the inclusion criteria for this SMQ which includes terms for conditions that increase the risk of pregnancy complication and placenta issues. Similar terms such as PT Placenta duplex and PT Placenta accreta are already included as narrow scope terms.

# Detail Report

CR Number: 2024054036		Implementation Date: 27-Feb-24	Related CR: 2024054036	
<u>Change Requested</u>	Add term to SMQ	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Testicular hypotrophy</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Fertility disorders (SMQ)</i>		<i>Testicular hypotrophy</i>	10090707
Term scope	<i>Narrow</i>		To SMQ	
			<i>Fertility disorders (SMQ)</i>	20000210
			Term scope	
			<i>Narrow</i>	
			Term_category	
			A	
			Term_weight	
			0	

MSSO      The proposal to add PT Testicular hypotrophy to Fertility disorders (SMQ) as a narrow term is approved as requested. This term fits the inclusion criteria for this SMQ.  
Comment:      Similar terms such as PT Testicular disorder and PT Semen volume decreased are already included as narrow scope terms.

CR Number: 2024054037		Implementation Date: 27-Feb-24	Related CR: 2024054037	
<u>Change Requested</u>	Add term to SMQ	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Testicular hypotrophy</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Sexual dysfunction (SMQ)</i>		<i>Testicular hypotrophy</i>	10090707
Term scope	<i>Broad</i>		To SMQ	
			<i>Sexual dysfunction (SMQ)</i>	20000238
			Term scope	
			<i>Broad</i>	
			Term_category	
			A	
			Term_weight	
			0	

MSSO      The proposal to add PT Testicular hypotrophy to Sexual dysfunction (SMQ) as a broad term is approved as requested. Testicular hypotrophy represents a reversible  
Comment:      decrease in testicular volume during the state of hypospermia associated to a medical cause (e.g. varicocele) or when receiving a male hormonal contraceptive treatment.  
Likewise, to existing PT Testicular atrophy, this PT will be added to the broad scope of this SMQ.

# Detail Report

CR Number: 2024054038		Implementation Date: 27-Feb-24	Related CR: 2024054038	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Autoimmune vasculitis</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Immune-mediated/autoimmune disorders (SMQ)</i>		<i>Autoimmune vasculitis</i>	10090809
Term scope	<i>Narrow</i>		To SMQ	
			<i>Immune-mediated/autoimmune disorders (SMQ)</i>	20000236
			Term scope	
			<i>Narrow</i>	
			Term_category	
			A	
			Term_weight	
			0	

**MSSO Comment:** The proposal to add PT Autoimmune vasculitis to Immune-mediated/autoimmune disorders (SMQ) as a narrow term is approved as requested. Vasculitis can occur as a disease unto itself, or in the context of an autoimmune disease such as rheumatoid arthritis, lupus or antiphospholipid syndrome. Terms referring to immune-mediated and autoimmune disorders which may potentially be associated with immunotherapeutic agents or vaccines are mostly added to the narrow scope.

CR Number: 2024054039		Implementation Date: 27-Feb-24	Related CR: 2024054039	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Myocarditis-myositis-myasthenia gravis overlap syndrome</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Immune-mediated/autoimmune disorders (SMQ)</i>		<i>Myocarditis-myositis-myasthenia gravis overlap syndrome</i>	10090724
Term scope	<i>Narrow</i>		To SMQ	
			<i>Immune-mediated/autoimmune disorders (SMQ)</i>	20000236
			Term scope	
			<i>Narrow</i>	
			Term_category	
			A	
			Term_weight	
			0	

**MSSO Comment:** The proposal to add PT Myocarditis-myositis-myasthenia gravis overlap syndrome to Immune-mediated/autoimmune disorders (SMQ) as a narrow term is approved as requested. In Myocarditis-myositis-myasthenia gravis overlap syndrome, peripheral nervous system-muscle-neuromuscular junction diseases coexist, is an extremely rare and life-threatening complication of immune checkpoint inhibitors. Terms referring to immune-mediated and autoimmune disorders which may potentially be associated with immunotherapeutic agents or vaccines are included in this SMQ. Since this condition exhibits a strong association to an autoimmune pathogenesis, it will be added to the narrow scope.



# Detail Report

CR Number: 2024054040		Implementation Date: 27-Feb-24	Related CR: 2024054040	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Splenic sarcoidosis</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Immune-mediated/autoimmune disorders (SMQ)</i>		<i>Splenic sarcoidosis</i>	10090740
Term scope	<i>Narrow</i>		To SMQ	
			<i>Immune-mediated/autoimmune disorders (SMQ)</i>	20000236
			Term scope	
			<i>Narrow</i>	
			Term_category	
			A	
			Term_weight	
			0	

**MSSO Comment:** The proposal to add PT Splenic sarcoidosis to Immune-mediated/autoimmune disorders (SMQ) as a narrow term is approved as requested. Sarcoidosis is thought to be due to an exaggerated inflammatory response to an environmental antigen in a genetically susceptible person. The unknown antigen triggers a cell-mediated immune response that is characterized by the accumulation of T cells and macrophages, release of cytokines and chemokines, and organization of responding cells into granulomas. Conditions where there is strong evidence, even if not fully confirmed, of an autoimmune or immune-mediated pathophysiologic process are to be included in this SMQ. Like other already existing sarcoidosis related terms, this new PT will be added to the narrow scope of the SMQ.

CR Number: 2024054041		Implementation Date: 27-Feb-24	Related CR: 2024054041	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Clock drawing test abnormal</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Dementia (SMQ)</i>		<i>Clock drawing test abnormal</i>	10090692
Term scope	<i>Broad</i>		To SMQ	
			<i>Dementia (SMQ)</i>	20000073
			Term scope	
			<i>Broad</i>	
			Term_category	
			A	
			Term_weight	
			0	

**MSSO Comment:** The proposal to add PT Clock drawing test abnormal to Dementia (SMQ) as a broad term is approved as requested. Clock drawing test abnormalities are characteristic of many neurological conditions including, most notably, dementia. Clock drawing is one of the components of screening dementia protocols used in clinical practice. Because abnormal testing is not specific for dementia alone, this term will be added to the broad terms of this SMQ.

# Detail Report

CR Number: 2024054042		Implementation Date: 27-Feb-24	Related CR: 2024054042	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Autoimmune vasculitis	Approved as Requested	Proposed PT	
To SMQ	Drug reaction with eosinophilia and systemic symptoms syndrome (SMQ)		Autoimmune vasculitis	10090809
Term scope	Broad		To SMQ	
			Drug reaction with eosinophilia and systemic symptoms syndrome (SMQ)	20000225
			Term scope	
			Broad	
			Term_category	
			B	
			Term_weight	
			0	
MSSO	The proposal to add PT Autoimmune vasculitis to Drug reaction with eosinophilia and systemic symptoms syndrome (SMQ) as a broad term is approved as requested.			
Comment:	This term fits the inclusion criteria for this SMQ. Similar terms such as PT Immune-mediated vasculitis and PT Autoimmune myositis are already included as broad scope terms.			

CR Number: 2024054043		Implementation Date: 27-Feb-24	Related CR: 2024054043	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Gemella infection	Approved as Requested	Proposed PT	
To SMQ	Opportunistic infections (SMQ)		Gemella infection	10090708
Term scope	Narrow		To SMQ	
			Opportunistic infections (SMQ)	20000235
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	
MSSO	The proposal to add PT Gemella infection to Opportunistic infections (SMQ) as a narrow term is approved as requested. Gemellae genus is involved in multiple distinct syndromes with a disparate range of anatomic sites, occurrences, invasiveness and immunocompetence of the patient. According to these published data, it appears that co-morbidities, immunosuppressive therapy and particular situations in previously immunocompetent individuals, such as dental treatments, are more important than age or gender in contracting Gemella diseases. Although there is an unavoidable bias toward publication of most serious cases, a careful literature screening supports that Gemella genus is a relatively uncommon, albeit recurrent and versatile pathogen, mostly in immunocompromised patients, with remarkable epidemiological differences between species.			
Comment:				

# Detail Report

CR Number: 2024054044		Implementation Date: 27-Feb-24	Related CR: 2024054044	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Zoster sine herpete</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Opportunistic infections (SMQ)</i>		<i>Zoster sine herpete</i>	10090802
Term scope	<i>Broad</i>		To SMQ	
			<i>Opportunistic infections (SMQ)</i>	20000235
			Term scope	
			<i>Broad</i>	
			Term_category	
			A	
			Term_weight	
			0	

**MSSO Comment:** The proposal to add PT Zoster sine herpete to Opportunistic infections (SMQ) as a broad term is approved as requested. Zoster sine herpete (ZSH) is a rare presentation of VZV reactivation. It can be seen in both immunocompromised and immunocompetent individuals, and can be associated with post-herpetic neuralgia, especially in immunocompromised hosts. ZSH is likely underreported and underdiagnosed due to the atypical absence of a rash and non-routine testing. Though it is as prevalent in the immunocompetent as in the immunosuppressed, literature is doing a higher remark in the latter due to the fact that it may evolve inadvertently to a more severe state (lowering the chances of appropriate early treatment). The term will be added in the broad scope, like its dermatologically evident neighbor, the PT Herpes zoster.

CR Number: 2024054045		Implementation Date: 27-Feb-24	Related CR: 2024054045	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Transduodenal ampullectomy</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Biliary tract disorders (SMQ)</i>		<i>Transduodenal ampullectomy</i>	10090779
Term scope	<i>Narrow</i>		To SMQ	
			<i>Biliary tract disorders (SMQ)</i>	20000125
			Term scope	
			<i>Narrow</i>	
			Term_category	
			A	
			Term_weight	
			0	

**MSSO Comment:** The proposal to add PT Transduodenal ampullectomy to Biliary tract disorders (SMQ) as a narrow term is approved as requested. Transduodenal ampullectomy is a feasible and effective surgical procedure for the treatment of selected patients with ampullary tumors. Like other existing procedures related to the biliary tract (such as PT Transduodenal sphincteroplasty) PT Transduodenal ampullectomy will be added to Biliary tract disorders (SMQ).

# Detail Report

CR Number: 2024054046		Implementation Date: 27-Feb-24	Related CR: 2024054046	
<u>Change Requested</u>	Add term to SMQ	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Involuntary vocalisation</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Dementia (SMQ)</i>		<i>Involuntary vocalisation</i>	10090790
Term scope	<i>Broad</i>		To SMQ	
			<i>Dementia (SMQ)</i>	20000073
			Term scope	
			<i>Broad</i>	
			Term_category	
			A	
			Term_weight	
			0	

MSSO      The proposal to add PT Involuntary vocalisation to Dementia (SMQ) as a broad term is approved as requested. Involuntary vocalizations are part of the spectrum of the  
Comment: "negative" behaviors which can be seen in patients with dementia. As this is a non-specific finding, it will be added to the broad terms of this SMQ.

CR Number: 2024054047		Implementation Date: 27-Feb-24	Related CR: 2024054047	
<u>Change Requested</u>	Add term to SMQ	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Pulmonary residual volume increased</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Asthma/bronchospasm (SMQ)</i>		<i>Pulmonary residual volume increased</i>	10090748
Term scope	<i>Broad</i>		To SMQ	
			<i>Asthma/bronchospasm (SMQ)</i>	20000025
			Term scope	
			<i>Broad</i>	
			Term_category	
			A	
			Term_weight	
			0	

MSSO      The proposal to add PT Pulmonary residual volume increased to Asthma/bronchospasm (SMQ) as a broad term is approved as requested. Residual volume is increased  
Comment: when there is impaired airflow during expiration, such as during bronchospasm, leading to air trapping in the lungs. The PT Pulmonary residual volume increased will be added to this SMQ with a broad scope in alignment with inclusion criteria.

# Detail Report

CR Number: 2024054048		Implementation Date: 27-Feb-24	Related CR: 2024054048	
<u>Change Requested</u>	Add term to SMQ	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Spinopelvic fixation	Approved as Requested	Proposed PT	
To SMQ	Osteoporosis/osteopenia (SMQ)		Spinopelvic fixation	10090710
Term scope	Broad		To SMQ	
			Osteoporosis/osteopenia (SMQ)	20000178
			Term scope	
			Broad	
			Term_category	
			A	
			Term_weight	
			0	

**MSSO** The proposal to add PT Spinopelvic fixation to Osteoporosis/osteopenia (SMQ) as a broad term is approved as requested. The PT Spinopelvic fixation will be added in  
**Comment:** V27.1 and is referenced in treatment of fragility fractures such as those associated with osteoporosis. The PT Spinopelvic fixation will be added to this SMQ with a broad scope in alignment with inclusion criteria in line with other included PTs such as Sacroiliac fusion.

CR Number: 2024054049		Implementation Date: 27-Feb-24	Related CR: 2024054049	
<u>Change Requested</u>	Add term to SMQ	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Pancreatic necrosectomy	Approved as Requested	Proposed PT	
To SMQ	Acute pancreatitis (SMQ)		Pancreatic necrosectomy	10090829
Term scope	Narrow		To SMQ	
			Acute pancreatitis (SMQ)	20000022
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	

**MSSO** The proposal to add PT Pancreatic necrosectomy to Acute pancreatitis (SMQ) as a narrow term is approved as requested. This term fits the inclusion criteria for this SMQ.  
**Comment:** Similar terms such as PT Pancreatic cyst drainage and PT Pancreatic pseudocyst drainage are already included as narrow scope terms.

# Detail Report

<b>CR Number:</b> 2024054050		<b>Implementation Date:</b> 27-Feb-24	<b>Related CR:</b> 2024054050	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Vaginal leiomyoma</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (SMQ)</i>		<i>Vaginal leiomyoma</i>	10090732
Term scope	<i>Broad</i>		To SMQ	
			<i>Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (SMQ)</i>	20000186
			Term scope	
			<i>Broad</i>	
			Term_category	
			A	
			Term_weight	
			0	

**MSSO Comment:** The proposal to add PT Vaginal leiomyoma to Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (SMQ) as a broad term is approved as requested. This term fits the inclusion criteria for this SMQ which includes terms for conditions that increase the risk of pregnancy complication. As such, depending on the size, the vaginal leiomyomas can cause mechanical obstruction. Similar term such as PT Varicose veins vaginal is already included as a broad scope term.

<b>CR Number:</b> 2024054051		<b>Implementation Date:</b> 27-Feb-24	<b>Related CR:</b> 2024054051	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Pericardial decompression syndrome</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Cardiomyopathy (SMQ)</i>		<i>Pericardial decompression syndrome</i>	10090665
Term scope	<i>Broad</i>		To SMQ	
			<i>Cardiomyopathy (SMQ)</i>	20000150
			Term scope	
			<i>Broad</i>	
			Term_category	
			A	
			Term_weight	
			0	

**MSSO Comment:** The proposal to add PT Pericardial decompression syndrome to Cardiomyopathy (SMQ) as a broad term is approved as requested. The PT Pericardial decompression syndrome represents a post-pericardial drainage low cardiac output syndrome. The exact pathophysiology is not well understood but seems to have a strong association with underlying ventricular dysfunction so the PT will be added to this SMQ under broad scope.

# Detail Report

<b>CR Number:</b> 2024054052		<b>Implementation Date:</b> 27-Feb-24	<b>Related CR:</b> 2024054052	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Myocarditis-myositis-myasthenia gravis overlap syndrome</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Cardiomyopathy (SMQ)</i>		<i>Myocarditis-myositis-myasthenia gravis overlap syndrome</i>	10090724
Term scope	<i>Broad</i>		To SMQ	
			<i>Cardiomyopathy (SMQ)</i>	20000150
			Term scope	
			<i>Broad</i>	
			Term_category	
			A	
			Term_weight	
			0	
<b>MSSO Comment:</b> The proposal to add PT Myocarditis-myositis-myasthenia gravis overlap syndrome to Cardiomyopathy (SMQ) as a broad term is approved as requested. The PT Myocarditis-myositis-myasthenia gravis overlap syndrome was added as an overlap syndrome in immune check-point inhibitor (ICI) treated patients. The PT will be added to this SMQ under broad scope in alignment with inclusion criteria for PTs containing "myocarditis" similar to included PT Immune-mediated myocarditis.				

<b>CR Number:</b> 2024054053		<b>Implementation Date:</b> 27-Feb-24	<b>Related CR:</b> 2024054053	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Percutaneous transluminal septal myocardial ablation</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Cardiomyopathy (SMQ)</i>		<i>Percutaneous transluminal septal myocardial ablation</i>	10090704
Term scope	<i>Broad</i>		To SMQ	
			<i>Cardiomyopathy (SMQ)</i>	20000150
			Term scope	
			<i>Broad</i>	
			Term_category	
			A	
			Term_weight	
			0	
<b>MSSO Comment:</b> The proposal to add PT Percutaneous transluminal septal myocardial ablation to Cardiomyopathy (SMQ) as a broad term is approved as requested. The PT Percutaneous transluminal septal myocardial ablation represents a treatment procedure for hypertrophic obstructive cardiomyopathy. PT Percutaneous transluminal septal myocardial ablation will be added to Cardiomyopathy (SMQ) under broad scope in alignment with inclusion criteria.				

# Detail Report

<b>CR Number:</b> 2024054054		<b>Implementation Date:</b> 28-Feb-24	<b>Related CR:</b> 2024054054	
<u>Change Requested</u>	Add term to SMQ	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Iatrogenic Kaposi sarcoma</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Skin malignant tumours (SMQ)</i>		<i>Iatrogenic Kaposi sarcoma</i>	10090840
Term scope	<i>Narrow</i>		To SMQ	
			<i>Skin malignant tumours (SMQ)</i>	20000204
			Term scope	
			<i>Narrow</i>	
			Term_category	
			A	
			Term_weight	
			0	

**MSSO Comment:** The proposal to add PT Iatrogenic Kaposi sarcoma to Skin malignant tumours (SMQ) as a narrow term is approved as requested. Kaposi sarcoma is typically considered a malignant condition. Iatrogenic Kaposi sarcoma meets the inclusion criterion: Terms for malignant and unspecified neoplasms with a clear reference to the skin. Iatrogenic Kaposi sarcoma will be added to the narrow scope of Skin malignant tumours (SMQ) in line with other already existing Kaposi sarcoma terms.

<b>CR Number:</b> 2024054055		<b>Implementation Date:</b> 27-Feb-24	<b>Related CR:</b> 2024054055	
<u>Change Requested</u>	Add term to SMQ	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Commotio cordis</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Arrhythmia related investigations, signs and symptoms (SMQ)</i>		<i>Commotio cordis</i>	10090682
Term scope	<i>Broad</i>		To SMQ	
			<i>Arrhythmia related investigations, signs and symptoms (SMQ)</i>	20000051
			Term scope	
			<i>Broad</i>	
			Term_category	
			A	
			Term_weight	
			0	

**MSSO Comment:** The proposal to add PT Commotio cordis to Arrhythmia related investigations, signs and symptoms (SMQ) as a broad term is approved as requested. Commotio cordis is defined as sudden cardiac arrest or death secondary to a blunt, nonpenetrating precordial impact. It is provoked by the simultaneous occurrence of specific mechanistic elements (e.g., timing, location, and velocity of impact) that result in ventricular fibrillation. It meets inclusion criterion: "All types of conditions which are related to cardiac arrhythmias, including conduction disturbances and repolarization defects. It includes appropriate ECG, investigations and heart rate terms". It will be added to the broad scope of Arrhythmia related investigations, signs and symptoms (SMQ) in line with other PTs like e.g. Cardiac arrest.



# Detail Report

CR Number: 2024054056		Implementation Date: 27-Feb-24	Related CR: 2024054056	
<a href="#">Change Requested</a>		<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Autoimmune vasculitis	Approved as Requested	Proposed PT	10090809
To SMQ	Vasculitis (SMQ)		Autoimmune vasculitis	
Term scope	Narrow		To SMQ	20000174
			Vasculitis (SMQ)	
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	

MSSO      The proposal to add PT Autoimmune vasculitis to Vasculitis (SMQ) as a narrow term is approved as requested. This term fits the Inclusion criteria for this SMQ for terms  
Comment: containing "vasculitis", for a narrow scope term.

CR Number: 2024054057		Implementation Date: 27-Feb-24	Related CR: 2024054057	
<a href="#">Change Requested</a>		<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Mesenteric thickening	Approved as Requested	Proposed PT	10090717
To SMQ	Retroperitoneal fibrosis (SMQ)		Mesenteric thickening	
Term scope	Broad		To SMQ	20000065
			Retroperitoneal fibrosis (SMQ)	
			Term scope	
			Broad	
			Term_category	
			A	
			Term_weight	
			0	

MSSO      The proposal to add PT Mesenteric thickening to Retroperitoneal fibrosis (SMQ) as a broad term is approved as requested. Mesenteric thickening could be indicative of  
Comment: mesenteric fibrosis (part of the narrow scope of this SMQ) or mesenteric panniculitis which could occur alongside fibrosclerotic disorders such as retroperitoneal fibrosis.  
The PT Mesenteric thickening will be added under broad scope of this SMQ.

# Detail Report

CR Number: 2024054058		Implementation Date: 27-Feb-24	Related CR: 2024054058		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed PT	Post pulmonary embolism syndrome	Approved as Requested	Proposed PT		
To SMQ	Embolic and thrombotic events, venous (SMQ)		Post pulmonary embolism syndrome		10090763
Term scope	Narrow		To SMQ		
			Embolic and thrombotic events, venous (SMQ)		20000084
			Term scope		
			Narrow		
			Term_category		
			A		
			Term_weight		
			0		

MSSO Comment: The proposal to add PT Post pulmonary embolism syndrome to Embolic and thrombotic events, venous (SMQ) as a narrow term is approved as requested. This term fits the inclusion criteria of this SMQ for embolism and thrombosis terms from HLGT Embolism and thrombosis. All terms are narrow scope.

CR Number: 2024054059		Implementation Date: 27-Feb-24	Related CR: 2024054059		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed PT	Post pulmonary embolism syndrome	Approved as Requested	Proposed PT		
To SMQ	Pulmonary hypertension (SMQ)		Post pulmonary embolism syndrome		10090763
Term scope	Narrow		To SMQ		
			Pulmonary hypertension (SMQ)		20000130
			Term scope		
			Narrow		
			Term_category		
			A		
			Term_weight		
			0		

MSSO Comment: The proposal to add PT Post pulmonary embolism syndrome to Pulmonary hypertension (SMQ) as a narrow term is approved as requested. This term fits the inclusion criteria for a narrow scope term of this SMQ, for highly specific etiologic conditions which often result in pulmonary hypertension.

# Detail Report

CR Number: 2024054060		Implementation Date: 27-Feb-24	Related CR: 2024054060	
<u>Change Requested</u>	Add term to SMQ	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Mesenteric panniculitis	Approved as Requested	Proposed PT	
To SMQ	Retroperitoneal fibrosis (SMQ)		Mesenteric panniculitis	10063031
Term scope	Broad		To SMQ	
			Retroperitoneal fibrosis (SMQ)	20000065
			Term scope	
			Broad	
			Term_category	
			A	
			Term_weight	
			0	

**MSSO Comment:** The proposal to add PT Mesenteric panniculitis to Retroperitoneal fibrosis (SMQ) as a broad term is approved as requested. Fibrosclerotic disorders including retroperitoneal fibrosis have been reported to occur alongside mesenteric panniculitis. The PT Mesenteric panniculitis will be added to Retroperitoneal fibrosis (SMQ) as broad scope term.

CR Number: 2024054062		Implementation Date: 01-Mar-24	Related CR: 2024054062	
<u>Change Requested</u>	Add a New Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	Prevertebral space infection	Approved as Requested	Proposed PT	
			Prevertebral space infection	10090879
			HLT primary	
			Muscle and soft tissue infections	10057192
			SOC primary	
			Infections and infestations	10021881
			HLT secondary	
			Musculoskeletal and connective tissue infections and inflammations NEC	10052776
			SOC secondary	
			Musculoskeletal and connective tissue disorders	10028395

**MSSO Comment:** The proposal to add a new term Prevertebral space infection is approved as requested. Prevertebral space infection is a serious condition characterized by the accumulation of pus in the space usually located behind the pharynx and in front of the cervical vertebrae. The prevertebral space serves as a conduit for the passage of structures between the head and neck and the thoracic cavity. Infections or abscesses in this space can lead to significant complications due to its proximity to vital structures such as the pharynx and major blood vessels. Prevertebral space infection will be added as a PT to primary HLT Muscle and soft tissue infections and to secondary HLT Musculoskeletal and connective tissue infections and inflammations NEC.

# Detail Report

<b>CR Number:</b> 2024057000		<b>Implementation Date:</b> 01-Mar-24	<b>Related CR:</b> 2024057000	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Intestinal ganglioneuromatosis</i>	Approved Not as Requested	Proposed PT <i>Intestinal ganglioneuromatosis</i>	10090880
			HLT primary <i>Neuromas</i>	10029312
			SOC primary <i>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</i>	10029104
			HLT secondary <i>Neuromas</i>	10029312
			SOC secondary <i>Nervous system disorders</i>	10029205

MSSO  
Comment: The proposal to add a new LLT Intestinal ganglioneuromatosis is approved but not as requested. Intestinal ganglioneuromatosis is a rare benign tumor characterized by proliferation of ganglion cells, nerve fibers and supporting cells of the enteric nervous system. This condition may affect any portion of the gastrointestinal tract, but the ileum, colon, and appendix are most frequently involved. Intestinal ganglioneuromatosis will be added as new PT to primary bi-axial HLT Neuromas (primary SOC Neoplasms benign, malignant and unspecified (incl cysts and polyps), secondary SOC Nervous system disorders) and secondary HLT Gastrointestinal neoplasms NEC.

<b>CR Number:</b> 2024061006		<b>Implementation Date:</b> 01-Mar-24	<b>Related CR:</b> 2024057000	
<a href="#">Change Requested</a>	Link a PT to a HLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Intestinal ganglioneuromatosis</i>	Approved as Requested	Proposed PT <i>Intestinal ganglioneuromatosis</i>	10090880
To HLT	<i>Gastrointestinal neoplasms NEC</i>		To HLT <i>Gastrointestinal neoplasms NEC</i>	10017993

MSSO  
Comment:

# Detail Report

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<b>CR Number:</b> 2024057001		<b>Implementation Date:</b> 01-Mar-24	<b>Related CR:</b> 2024057001		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed LLT	Orofacial Pain	Rejected			

**MSSO Comment:** The proposal to add a new LLT Orofacial Pain is not approved. Orofacial pain encompasses a wide range of conditions and disorders that involve pain or discomfort in the mouth, jaws, face, and adjacent areas. There are existing MedDRA terms for pain in these areas. The proposed term will not be added, as further granularity on PT level might lead to signal dispersion. Please refer to Section 3.5 of the MedDRA Term Selection: Points to Consider Document regarding coding approaches/considerations.

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<b>CR Number:</b> 2024057002		<b>Implementation Date:</b> 01-Mar-24	<b>Related CR:</b> 2024057002		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed LLT	Exposed to maternal infection in utero	Approved Not as Requested	Proposed PT		
			Exposed to maternal infection in utero		10090881
			HLT primary		
			Exposures associated with pregnancy, delivery and lactation		10071949
			SOC primary		
			Injury, poisoning and procedural complications		10022117
			HLT secondary		
			Exposures associated with pregnancy, delivery and lactation		10071949
			SOC secondary		
			Pregnancy, puerperium and perinatal conditions		10036585

**MSSO Comment:** The proposal to add a new LLT Exposed to maternal infection in utero is approved but not as requested. Exposure to a pathogenic agent in utero needs careful follow up since infections in pregnancy can cause prematurity or stillbirth, or can be vertically transmitted to the fetus leading to congenital infection and severe disease. Exposed to maternal infection in utero will be added as a new PT to bi-axial HLT Exposures associated with pregnancy, delivery and lactation (primary SOC Injury, poisoning and procedural complications and secondary SOC Pregnancy, puerperium and perinatal conditions).

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# Detail Report

CR Number: 2024057003		Implementation Date: 01-Mar-24	Related CR: 2024057003		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed Term	Neonatal drug withdrawal symptoms	Rejected			

MSSO Comment: The proposal to add a new term Neonatal drug withdrawal symptoms is not approved. The proposed concept can be represented by existing PT Drug withdrawal syndrome neonatal.

CR Number: 2024057004		Implementation Date: 01-Mar-24	Related CR: 2024057004		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed PT	Pharyngolaryngo-oesophagectomy	Approved Not as Requested	Proposed PT Pharyngo-laryngo-oesophagectomy	10090873	
			HLT primary Head, neck and oral cavity therapeutic procedures NEC	10052723	
			SOC primary Surgical and medical procedures	10042613	

MSSO Comment: The proposal to add a new PT Pharyngolaryngo-oesophagectomy is approved but not as requested. Esophageal invasion in hypopharyngeal cancer is an uncommon lesion with a poor prognosis, in which pharyngo-laryngo-esophagectomy is the most effective treatment option. Reconstruction of the gastrointestinal tract in the same period of surgery is required. The proposed term will be modified for the British English spelling including hyphens and added as new PT Pharyngo-laryngo-oesophagectomy to HLT Head, neck and oral cavity therapeutic procedures NEC. In a related change, the American English spelled counterpart LLT Pharyngo-laryngo-esophagectomy will be added to new PT Pharyngo-laryngo-oesophagectomy.

CR Number: 2024061005		Implementation Date: 01-Mar-24	Related CR: 2024057004		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed LLT	Pharyngo-laryngo-esophagectomy	Approved as Requested	Proposed LLT Pharyngo-laryngo-esophagectomy	10090877	Current
To PT	Pharyngo-laryngo-oesophagectomy		To PT Pharyngo-laryngo-oesophagectomy	10090873	

MSSO Comment:

# Detail Report

<b>CR Number:</b> 2024057008		<b>Implementation Date:</b> 05-Mar-24	<b>Related CR:</b> 2024057008		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed Term	Masticator space lesion	Rejected			

**MSSO Comment:** The proposal to add a new term Masticator space lesion is not approved. As stated in section 5, PT AND LLT NAMING CONVENTIONS of the MedDRA Introductory Guide, "lesion terms may be considered for inclusion in MedDRA when the word "lesion" is part of a medical concept, e.g., PT Glomerulonephritis minimal lesion or a well-documented medical concept, e.g., LLT Brain lesion. However, the term will not be added when adding a broad "lesion" term only adds an additional imprecise term.

<b>CR Number:</b> 2024058000		<b>Implementation Date:</b> 01-Mar-24	<b>Related CR:</b> 2024058000		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed Term	Clostridioides difficile test negative	Approved as Requested	Proposed LLT Clostridioides difficile test negative		10090882 Current
			To PT Clostridium test negative		10070271

**MSSO Comment:** The proposal to add a new term Clostridioides difficile test negative is approved as requested. A negative test result for the C. difficile likely indicates that the person's diarrhea and related symptoms are not due to toxin-producing C. difficile. In 2016, the genus Clostridium was reclassified, and Clostridioides difficile became the accepted name for the bacterium previously known as Clostridium difficile. Clostridioides difficile test negative will be added as an LLT under PT Clostridium test negative.

<b>CR Number:</b> 2024058001		<b>Implementation Date:</b> 05-Mar-24	<b>Related CR:</b> 2024058001		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed LLT	Ischaemic cerebellar infarction	Approved as Requested	Proposed LLT Ischaemic cerebellar infarction		10090887 Current
To PT	Cerebellar infarction		To PT Cerebellar infarction		10008034

**MSSO Comment:** The proposal to add a new LLT Ischaemic cerebellar infarction to PT Cerebellar infarction is approved as requested. Cerebellar infarcts are roughly divided into ischemic and hemorrhagic events. In a related change, the American English spelled counterpart LLT Ischemic cerebellar infarction will also be added under PT Cerebellar infarction.

# Detail Report

<b>CR Number:</b> 2024065004		<b>Implementation Date:</b> 05-Mar-24	<b>Related CR:</b> 2024058001		
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed LLT	<i>Ischemic cerebellar infarction</i>	Approved as Requested	Proposed LLT		
To PT	<i>Cerebellar infarction</i>		<i>Ischemic cerebellar infarction</i>	10090888	Current
			To PT		
			<i>Cerebellar infarction</i>	10008034	

MSSO  
Comment:

<b>CR Number:</b> 2024058002		<b>Implementation Date:</b> 05-Mar-24	<b>Related CR:</b> 2024058002		
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed PT	<i>Cerebellar infarction</i>	Rejected			
To SMQ	<i>Embolic and thrombotic events, arterial (SMQ)</i>				
Term scope	<i>Narrow</i>				

MSSO  
Comment: The proposal to add PT Cerebellar infarction to Embolic and thrombotic events, arterial (SMQ) as a narrow term is not approved. Although cerebellar infarction typically involves any of three arteries supplying the cerebellum; rarely, deficiency of the collateral venous drainage pathway may induce a localized cerebellar infarction. As such the PT Cerebellar infarction will not be moved from SMQ Embolic and thrombotic events, vessel type unspecified and mixed arterial and venous to SMQ Embolic and thrombotic events, arterial.

<b>CR Number:</b> 2024059000		<b>Implementation Date:</b> 05-Mar-24	<b>Related CR:</b> 2024059000		
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed Term	<i>Intraductal papillary mucinous neoplasm of the biliary tract</i>	Approved as Requested	Proposed LLT		
			<i>Intraductal papillary mucinous neoplasm of the biliary tract</i>	10090889	Current
			To PT		
			<i>Intraductal papillary mucinous neoplasm</i>	10070999	

MSSO  
Comment: The proposal to add a new term Intraductal papillary mucinous neoplasm of the biliary tract is approved as requested. Intraductal papillary neoplasm of the liver and bile ducts is a grossly visible premalignant neoplasm with intraductal papillary or villous growth of biliary-type epithelium, which often forms intraluminal papillary masses and increased mucin secretion, resulting in obstruction and dilation of the biliary tree. Intraductal papillary mucinous neoplasm of the biliary tract will be added as LLT under PT Intraductal papillary mucinous neoplasm. In an associated change, the PT Intraductal papillary mucinous neoplasm will receive a new secondary link to the HLT Hepatobiliary neoplasms NEC. In addition, a new LLT named Intraductal papillary mucinous neoplasm of the pancreas will also be added to the PT Intraductal papillary mucinous neoplasm to warrant a clear differentiation of the anatomical residing site of a type of premalignant lesions with histological similarities but possible appearance in different anatomical locations.



# Detail Report

<b>CR Number:</b> 2024065006		<b>Implementation Date:</b> 05-Mar-24	<b>Related CR:</b> 2024059000		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Link a PT to a HLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed PT	<i>Intraductal papillary mucinous neoplasm</i>	Approved as Requested	Proposed PT		
To HLT	<i>Hepatobiliary neoplasms NEC</i>		<i>Intraductal papillary mucinous neoplasm</i>		10070999
			To HLT		
			<i>Hepatobiliary neoplasms NEC</i>		10019817

MSSO  
Comment:

<b>CR Number:</b> 2024065007		<b>Implementation Date:</b> 05-Mar-24	<b>Related CR:</b> 2024059000		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed LLT	<i>Intraductal papillary mucinous neoplasm of the pancreas</i>	Approved as Requested	Proposed LLT		
To PT	<i>Intraductal papillary mucinous neoplasm</i>		<i>Intraductal papillary mucinous neoplasm of the pancreas</i>		10090891 Current
			To PT		
			<i>Intraductal papillary mucinous neoplasm</i>		10070999

MSSO  
Comment:

<b>CR Number:</b> 2024059001		<b>Implementation Date:</b> 05-Mar-24	<b>Related CR:</b> 2024059001		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed Term	<i>Veloergometry</i>	Approved as Requested	Proposed LLT		
			<i>Veloergometry</i>		10090890 Current
			To PT		
			<i>Exercise electrocardiogram</i>		10015644

MSSO  
Comment: The proposal to add a new term Veloergometry is approved as requested. Veloergometry is a test of the cardiovascular system under conditions of increased physical activity. During the procedure, blood pressure is measured and a cardiogram is recorded. Veloergometry will be added as an LLT to the PT Exercise electrocardiogram, aligned with existing LLT Bicycle ergometry.

# Detail Report

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CR Number: 2024059002	Implementation Date: 05-Mar-24	Related CR: 2024059002	MedDRA Code #
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>
Proposed Term	<i>Paroxysmal phenomena</i>	Rejected	

MSSO Comment: The proposal to add a new term Paroxysmal phenomena is not approved. The proposed term is a modifier indicating the sudden recurrence or intensification of a condition or symptoms (such as in a spasm or seizure). The term has very limited value without the context of the condition.

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CR Number: 2024059003	Implementation Date: 05-Mar-24	Related CR: 2024059003	MedDRA Code #
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>
Proposed LLT	<i>Papular-purpuric gloves-and-socks syndrome</i>	Approved Not as Requested	Proposed PT
To PT	<i>Purpura fulminans</i>		<i>Papular-purpuric gloves-and-socks syndrome</i> 10090892
			HLT primary
			<i>Parvoviral infections</i> 10034098
			SOC primary
			<i>Infections and infestations</i> 10021881
			HLT secondary
			<i>Purpura and related conditions</i> 10037555
			SOC secondary
			<i>Skin and subcutaneous tissue disorders</i> 10040785

MSSO Comment: The proposal to add a new LLT Papular-purpuric gloves-and-socks syndrome to PT Purpura fulminans is approved but not as requested. Papular-purpuric gloves and socks syndrome is a distinctive manifestation of parvovirus B19 infection, but it has occasionally been linked with etiologic agents other than Parvovirus B19. Papular-purpuric gloves and socks syndrome is an illness characterized by pruritic painful acral erythema associated with fever and mucosal lesions. Papular-purpuric gloves-and-socks syndrome will be added as PT linked to primary HLT Parvoviral infections, and to secondary HLT Purpura and related conditions.

# Detail Report

CR Number: 2024060000		Implementation Date: 05-Mar-24	Related CR: 2024060000	
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Vibrio fluvialis infection</i>	Approved as Requested	Proposed PT	
HLT primary	<i>Vibrio infections</i>		<i>Vibrio fluvialis infection</i>	10090893
SOC primary	<i>Infections and infestations</i>		HLT primary	
			<i>Vibrio infections</i>	10047400
			SOC primary	
			<i>Infections and infestations</i>	10021881

**MSSO Comment:** The proposal to add a new PT *Vibrio fluvialis infection* to primary HLT *Vibrio infections* in SOC *Infections and infestations* is approved as requested. *Vibrio fluvialis* is a bacterium belonging to the *Vibrio* genus, known to cause infections in humans. *Vibrio fluvialis* is typically found in aquatic environments. Infections with *Vibrio fluvialis* often occur through the ingestion of contaminated food or water, particularly raw or undercooked seafood. *Vibrio fluvialis* infections typically present with gastrointestinal symptoms such as diarrhea, abdominal cramps, nausea, vomiting, and occasionally fever. Rarely, the infection can lead to septicemia in individuals with weakened immune systems.

CR Number: 2024060001		Implementation Date: 18-Mar-24	Related CR: 2024060001	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Epidermoid cyst (acquired)</i>	Approved Not as Requested After Suspension	Proposed LLT	
			<i>Acquired epidermoid cyst</i>	10090929 Current
			To PT	
			<i>Dermal cyst</i>	10012426

**MSSO Comment:** The proposal to add a new term *Epidermoid cyst (acquired)* is approved but not as requested after suspension. *Epidermoid cyst* is a common benign disease of the skin caused by inflammation of hair cortex follicles and proliferation of epidermal cells, and it can be congenital or acquired. Determining whether an *epidermoid cyst* is congenital or acquired can be difficult. The proposed term will be modified to the natural word order and added as LLT *Acquired epidermoid cyst* to PT *Dermal cyst*.

CR Number: 2024060002		Implementation Date: 04-Apr-24	Related CR: 2024060002	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Acute exacerbation of chronic rhinosinusitis</i>	Approved After Suspension	Proposed LLT	
			<i>Acute exacerbation of chronic rhinosinusitis</i>	10090973 Current
			To PT	
			<i>Sinusitis</i>	10040753

**MSSO Comment:** The proposal to add a new term *Acute exacerbation of chronic rhinosinusitis* is approved as requested after suspension. Chronic sinusitis involves many factors that combine to create chronic inflammation (such as allergies, structural abnormalities, environmental irritants, mucociliary dysfunction, etc) with infectious organisms. Exacerbations over a chronic inflammation state are characteristic both in children and adults. In exacerbations of chronic sinusitis, as the condition presents acutely imposed on a chronic condition, the concept is best placed under the base condition of sinusitis. *Acute exacerbation of chronic rhinosinusitis* will be added as an LLT to PT *Sinusitis*.

# Detail Report

<b>CR Number:</b> 2024060003		<b>Implementation Date:</b> 05-Mar-24	<b>Related CR:</b> 2024060003		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed Term	Male hot flashes	Rejected			

**MSSO Comment:** The proposal to add a new term Male hot flashes is not approved. In general, gender specific terms are not included in MedDRA because patient gender is traditionally considered a database variable. However, a special case has been made for instances in which the gender of the patient makes the concept clinically distinct as for certain breast and reproductive tract disorders. The underlining pathogenesis is similar for both males and females.

<b>CR Number:</b> 2024060004		<b>Implementation Date:</b> 05-Mar-24	<b>Related CR:</b> 2024060004		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed PT	Breast ablation	Approved as Requested	Proposed PT		
HLT primary	Breast therapeutic procedures NEC		Breast ablation		10090883
SOC primary	Surgical and medical procedures		HLT primary		
			Breast therapeutic procedures NEC		10027659
			SOC primary		
			Surgical and medical procedures		10042613

**MSSO Comment:** The proposal to add a new PT Breast ablation to primary HLT Breast therapeutic procedures NEC in SOC Surgical and medical procedures is approved as requested. Ablative techniques used in breast cancer are cryoablation, radiofrequency ablation, microwave ablation, high-intensity focused ultrasound, and laser ablation. In a related change, PT Laser ablation of breast will be demoted under PT Breast ablation. Furthermore, PT Prostate cryoablation will be demoted under PT Prostate ablation.

<b>CR Number:</b> 2024065002		<b>Implementation Date:</b> 05-Mar-24	<b>Related CR:</b> 2024060004		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Demote a PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
PT to merge	Laser ablation of breast	Approved as Requested	PT to merge		
To PT	Breast ablation		Laser ablation of breast		10089465 Current
			To PT		
			Breast ablation		10090883

**MSSO Comment:**

# Detail Report

CR Number: 2024065003		Implementation Date: 05-Mar-24	Related CR: 2024060004		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Demote a PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
PT to merge	Prostate cryoablation	Approved as Requested	PT to merge		
To PT	Prostate ablation		Prostate cryoablation	10073181	Current
			To PT		
			Prostate ablation	10074432	

MSSO  
Comment:

CR Number: 2024060005		Implementation Date: 05-Mar-24	Related CR: 2024060005		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed PT	Central nervous system bacterial infection	Approved as Requested	Proposed PT		
HLT primary	Bacterial infections NEC		Central nervous system bacterial infection	10090884	
SOC primary	Infections and infestations		HLT primary		
			Bacterial infections NEC	10004047	
			SOC primary		
			Infections and infestations	10021881	
			HLT secondary		
			Nervous system infections NEC	10021888	
			SOC secondary		
			Nervous system disorders	10029205	

MSSO  
Comment: The proposal to add a new PT Central nervous system bacterial infection to primary HLT Bacterial infections NEC in SOC Infections and infestations and secondary HLT Nervous system infections NEC in SOC Nervous system disorders is approved as requested. The central nervous system may be infected by a wide variety of bacteria. The spectrum of these infections varies from focal infections, such as brain abscesses, to generalized entities such as meningoencephalitis.

# Detail Report

CR Number: 2024060006		Implementation Date: 05-Mar-24	Related CR: 2024060006	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	Goblet cell adenocarcinoma	Approved as Requested	Proposed LLT Goblet cell adenocarcinoma To PT Adenocarcinoma of appendix	10090894 Current  10073359
MSSO Comment:	The proposal to add a new term Goblet cell adenocarcinoma is approved as requested. Goblet cell adenocarcinomas (GCA) of the appendix are a subtype of appendiceal cancer. GCA are defined by a unique combination of two types of cancer cells – neuroendocrine (carcinoid) and epithelial (adenocarcinoma). These tumors are more aggressive than neuroendocrine tumors and are now treated and staged like appendiceal adenocarcinomas. Goblet cell adenocarcinoma will be added as sub-concept LLT under PT Adenocarcinoma of appendix.			

CR Number: 2024061000		Implementation Date: 08-Mar-24	Related CR: 2024061000	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	Traumatic subarachnoid haemorrhage	Approved as Requested	Proposed PT Traumatic subarachnoid haemorrhage HLT primary Cerebral injuries NEC SOC primary Injury, poisoning and procedural complications HLT secondary Traumatic central nervous system haemorrhages SOC secondary Nervous system disorders	10090895  10052638  10022117  10044518  10029205
MSSO Comment:	The proposal to add a new term Traumatic subarachnoid haemorrhage is approved as requested. MedDRA refrains from adding new terms with the modifier "traumatic", since they represent one of the possible etiologies of multiple conditions, which would lead to the overpopulation of the terminology. However, traumatic subarachnoid hemorrhage (called also secondary and the most frequent cause) is usually considered a separate disorder from the spontaneous (primary) subarachnoid hemorrhage (which usually results from a ruptured aneurysm). Therefore, the proposed term Traumatic subarachnoid haemorrhage will be added as PT with a primary link to HLT Cerebral injuries NEC and a secondary link to HLT Traumatic central nervous system haemorrhages. In a related change, the LLT Traumatic subarachnoid hemorrhage will be added as LLT under the new PT Traumatic subarachnoid haemorrhage to represent its American spelled counterpart. Furthermore, the following LLTs will be moved from PT Subarachnoid haemorrhage to the new PT Traumatic subarachnoid haemorrhage: LLT Subarac hem following inj, with open intcran wound, with brief loc; LLT Subarac hem following inj, with open intcran wound, with concussion, unspec ; LLT Subarac hem following inj, with open intcran wound, with loc of unspec duration ; LLT Subarac hem following inj, with open intcran wound, with moderate loc ; LLT Subarac hem following inj, with open intcran wound, with no loc ; LLT Subarac hem following inj, with open intcran wound, with prolonged loc and return to pecl ; LLT Subarac hem following inj, with open intcran wound, with prolonged loc, w/o return to pecl ; LLT Subarac hem following inj, with open intcran wound, with state of consciousness unspec ; LLT Subarachnoid hemorrhage following injury with open intra-cranial wound ; and LLT Subarachnoid hemorrhage following injury, with open intracranial wound, with concussion, unspecified.			

# Detail Report

CR Number: 2024068012		Implementation Date: 08-Mar-24	Related CR: 2024061000	
<a href="#">Change Requested</a>	Link (move) an LLT to another PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Subarachnoid hemorrhage following injury with open intra-cranial wound	Approved as Requested	Proposed LLT	
			Subarachnoid hemorrhage following injury with open intra-cranial wound	10042321 Non-Current
From PT	Subarachnoid haemorrhage		From PT	
To PT	Traumatic subarachnoid haemorrhage		Subarachnoid haemorrhage	10042316
			To PT	
			Traumatic subarachnoid haemorrhage	10090895

MSSO  
Comment:

CR Number: 2024068004		Implementation Date: 08-Mar-24	Related CR: 2024061000	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Traumatic subarachnoid hemorrhage	Approved as Requested	Proposed LLT	
			Traumatic subarachnoid hemorrhage	10090896 Current
To PT	Traumatic subarachnoid haemorrhage		To PT	
			Traumatic subarachnoid haemorrhage	10090895

MSSO  
Comment:

# Detail Report

CR Number: 2024068013		Implementation Date: 08-Mar-24	Related CR: 2024061000	
<a href="#">Change Requested</a>	Link (move) an LLT to another PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Subarachnoid hemorrhage following injury, with open intracranial wound, with concussion, unspecified	Approved as Requested	Proposed LLT Subarachnoid hemorrhage following injury, with open intracranial wound, with concussion, unspecified	10042323 Non-Current
From PT	Subarachnoid haemorrhage		From PT	
To PT	Traumatic subarachnoid haemorrhage		Subarachnoid haemorrhage	10042316
			To PT	
			Traumatic subarachnoid haemorrhage	10090895

MSSO  
Comment:

CR Number: 2024068011		Implementation Date: 08-Mar-24	Related CR: 2024061000	
<a href="#">Change Requested</a>	Link (move) an LLT to another PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Subarac hem following inj, with open intcran wound, with state of consciousness unspec	Approved as Requested	Proposed LLT Subarac hem following inj, with open intcran wound, with state of consciousness unspec	10042315 Non-Current
From PT	Subarachnoid haemorrhage		From PT	
To PT	Traumatic subarachnoid haemorrhage		Subarachnoid haemorrhage	10042316
			To PT	
			Traumatic subarachnoid haemorrhage	10090895

MSSO  
Comment:



# Detail Report

CR Number: 2024068010		Implementation Date: 08-Mar-24	Related CR: 2024061000	
<a href="#">Change Requested</a>	Link (move) an LLT to another PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Subarac hem following inj, with open intcran wound, with prolonged loc and return to pecl	Approved as Requested	Proposed LLT	10042313 Non-Current
From PT	Subarachnoid haemorrhage		Subarac hem following inj, with open intcran wound, with prolonged loc and return to pecl	
To PT	Traumatic subarachnoid haemorrhage		From PT	10042316
		Subarachnoid haemorrhage		
		To PT	10090895	
		Traumatic subarachnoid haemorrhage		
MSSO Comment:				

CR Number: 2024068008		Implementation Date: 08-Mar-24	Related CR: 2024061000	
<a href="#">Change Requested</a>	Link (move) an LLT to another PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Subarac hem following inj, with open intcran wound, with moderate loc	Approved as Requested	Proposed LLT	10042311 Non-Current
From PT	Subarachnoid haemorrhage		Subarac hem following inj, with open intcran wound, with moderate loc	
To PT	Traumatic subarachnoid haemorrhage		From PT	10042316
		Subarachnoid haemorrhage		
		To PT	10090895	
		Traumatic subarachnoid haemorrhage		
MSSO Comment:				

# Detail Report

CR Number: 2024068005		Implementation Date: 08-Mar-24	Related CR: 2024061000		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Link (move) an LLT to another PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed LLT	<i>Subarac hem following inj, with open intcran wound, with brief loc</i>	Approved as Requested	Proposed LLT		
From PT	<i>Subarachnoid haemorrhage</i>		<i>Subarac hem following inj, with open intcran wound, with brief loc</i>	10042308	Non-Current
To PT	<i>Traumatic subarachnoid haemorrhage</i>		From PT		
			<i>Subarachnoid haemorrhage</i>	10042316	
			To PT		
			<i>Traumatic subarachnoid haemorrhage</i>	10090895	

MSSO  
Comment:

CR Number: 2024068009		Implementation Date: 08-Mar-24	Related CR: 2024061000		<a href="#">MedDRA Code #</a>	
<a href="#">Change Requested</a>	Link (move) an LLT to another PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>			
Proposed LLT	<i>Subarac hem following inj, with open intcran wound, with no loc</i>	Approved as Requested	Proposed LLT			
From PT	<i>Subarachnoid haemorrhage</i>		<i>Subarac hem following inj, with open intcran wound, with no loc</i>	10042312	Non-Current	
To PT	<i>Traumatic subarachnoid haemorrhage</i>		From PT			
			<i>Subarachnoid haemorrhage</i>	10042316		
			To PT			
			<i>Traumatic subarachnoid haemorrhage</i>	10090895		

MSSO  
Comment:

# Detail Report

CR Number: 2024068014		Implementation Date: 08-Mar-24	Related CR: 2024061000		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Link (move) an LLT to another PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed LLT	Subarac hem following inj, with open intcran wound, with prolonged loc, w/o return to pecl	Approved as Requested	Proposed LLT	10042314	Non-Current
From PT	Subarachnoid haemorrhage		Subarac hem following inj, with open intcran wound, with prolonged loc, w/o return to pecl		
To PT	Traumatic subarachnoid haemorrhage		From PT	10042316	
			Subarachnoid haemorrhage		
			To PT	10090895	
			Traumatic subarachnoid haemorrhage		

MSSO  
Comment:

CR Number: 2024068006		Implementation Date: 08-Mar-24	Related CR: 2024061000		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Link (move) an LLT to another PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed LLT	Subarac hem following inj, with open intcran wound, with concussion, unspec	Approved as Requested	Proposed LLT	10042309	Non-Current
From PT	Subarachnoid haemorrhage		Subarac hem following inj, with open intcran wound, with concussion, unspec		
To PT	Traumatic subarachnoid haemorrhage		From PT	10042316	
			Subarachnoid haemorrhage		
			To PT	10090895	
			Traumatic subarachnoid haemorrhage		

MSSO  
Comment:

# Detail Report

CR Number: 2024068007		Implementation Date: 08-Mar-24	Related CR: 2024061000		
<a href="#">Change Requested</a>	Link (move) an LLT to another PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed LLT	Subarac hem following inj, with open intcran wound, with loc of unspec duration	Approved as Requested	Proposed LLT		
			Subarac hem following inj, with open intcran wound, with loc of unspec duration	10042310	Non-Current
From PT	Subarachnoid haemorrhage		From PT		
To PT	Traumatic subarachnoid haemorrhage		Subarachnoid haemorrhage	10042316	
			To PT		
			Traumatic subarachnoid haemorrhage	10090895	
MSSO					
Comment:					

CR Number: 2024061001		Implementation Date: 05-Mar-24	Related CR: 2024061001		
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed LLT	Gastritis cystica profunda	Approved Not as Requested	Proposed PT		
			Gastritis cystica profunda	10090885	
			HLT primary		
			Gastritis (excl infective)	10017854	
			SOC primary		
			Gastrointestinal disorders	10017947	
			HLT secondary		
			Gastrointestinal and hepatobiliary procedural complications	10017927	
			SOC secondary		
			Injury, poisoning and procedural complications	10022117	
MSSO					
Comment: The proposal to add a new LLT Gastritis cystica profunda is approved but not as requested. Gastritis cystica profunda is a type of gastritis in which there are cysts in the submucosa of the stomach, consisting of abnormal extensions of gastric glands; it is most often a late complication of partial gastrectomy and may be due to ischemia or inflammation at the suture site. Gastritis cystica profunda will be added as new PT under primary HLT Gastritis (excl infective) and to secondary HLT Gastrointestinal and hepatobiliary procedural complications.					

# Detail Report

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<b>CR Number:</b> 2024061002		<b>Implementation Date:</b> 05-Mar-24	<b>Related CR:</b> 2024061002	<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	
Proposed LLT	Periarteritis	Approved as Requested	Proposed LLT	
To PT	Arteritis		Periarteritis	10090886 Current
			To PT	
			Arteritis	10003230

MSSO Comment: The proposal to add a new LLT Periarteritis to PT Arteritis is approved as requested. Periarteritis is defined as inflammation of the external coats of an artery and of the tissues around the artery.

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<b>CR Number:</b> 2024061003		<b>Implementation Date:</b> 05-Mar-24	<b>Related CR:</b> 2024061003	<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	
Proposed LLT	Myoischemia	Rejected		

MSSO Comment: The proposal to add a new LLT Myoischemia is not approved. The proposed term may lead to confusion and refer to myocardial ischemia, please provide use case for the term. As well, existing LLT/PT Muscle hypoxia may be used depending on your specific scenario.

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<b>CR Number:</b> 2024062000		<b>Implementation Date:</b> 22-May-24	<b>Related CR:</b> 2024062000	<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a new SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	
Proposed SMQ	Anxio-depressive syndrome (including sleep disorder and suicide)	Rejected After Suspension		

MSSO Comment: The proposal to add a new SMQ Anxio-depressive syndrome (including sleep disorder and suicide) is not approved after suspension. An international team of regulatory and industry representatives (ICH M1 Points to Consider (PtC) Working group) evaluated this request and does not recommend the development of this SMQ. PT Mixed anxiety and depressive disorder is already available for coding use in MedDRA and is included in Depression and suicide/self-injury (SMQ). The already existing Depression and suicide/self-injury (SMQ) can be modified to create a Customized MedDRA Query Based on an SMQ, for example, by adding relevant terms from HLTs/HLGTs such as HLGT Anxiety disorders and symptoms." For more specific details related to customized searches, please refer to the MedDRA® DATA RETRIEVAL AND PRESENTATION:POINTS TO CONSIDER document (Release 3.24, March 2024) SECTION 5 –CUSTOMISED SEARCHES.

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# Detail Report

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<b>CR Number:</b> 2024064000		<b>Implementation Date:</b> 08-Mar-24	<b>Related CR:</b> 2024064000		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Link (move) an LLT to another PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed LLT	<i>Perineural invasion</i>	Rejected			
From PT	<i>Metastases to nervous system</i>				
To PT	<i>Metastases to peripheral nervous system</i>				
<b>MSSO Comment:</b>	The proposal to move the LLT Perineural invasion from PT Metastases to nervous system to PT Metastases to peripheral nervous system is not approved. Perineural invasion is more commonly associated with the peripheral nervous system (local invasion with the ability to lead to distant metastasis) but can also occur in/around the central nervous system (CNS) and lead to CNS metastasis.				

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<b>CR Number:</b> 2024065000		<b>Implementation Date:</b> 08-Mar-24	<b>Related CR:</b> 2024065000		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Demote a PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
PT to merge	<i>Percutaneous coronary intervention</i>	Rejected			
To PT	<i>Coronary angioplasty</i>				
<b>MSSO Comment:</b>	The proposal to demote the PT Percutaneous coronary intervention under PT Coronary angioplasty is not approved. Coronary angioplasty is a specific procedure within the broader category of percutaneous coronary intervention. While angioplasty focuses on widening narrowed arteries using a balloon, percutaneous coronary intervention includes a range of procedures beyond angioplasty, such as stent placement. The broader term should not be subsumed under the narrower description. Considerations are given for impact on legacy data, and in this instance movement of these terms will be impacted.				

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<b>CR Number:</b> 2024065001		<b>Implementation Date:</b> 08-Mar-24	<b>Related CR:</b> 2024065001		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Reassign Primary SOC	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed PT	<i>Prepuce redundant</i>	Rejected			
Old Primary SOC	<i>Reproductive system and breast disorders</i>				
New Primary SOC	<i>Congenital, familial and genetic disorders</i>				
<b>MSSO Comment:</b>	The proposal to reassign the primary SOC of PT Prepuce redundant from current SOC Reproductive system and breast disorders to SOC Congenital, familial and genetic disorders is not approved. Several causes can lead to redundant foreskin, with genetic predisposition being one of these. Other factors include obesity, incomplete or improper circumcision, hormonal changes during puberty, repeated irritation and inflammation.				

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# Detail Report

<b>CR Number:</b> 2024065005		<b>Implementation Date:</b> 08-Mar-24	<b>Related CR:</b> 2024065005	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	Lacrimonal gland biopsy	Approved as Requested	Proposed PT Lacrimonal gland biopsy	10090897
			HLT primary Ophthalmic histopathology and imaging procedures	10030866
			SOC primary Investigations	10022891

**MSSO Comment:** The proposal to add a new term Lacrimonal gland biopsy is approved as requested. In a 2009 study, it was found that all lacrimonal gland lesions, including suspected pleomorphic adenoma of the lacrimonal gland, which is completely excised without prior incisional biopsy due to higher risk for recurrence and malignant transformation after biopsy, must undergo preoperative biopsy. Lacrimonal gland biopsy will be added as new PT under HLT Ophthalmic histopathology and imaging procedures.

<b>CR Number:</b> 2024066001		<b>Implementation Date:</b> 08-Mar-24	<b>Related CR:</b> 2024066001	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Blood in bladder	Rejected		

**MSSO Comment:** The proposal to add a new LLT Blood in bladder is not approved. The proposed term could be misleading, since it can be interpreted as a sign of urinary bladder bleeding (of the wall bladder itself, such as in cystitis, which is represented in PT Urinary bladder haemorrhage) or as the presence of blood in urine, which is represented in MedDRA as a diagnose (PT Haematuria) and as an investigation (PT Blood in urine). Consider any of the LLTs under the above mentioned PTs for a more precise coding. Please, also remember that English is the preferred language for change request submission, as well as it is preferred to include a justification for the need of the proposed term.

<b>CR Number:</b> 2024066003		<b>Implementation Date:</b> 15-Mar-24	<b>Related CR:</b> 2024066003	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Spastic movement disorder	Rejected		
To PT	Movement disorder			

**MSSO Comment:** The proposal to add a new LLT Spastic movement disorder to PT Movement disorder is not approved. Movement disorder is an unspecific term. MedDRA already includes many terms relating to spasticity, from general LLT/PT Spasticity to more precise spastic entities. Spasticity per se is associated with movement disorders to a higher or lesser extent. Adding the proposed term as an LLT under the PT Movement disorder might lead to signal dispersion.

# Detail Report

<b>CR Number:</b> 2024066004		<b>Implementation Date:</b> 08-Mar-24	<b>Related CR:</b> 2024066004		
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed PT	<i>Hodophobia</i>	Approved as Requested	Proposed PT		
HLT primary	<i>Fear symptoms and phobic disorders (incl social phobia)</i>		<i>Hodophobia</i>	10090898	
SOC primary	<i>Psychiatric disorders</i>		HLT primary		
			<i>Fear symptoms and phobic disorders (incl social phobia)</i>	10068299	
			SOC primary		
			<i>Psychiatric disorders</i>	10037175	
<b>MSSO Comment:</b>	The proposal to add a new PT Hodophobia to primary HLT Fear symptoms and phobic disorders (incl social phobia) in SOC Psychiatric disorders is approved as requested. Hodophobia is the extreme, irrational, and persistent fear of traveling.				

<b>CR Number:</b> 2024066005		<b>Implementation Date:</b> 08-Mar-24	<b>Related CR:</b> 2024066005	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Fear of Traveling</i>	Approved Not as Requested	Proposed PT	
To PT	<i>Hodophobia</i>		<i>Fear of travelling</i>	10090899
			HLT primary	
			<i>Fear symptoms and phobic disorders (incl social phobia)</i>	10068299
			SOC primary	
			<i>Psychiatric disorders</i>	10037175
<b>MSSO Comment:</b> The proposal to add a new LLT Fear of Traveling to PT Hodophobia is approved but not as requested. Fear of traveling, is a lesser manifestation of a phobia of the same. Proposed term will be modified for MedDRA capitalization conventions and added as PT Fear of travelling to HLT Fear symptoms and phobic disorders (incl social phobia). In a related change, the American English spelled counterpart Fear of traveling will be added as an LLT to PT Fear of travelling.				

<b>CR Number:</b> 2024068016		<b>Implementation Date:</b> 08-Mar-24	<b>Related CR:</b> 2024066005	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Fear of traveling</i>	Approved as Requested	Proposed LLT	
To PT	<i>Fear of travelling</i>		<i>Fear of traveling</i>	10090900 Current
			To PT	
			<i>Fear of travelling</i>	10090899
<b>MSSO Comment:</b>				



# Detail Report

CR Number: 2024066006		Implementation Date: 15-Mar-24	Related CR: 2024066006	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	Accessory ostium of maxillary sinus	Approved as Requested	Proposed PT	
			Accessory ostium of maxillary sinus	10090901
			HLT primary	
			Nasal disorders congenital	10028739
			SOC primary	
			Congenital, familial and genetic disorders	10010331
			HLT secondary	
			Paranasal sinus disorders (excl infections and neoplasms)	10040743
			SOC secondary	
			Respiratory, thoracic and mediastinal disorders	10038738

**MSSO Comment:** The proposal to add a new term Accessory ostium of maxillary sinus is approved as requested. Accessory maxillary ostium (AMO) is one of the anatomical variations in the maxillary sinus. The presence of an AMO is reportedly more frequent in patients with chronic maxillary sinusitis because it is often associated with an increase of mucus retention cysts and mucosal thickening. Accessory ostium of maxillary sinus will be added as PT with a primary link to HLT Nasal disorders congenital and a secondary link to HLT Paranasal sinus disorders (excl infections and neoplasms).

CR Number: 2024067000		Implementation Date: 15-Mar-24	Related CR: 2024067000	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Durysta- bimatoprost Implant	Rejected		

**MSSO Comment:** The proposal to add a new LLT Durysta- bimatoprost Implant is not approved. The proposed term Durysta- bimatoprost Implant is a trade name for an intraocular sustained-release biodegradable implant that delivers bimatoprost, a prostaglandin analogue, directly into the eye. The MSSO refrains from adding trade names to MedDRA.

# Detail Report

<b>CR Number:</b> 2024067001		<b>Implementation Date:</b> 13-Mar-24	<b>Related CR:</b> 2024067001	
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Intracameral implant	Approved as Requested	Proposed PT Intracameral implant	10090902
			HLT primary Iris and ciliary body therapeutic procedures	10022947
			SOC primary Surgical and medical procedures	10042613

**MSSO Comment:** The proposal to add a new PT Intracameral implant is approved as requested. Intracameral implants are devices or substances that are placed directly into the anterior chamber of the eye. These implants are used for various purposes in ophthalmology, such as delivering medications for the treatment of conditions like glaucoma or infections. Intracameral implant will be added as a PT linked to HLT Iris and ciliary body therapeutic procedures.

<b>CR Number:</b> 2024067002		<b>Implementation Date:</b> 13-Mar-24	<b>Related CR:</b> 2024067002	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Hyperplasia of thymus	Approved as Requested	Proposed LLT Hyperplasia of thymus	10090903 Current
To PT	Thymus enlargement		To PT Thymus enlargement	10065588

**MSSO Comment:** The proposal to add a new LLT Hyperplasia of thymus to PT Thymus enlargement is approved as requested. Thymic hyperplasia consists of an increase, generally diffuse and symmetrical, in the size of the thymus and can occur due to a true proliferation of epithelial cells or due to an increase in the presence of lymphoid follicles in this organ.

<b>CR Number:</b> 2024067003		<b>Implementation Date:</b> 13-Mar-24	<b>Related CR:</b> 2024067003	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Lack of umbilicus	Approved Not as Requested	Proposed LLT Absence of umbilical cord syndrome	10090907 Current
			To PT Body stalk anomaly	10090905

**MSSO Comment:** The proposal to add a new LLT Lack of umbilicus is approved but not as requested. Body stalk anomaly also known as absence of the umbilical cord syndrome is a fatal condition resulting from maldevelopment of embryonic body folding and is associated with multiple congenital defects. Proposed term will be modified to the form most found in literature and added as LLT Absence of umbilical cord syndrome under PT Body stalk anomaly (added in change request 2024067005).

# Detail Report

CR Number: 2024067004		Implementation Date: 15-Mar-24	Related CR: 2024067004	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Absent Navel	Approved Not as Requested	Proposed PT Absent navel	10090906
			HLT primary Abdominal wall conditions NEC	10052777
			SOC primary Gastrointestinal disorders	10017947
			HLT secondary Gastrointestinal and hepatobiliary procedural complications	10017927
			SOC secondary Injury, poisoning and procedural complications	10022117

**MSSO Comment:** The proposal to add a new LLT Absent Navel is approved but not as requested. There are many causes for absence of a navel such as congenital- related to conditions at birth, surgical removal, or injury. Proposed term will be modified for MedDRA capitalization conventions and added as new PT Absent navel under primary HLT Abdominal wall conditions NEC and secondary HLT Gastrointestinal and hepatobiliary procedural complications.

CR Number: 2024067005		Implementation Date: 15-Mar-24	Related CR: 2024067005	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Body stalk anomaly	Approved Not as Requested	Proposed PT Body stalk anomaly	10090905
			HLT primary Gastrointestinal tract disorders congenital NEC	10027679
			SOC primary Congenital, familial and genetic disorders	10010331
			HLT secondary Abdominal wall conditions NEC	10052777
			SOC secondary Gastrointestinal disorders	10017947

**MSSO Comment:** The proposal to add a new LLT Body stalk anomaly is approved but not as requested. Body stalk anomaly is usually characterized by the presence of a major anterior body wall defect, limb deformities, kyphoscoliosis, an absent or short umbilical cord and/or craniofacial defects. Various other fetal abnormalities might be present and maternal serum alpha-fetoprotein (AFP) is commonly increased. Body stalk anomaly will be added as new PT under primary HLT Gastrointestinal tract disorders congenital NEC and secondary HLT Abdominal wall conditions NEC.

# Detail Report

<b>CR Number:</b> 2024067006		<b>Implementation Date:</b> 15-Mar-24	<b>Related CR:</b> 2024067006	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Male genital tract ultrasound	Approved Not as Requested	Proposed PT Male genital tract ultrasound	10090904
			HLT primary Reproductive organ and breast imaging procedures	10038602
			SOC primary Investigations	10022891

**MSSO Comment:** The proposal to add a new LLT Male genital tract ultrasound is approved but not as requested. Male genital tract ultrasound is a useful tool in detecting abnormalities related to impaired male reproductive health. Testicular volume (TV) is tightly associated with both sperm and hormonal parameters. Ultrasound offers a greater accuracy in TV measurement than Prader orchidometer. Male genital tract ultrasound will be added as a new PT under HLT Reproductive organ and breast imaging procedures.

<b>CR Number:</b> 2024067007		<b>Implementation Date:</b> 15-Mar-24	<b>Related CR:</b> 2024067007	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Tripped	Rejected		

**MSSO Comment:** The proposal to add a new LLT Tripped is not approved. For purposes of MedDRA the causality of an event is not captured, rather the event itself is coded. In this instance, the "fall" is the event and the reasons for or cause-effect relationship terms cannot be added.

<b>CR Number:</b> 2024067008		<b>Implementation Date:</b> 15-Mar-24	<b>Related CR:</b> 2024067008	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	MSCT scan	Approved Not as Requested	Proposed LLT MSCT coronary angiography	10090908 Current
			To PT Computerised tomogram heart	10088901

**MSSO Comment:** The proposal to add a new LLT MSCT scan is approved but not as requested. Multislice spiral computed tomography (MSCT) coronary angiography is a promising non-invasive technique for the detection of coronary stenoses and allows more reliable detection of coronary plaques and significant obstructive coronary lesions. Proposed term will be modified for specificity for coronary application as in justification and added as sub-concept LLT MSCT coronary angiography under PT Computerised tomogram heart. In a related change, the spelled out counterpart LLT Multislice spiral computed tomography coronary angiography will also be added under PT Computerised tomogram heart.

# Detail Report

<b>CR Number:</b> 2024075001		<b>Implementation Date:</b> 15-Mar-24	<b>Related CR:</b> 2024067008	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Multislice spiral computed tomography coronary angiography	Approved as Requested	Proposed LLT	
To PT	Computerised tomogram heart		Multislice spiral computed tomography coronary angiography	10090909 Current
			To PT	
			Computerised tomogram heart	10088901

MSSO  
Comment:

<b>CR Number:</b> 2024067009		<b>Implementation Date:</b> 13-Mar-24	<b>Related CR:</b> 2024067009	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Mallet toe	Approved as Requested	Proposed LLT	
To PT	Foot deformity		Mallet toe	10090910 Current
			To PT	
			Foot deformity	10061159

MSSO  
Comment: The proposal to add a new LLT Mallet toe to PT Foot deformity is approved as requested. A mallet toe bends downwards at the joint closest to the tip of the toe. It can be flexible or rigid, depending on the remaining mobility. It is most common in the second toe, as this is often the longest of the four smaller toes, but it can occur in the third and fourth toes.

<b>CR Number:</b> 2024067010		<b>Implementation Date:</b> 15-Mar-24	<b>Related CR:</b> 2024067010	
<a href="#">Change Requested</a>	Demote a PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
PT to merge	Mallet finger	Rejected		
To PT	Hand deformity			

MSSO  
Comment: The proposal to demote the PT Mallet finger under PT Hand deformity is not approved. A mallet finger is a deformity of the finger typically caused by injury. Mallet finger, also known as baseball finger or dropped finger, is a condition that occurs when the extensor tendon on the back of the finger is damaged, leading to an inability to fully extend the fingertip. Risk factors for developing mallet finger include participating in sports like basketball, volleyball, or baseball, where there is a high risk of finger injuries.

# Detail Report

CR Number: 2024067011		Implementation Date: 15-Mar-24	Related CR: 2024067011	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Reticulocyte analysis abnormal</i>	Rejected		

MSSO Comment: The proposal to add a new LLT Reticulocyte analysis abnormal is not approved. If the results mentioned in the justification are a group of specific results (count, percentage, hemoglobin concentration of reticulocytes), please take into account the point "3.14.4 Grouped investigation result terms" of the MedDRA Term Selection Points to Consider document, and select a term for each investigation result as reported.

CR Number: 2024068000		Implementation Date: 15-Mar-24	Related CR: 2024068000	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Hereditary breast and ovarian cancer syndrome</i>	Approved as Requested	Proposed PT <i>Hereditary breast and ovarian cancer syndrome</i>	10090911
			HLT primary <i>Breast disorders congenital</i>	10006233
			SOC primary <i>Congenital, familial and genetic disorders</i>	10010331
			HLT secondary <i>Breast neoplasms unspecified malignancy</i>	10006292
			SOC secondary <i>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</i>	10029104

MSSO Comment: The proposal to add a new term Hereditary breast and ovarian cancer syndrome is approved as requested. Hereditary breast and ovarian cancer (HBOC) syndrome is an inherited cancer-predisposition syndrome. Affected individuals have a significantly greater risk of developing certain cancers, particularly breast cancer, in both men and women, and ovarian cancer in women. In HBOC syndrome, there is usually a family history of cancer and the variant gene is inherited. Even if the proposed concept still represents a risk factor and not a declared malignancy, its highly malignant potential for breast and ovarian cancer favors mapping the term as a potential malignancy. Therefore, Hereditary breast and ovarian cancer syndrome will be added as PT with a primary link to HLT Breast disorders congenital, to secondary HLT Breast neoplasms unspecified malignancy and to secondary HLT Ovarian and fallopian tube cysts and neoplasms.

# Detail Report

<b>CR Number:</b> 2024075002		<b>Implementation Date:</b> 15-Mar-24	<b>Related CR:</b> 2024068000	
<a href="#">Change Requested</a>	Link a PT to a HLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Hereditary breast and ovarian cancer syndrome</i>	Approved as Requested	Proposed PT	
To HLT	<i>Ovarian and fallopian tube cysts and neoplasms</i>		<i>Hereditary breast and ovarian cancer syndrome</i>	10090911
			To HLT	
			<i>Ovarian and fallopian tube cysts and neoplasms</i>	10033121

MSSO  
Comment:

<b>CR Number:</b> 2024068001		<b>Implementation Date:</b> 15-Mar-24	<b>Related CR:</b> 2024068001	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Beer potomania</i>	Approved as Requested	Proposed LLT	
			<i>Beer potomania</i>	10090913 Current
			To PT	
			<i>Hyponatraemia</i>	10021036

MSSO  
Comment: The proposal to add a new term Beer potomania is approved as requested. Beer potomania is a unique syndrome of hyponatremia which is described as the excessive intake of alcohol, particularly beer, together with poor dietary solute intake. The presence of inadequate solute in the kidney eventually causes dilutional hyponatremia secondary to reduced clearance of excess fluid from the body. Beer potomania will be added as a sub-concept LLT to PT Hyponatraemia.

<b>CR Number:</b> 2024068002		<b>Implementation Date:</b> 15-Mar-24	<b>Related CR:</b> 2024068002	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Intracranial calcification</i>	Approved as Requested	Proposed PT	
			<i>Intracranial calcification</i>	10090912
			HLT primary	
			<i>Structural brain disorders NEC</i>	10042259
			SOC primary	
			<i>Nervous system disorders</i>	10029205

MSSO  
Comment: The proposal to add a new term Intracranial calcification is approved as requested. Many conditions can present with accumulation of calcium in the brain and manifest with a variety of neurological symptoms. Brain calcifications can be secondary to various pathological conditions (e.g., calcium-phosphate metabolism derangement, autoimmune disorders and infections, among others). Intracranial calcification will be added as PT to the HLT Structural brain disorders NEC. In a related change, PT Cerebellar calcification and PT Cerebral calcification will be demoted to the new PT Intracranial calcification.

# Detail Report

<b>CR Number:</b> 2024075004		<b>Implementation Date:</b> 15-Mar-24	<b>Related CR:</b> 2024068002	
<a href="#">Change Requested</a>	Demote a PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
PT to merge	<i>Cerebral calcification</i>	Approved as Requested	PT to merge	
To PT	<i>Intracranial calcification</i>		<i>Cerebral calcification</i>	10066296 Current
			To PT	
			<i>Intracranial calcification</i>	10090912

MSSO  
Comment:

<b>CR Number:</b> 2024075003		<b>Implementation Date:</b> 15-Mar-24	<b>Related CR:</b> 2024068002	
<a href="#">Change Requested</a>	Demote a PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
PT to merge	<i>Cerebellar calcification</i>	Approved as Requested	PT to merge	
To PT	<i>Intracranial calcification</i>		<i>Cerebellar calcification</i>	10081238 Current
			To PT	
			<i>Intracranial calcification</i>	10090912

MSSO  
Comment:

<b>CR Number:</b> 2024071000		<b>Implementation Date:</b> 15-Mar-24	<b>Related CR:</b> 2024071000	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Lingual frenotomy</i>	Approved as Requested	Proposed LLT	
			<i>Lingual frenotomy</i>	10090914 Current
			To PT	
			<i>Tongue tie operation</i>	10043988

MSSO  
Comment: The proposal to add a new LLT Lingual frenotomy is approved as requested. A lingual frenotomy is a surgical procedure aimed at correcting a condition called ankyloglossia, commonly known as tongue-tie. In this procedure, a small incision or release is made to the lingual frenulum, which is the band of tissue connecting the bottom of the tongue to the floor of the mouth. Lingual frenotomy will be added as a synonym LLT to PT Tongue tie operation.



# Detail Report

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<b>CR Number:</b> 2024071001		<b>Implementation Date:</b> 18-Mar-24	<b>Related CR:</b> 2024071001	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Inflammatory fibroid polyp gastrointestinal</i>	Approved Not as Requested	Proposed LLT <i>Gastrointestinal inflammatory fibroid polyp</i>	10090925 Current
			To PT <i>Gastrointestinal polyp</i>	10079055
<b>MSSO Comment:</b> The proposal to add a new LLT Inflammatory fibroid polyp gastrointestinal is approved but not as requested. Inflammatory fibroid polyps are rare, benign tumors that can arise throughout the gastrointestinal tract. Although the molecular pathogenesis of these lesions has been well characterized, their morphologic features often vary. The proposed term will be modified to follow the natural word order and added as the LLT Gastrointestinal inflammatory fibroid polyp to the PT Gastrointestinal polyp.				

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<b>CR Number:</b> 2024071002		<b>Implementation Date:</b> 18-Mar-24	<b>Related CR:</b> 2024071002	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Post procedure syncope</i>	Rejected		
<b>MSSO Comment:</b> The proposal to add a new LLT Post procedure syncope is not approved. To avoid the overpopulation of MedDRA, the MSSO refrains from adding new "post procedural" terms, which combine a medical concept with additional medical wording related to etiology and/or pathophysiology. Section 3.5 of the MedDRA Term Selection Points to Consider (MTS:PTC) document defines these as "combination terms".				

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<b>CR Number:</b> 2024072000		<b>Implementation Date:</b> 15-Mar-24	<b>Related CR:</b> 2024072000	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Scrotal itching</i>	Approved as Requested	Proposed LLT <i>Scrotal itching</i>	10090915 Current
			To PT <i>Pruritus genital</i>	10037093
<b>MSSO Comment:</b> The proposal to add a new term Scrotal itching is approved as requested. Scrotal pruritus, also known as itching of the scrotum, is characterized by persistent itching and discomfort in the skin of the scrotum. Scrotal itching will be added as sub-concept LLT to PT Pruritus genital.				

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# Detail Report

CR Number: 2024072001		Implementation Date: 18-Mar-24	Related CR: 2024072001		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Rename PT/LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Term to modify	Epidermoid cyst	Rejected			
Replacement term	Congenital epidermoid cyst				

MSSO Comment: The proposal to rename PT/LLT Epidermoid cyst to Congenital epidermoid cyst is not approved. The proposed term is the congenital form of epidermoid cyst as it is under PT Dermoid cyst. The acquired form of the concept will be addressed in change request 2024060001.

CR Number: 2024072002		Implementation Date: 18-Mar-24	Related CR: 2024072002		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed LLT	Adrenal antibody	Approved Not as Requested	Proposed PT		
			Adrenal antibody test		10090926
			HLT primary		
			Autoimmunity analyses		10003828
			SOC primary		
			Investigations		10022891

MSSO Comment: The proposal to add a new LLT Adrenal antibody is approved but not as requested. Adrenal antibodies are serum antibodies to adrenal cortical cells, usually of all three zones, and are seen in 60% of patients with idiopathic Addison disease. Proposed term will be modified for clarity and added as PT Adrenal antibody test under HLT Autoimmunity analyses.

CR Number: 2024072003		Implementation Date: 18-Mar-24	Related CR: 2024072003		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed LLT	Adrenal antibody positive	Approved Not as Requested	Proposed PT		
			Adrenal antibody test positive		10090927
			HLT primary		
			Autoimmunity analyses		10003828
			SOC primary		
			Investigations		10022891

MSSO Comment: The proposal to add a new LLT Adrenal antibody positive is approved but not as requested. Adrenal antibodies are serum antibodies to adrenal cortical cells, usually of all three zones, and are seen in 60% of patients with idiopathic Addison disease. Proposed term will be modified for clarity and added as PT Adrenal antibody test positive under HLT Autoimmunity analyses.

# Detail Report

<b>CR Number:</b> 2024072004		<b>Implementation Date:</b> 18-Mar-24	<b>Related CR:</b> 2024072004	
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Adrenal antibody negative	Approved Not as Requested	Proposed PT Adrenal antibody test negative	10090928
			HLT primary Autoimmunity analyses	10003828
			SOC primary Investigations	10022891

**MSSO Comment:** The proposal to add a new LLT Adrenal antibody negative is approved but not as requested. Adrenal antibodies are serum antibodies to adrenal cortical cells, usually of all three zones, and are seen in 60% of patients with idiopathic Addison disease. Proposed term will be modified for clarity and added as PT Adrenal antibody test negative under HLT Autoimmunity analyses.

<b>CR Number:</b> 2024072005		<b>Implementation Date:</b> 15-Mar-24	<b>Related CR:</b> 2024072005	
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Hep-2 antinuclear antibody positive	Approved Not as Requested	Proposed LLT HEp-2 antinuclear antibody positive	10090918 Current
			To PT Antinuclear antibody positive	10060055

**MSSO Comment:** The proposal to add a new LLT Hep-2 antinuclear antibody positive is approved but not as requested. The proposed term will be modified for capitalization and added as LLT HEp-2 antinuclear antibody positive to PT Antinuclear antibody positive as a qualified counterpart of the LLT HEP-2 antinuclear antibody added in change request 2024072007.

<b>CR Number:</b> 2024072006		<b>Implementation Date:</b> 15-Mar-24	<b>Related CR:</b> 2024072006	
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Hep-2 antinuclear antibody negative	Approved Not as Requested	Proposed LLT HEp-2 antinuclear antibody negative	10090916 Current
			To PT Antinuclear antibody negative	10002809

**MSSO Comment:** The proposal to add a new LLT Hep-2 antinuclear antibody negative is approved but not as requested. The proposed term will be modified for capitalization and added as LLT HEp-2 antinuclear antibody negative to PT Antinuclear antibody negative as a qualified counterpart of the LLT HEP-2 antinuclear antibody added in change request 2024072007.

# Detail Report

<b>CR Number:</b> 2024072007		<b>Implementation Date:</b> 15-Mar-24	<b>Related CR:</b> 2024072007	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Hep-2 antinuclear antibody</i>	Approved Not as Requested	Proposed LLT <i>HEp-2 antinuclear antibody</i>	10090917 Current
			To PT <i>Antinuclear antibody</i>	10002807
<b>MSSO Comment:</b> The proposal to add a new LLT Hep-2 antinuclear antibody is approved but not as requested. HEp-2 cells are a particular type of immortalized neoplastic culture cells that are used as a substrate in the diagnosis of antinuclear antibodies. The name is an acronym coined by the original research group comes from Human Epidermoid carcinoma strain #2. HEp-2 cells are currently one of the most common substrates for ANA detection by immunofluorescence. The proposed term will be modified for capitalization and added as LLT HEp-2 antinuclear antibody to PT Antinuclear antibody to represent a technical methodology in the elicitation of antinuclear antibodies.				

<b>CR Number:</b> 2024072008		<b>Implementation Date:</b> 15-Mar-24	<b>Related CR:</b> 2024072008	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Cerebral stroke</i>	Approved as Requested	Proposed LLT <i>Cerebral stroke</i>	10090922 Current
			To PT <i>Cerebrovascular accident</i>	10008190
<b>MSSO Comment:</b> The proposal to add a new LLT Cerebral stroke is approved as requested. A cerebral stroke, commonly referred to as a stroke, occurs when the blood supply to part of the brain is interrupted or reduced, depriving brain tissue of oxygen and nutrients. Cerebral stroke will be added as a synonym LLT to PT Cerebrovascular accident.				

<b>CR Number:</b> 2024072009		<b>Implementation Date:</b> 15-Mar-24	<b>Related CR:</b> 2024072009	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Spinal intradural haematoma</i>	Approved as Requested	Proposed LLT <i>Spinal intradural haematoma</i>	10090920 Current
			To PT <i>Spinal subdural haematoma</i>	10050164
<b>MSSO Comment:</b> The proposal to add a new LLT Spinal intradural haematoma is approved as requested. Spinal intradural haematoma is a bleeding into the space between dura mater and arachnoid mater in the spine. The bleeding is contained within the dural sac and can compress the spinal cord or nerve roots within this space. In some publications it is used synonymously with spinal subdural haematoma. LLT Spinal intradural haematoma with its American English counterpart LLT Spinal intradural hematoma will both be added to PT Spinal subdural haematoma.				

# Detail Report

CR Number: 2024075005		Implementation Date: 15-Mar-24	Related CR: 2024072009	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Spinal intradural hematoma	Approved as Requested	Proposed LLT	10090923 Current
To PT	Spinal subdural haematoma		Spinal intradural hematoma	
			To PT	
			Spinal subdural haematoma	10050164

MSSO  
Comment:

CR Number: 2024072010		Implementation Date: 15-Mar-24	Related CR: 2024072010	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Pentastomiasis	Approved Not as Requested	Proposed PT	10090919
			Pentastomiasis	
			HLT primary	10028914
			Nematode infections	
			SOC primary	10021881
			Infections and infestations	
			HLT secondary	10057190
			Respiratory tract infections NEC	
			SOC secondary	10038738
			Respiratory, thoracic and mediastinal disorders	

MSSO  
Comment: The proposal to add a new LLT Pentastomiasis is approved but not as requested. Pentastomiasis, also known as linguatuliasis, is a parasitic infection caused by organisms known as pentastomes. Although a pentastome is not a worm, it is a crustacean adopting the shape of a worm in its adaptation process to parasitism and therefore will be added as a PT Pentastomiasis to primary HLT Nematode infections and to secondary HLT Respiratory tract infections NEC.

# Detail Report

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<b>CR Number:</b> 2024072011		<b>Implementation Date:</b> 15-Mar-24	<b>Related CR:</b> 2024072011		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed LLT	Winter vomiting bug	Rejected			

**MSSO Comment:** The proposal to add a new LLT Winter vomiting bug is not approved. "Winter vomiting bug" is a colloquial term often used to refer to norovirus, which is a highly contagious virus that causes gastroenteritis. As this is not a clearly defined medical diagnosis, as well as the translation difficulties it may pose, MSSO refrains from adding this colloquial term. Please consider existing MedDRA terms in line with your company-specific coding conventions.

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<b>CR Number:</b> 2024072012		<b>Implementation Date:</b> 15-Mar-24	<b>Related CR:</b> 2024072012		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed LLT	Drug-induced Hemophagocytic lymphohistiocytosis	Rejected			

**MSSO Comment:** The proposal to add a new LLT Drug-induced Hemophagocytic lymphohistiocytosis is not approved. Hemophagocytic lymphohistiocytosis is an aggressive and life-threatening syndrome of excessive immune activation. It most frequently affects infants from birth to 18 months of age, but the disease is also observed in children and adults of all ages. Hemophagocytic lymphohistiocytosis can occur as a familial or sporadic disorder, and it can be triggered by a variety of events that disrupt immune homeostasis. Infection is a common trigger both in those with a genetic predisposition and in sporadic cases. The MSSO considers the proposed term Drug-induced Hemophagocytic lymphohistiocytosis to be of a "due to" nature. Terms that state or imply a "due to" concept are generally not added to MedDRA because causality is not inherent in the coded term, but is instead determined by the reporter/investigator or by the sponsor.

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<b>CR Number:</b> 2024072013		<b>Implementation Date:</b> 15-Mar-24	<b>Related CR:</b> 2024072013		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed LLT	Anaphylaxis to sea food	Rejected			

**MSSO Comment:** The proposal to add a new LLT Anaphylaxis to sea food is not approved. Anaphylaxis to seafood refers to a severe and potentially life-threatening allergic reaction that occurs after consuming seafood or being exposed to substances derived from seafood. Seafood, including fish and shellfish such as shrimp, crab, lobster, and mollusks, contains proteins that can trigger an allergic response in sensitive individuals. The MSSO refrains from adding the requested term to avoid the overpopulation of MedDRA. There are existing terms for specific food allergies and anaphylactic shock due to food (including fish and crustaceans). Please also consider that based on the MedDRA term selection points to consider document, coding to more than one term or coding to a less specific term is possible and can be considered depending on your company specific coding guidelines.

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# Detail Report

<b>CR Number:</b> 2024072014		<b>Implementation Date:</b> 15-Mar-24	<b>Related CR:</b> 2024072014	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Bradykinin-mediated angioedema</i>	Approved as Requested	Proposed LLT <i>Bradykinin-mediated angioedema</i>	10090921 Current
			To PT <i>Angioedema</i>	10002424
<b>MSSO Comment:</b> The proposal to add a new LLT Bradykinin-mediated angioedema is approved as requested. Angioedema can occur due to vasodilation and increased vascular permeability resulting from the inflammatory mediator bradykinin, either due to overproduction of bradykinin or inhibition of bradykinin degradation. Mast cells are not believed to be involved in this form of angioedema, and pruritus and urticaria are absent. Bradykinin-mediated angioedema, unlike histamine-mediated angioedema, frequently affects the gastrointestinal mucosa, leading to bowel wall edema and presenting with episodes of abdominal pain, nausea, vomiting, and/or diarrhea. Bradykinin-mediated angioedema will be added as LLT to PT Angioedema.				

<b>CR Number:</b> 2024072015		<b>Implementation Date:</b> 21-Mar-24	<b>Related CR:</b> 2024072015	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Restricted prosthetic valve leaflet motion</i>	Approved as Requested	Proposed LLT <i>Restricted prosthetic valve leaflet motion</i>	10090934 Current
To PT	<i>Prosthetic cardiac valve malfunction</i>		To PT <i>Prosthetic cardiac valve malfunction</i>	10073511
<b>MSSO Comment:</b> The proposal to add a new LLT Restricted prosthetic valve leaflet motion to PT Prosthetic cardiac valve malfunction is approved as requested. Reduced leaflet motion refers to an abnormally decreased mobility of one or more valvular leaflets after transcatheter implantation of prosthetic heart valves and has gained clinical significance for the diagnosis of subclinical leaflet thrombosis.				

<b>CR Number:</b> 2024072016		<b>Implementation Date:</b> 18-Mar-24	<b>Related CR:</b> 2024072016	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Ventricular pseudoaneurysm</i>	Approved as Requested	Proposed LLT <i>Ventricular pseudoaneurysm</i>	10090935 Current
			To PT <i>Cardiac pseudoaneurysm</i>	10048974
<b>MSSO Comment:</b> The proposal to add a new term Ventricular pseudoaneurysm is approved as requested. A pseudoaneurysm refers to a contained rupture of the myocardium with a tenuous pericardium walling off the leak. It needs to be differentiated from a true aneurysm by the fact that there is lack of myocardial tissue in the wall of a pseudoaneurysm. The differentiation between the two is pertinent as true aneurysms can be treated medically while pseudoaneurysms require urgent surgical treatment. Untreated pseudoaneurysms carry a high risk of rupture and mortality. Ventricular pseudoaneurysm will be added as a quasi synonym LLT of PT Cardiac pseudoaneurysm.				

# Detail Report

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<b>CR Number:</b> 2024072017		<b>Implementation Date:</b> 21-Mar-24	<b>Related CR:</b> 2024072017	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Immune-related hypopituitarism</i>	Approved Not as Requested	Proposed LLT <i>Immune-mediated hypopituitarism</i>	10090937 Current
			To PT <i>Immune-mediated hypophysitis</i>	10085025
MSSO Comment:	The proposal to add a new term Immune-related hypopituitarism is approved but not as requested. In the last decade, hypophysitis has emerged as a frequent complication of anticancer immunotherapy, immune-related hypopituitarism being subsequent to it. Immune-mediated hypopituitarism is usually defined as the result of deficiency in at least two anterior pituitary hormones. The proposed term will be modified for consistent naming to Immune-mediated hypopituitarism and will be added as an LLT to PT Immune-mediated hypophysitis.			

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<b>CR Number:</b> 2024072018		<b>Implementation Date:</b> 21-Mar-24	<b>Related CR:</b> 2024072018	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Radiation laryngitis</i>	Approved as Requested	Proposed LLT <i>Radiation laryngitis</i>	10090936 Current
			To PT <i>Radiation larynx injury</i>	10068571
MSSO Comment:	The proposal to add a new term Radiation laryngitis is approved as requested. Radiation induced laryngitis can develop after radiation for primary laryngeal cancer or when the larynx is in the radiation field for a non-laryngeal malignancy. The effects are dose dependent and lead to variable degrees of dysphonia in both short- and long-term follow-up. Radiation laryngitis will be added as LLT to the PT Radiation larynx injury.			

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<b>CR Number:</b> 2024073000		<b>Implementation Date:</b> 21-Mar-24	<b>Related CR:</b> 2024073000	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Hemorrhagic vitreous detachment</i>	Rejected		
MSSO Comment:	The proposal to add a new term Hemorrhagic vitreous detachment is not approved. The most common cause of a vitreous hemorrhage is posterior vitreous detachment. The proposed term combines a medical concept with additional medical wording related to etiology and/or pathophysiology. Section 3.5 of the MedDRA Term Selection Points to Consider (MTS:PTC) document defines these as "combination terms". When considering the addition of such combination terms, MedDRA generally attempts to limit inclusion to those terms which describe important, distinct and robust medical concepts which are internationally recognized diagnostic entities. Examples include terms such as diabetic retinopathy, hypertensive cardiomegaly and eosinophilic pneumonia. Please refer to Section 3.5 of the MedDRA Term Selection: Points to Consider Document regarding coding approaches/considerations.			

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# Detail Report

<b>CR Number:</b> 2024073001		<b>Implementation Date:</b> 18-Mar-24	<b>Related CR:</b> 2024073001	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Salivary stasis	Approved Not as Requested	Proposed PT	
			Salivary stasis	10090924
			HLT primary	
			Oral dryness and saliva altered	10030975
			SOC primary	
			Gastrointestinal disorders	10017947

**MSSO Comment:** The proposal to add a new LLT Salivary stasis is approved but not as requested. Salivary stasis is one of the main precipitating factors of acute suppurative sialadenitis. Salivary stasis can be caused by medications or sialolithiasis. It is associated with dehydration and common medications, including tricyclic antidepressants, antipsychotics, benzodiazepines, anticholinergics,  $\beta$ -blockers, and antihistamines. Salivary stasis will be added as PT to HLT Oral dryness and saliva altered.

<b>CR Number:</b> 2024073002		<b>Implementation Date:</b> 18-Mar-24	<b>Related CR:</b> 2024073002	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	Convulsive crisis	Rejected		

**MSSO Comment:** The proposal to add a new term Convulsive crisis is not approved. The proposed term is not well translated and conveys different degrees of seizure in different languages.

<b>CR Number:</b> 2024073003		<b>Implementation Date:</b> 18-Mar-24	<b>Related CR:</b> 2024073003	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Prothrombotic state	Rejected		

**MSSO Comment:** The proposal to add a new LLT Prothrombotic state is not approved. Existing PTs may represent the concept depending on case scenario, since prothrombotic state is a very broad concept used to describe any condition or situation in which the blood is more prone to clotting. This can encompass thrombophilia but also includes other factors such as inflammation, certain medical conditions (like cancer or autoimmune diseases), certain medications, immobility, surgery, pregnancy, and advanced age, among others.

# Detail Report

<b>CR Number:</b> 2024074001		<b>Implementation Date:</b> 25-Mar-24	<b>Related CR:</b> 2024074001	
<u>Change Requested</u>	Add a New Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	<i>Prurigo pigmentosa</i>	Approved as Requested	Proposed PT <i>Prurigo pigmentosa</i>	10090947
			HLT primary <i>Dermal and epidermal conditions NEC</i>	10012424
			SOC primary <i>Skin and subcutaneous tissue disorders</i>	10040785
			HLT secondary <i>General nutritional disorders NEC</i>	10018067
			SOC secondary <i>Metabolism and nutrition disorders</i>	10027433

**MSSO Comment:** The proposal to add a new term Prurigo pigmentosa is approved as requested. Prurigo pigmentosa is a rare inflammatory skin condition associated with ketosis. It is characterised by a recurrent itchy rash with netlike hyperpigmentation. Prurigo pigmentosa will be added as a new PT under primary HLT Dermal and epidermal conditions NEC and secondary HLT General nutritional disorders NEC.

<b>CR Number:</b> 2024074002		<b>Implementation Date:</b> 25-Mar-24	<b>Related CR:</b> 2024074002	
<u>Change Requested</u>	Add a New PT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Infected bartholin's cyst</i>	Approved Not as Requested	Proposed LLT <i>Infected Bartholin's cyst</i>	10090948 Current
HLT primary	<i>Female reproductive tract infections</i>		To PT <i>Bartholinitis</i>	10004142
SOC primary	<i>Infections and infestations</i>			

**MSSO Comment:** The proposal to add a new PT Infected bartholin's cyst to primary HLT Female reproductive tract infections in SOC Infections and infestations and secondary HLT Vulvovaginal cysts and neoplasms in SOC Reproductive system and breast disorders is approved but not as requested. When a Bartholin's cyst gets infected, it can become tender, swollen, and red. The proposed term will be modified for MedDRA capitalization standards to Infected Bartholin's cyst and will be added as an LLT to PT Bartholinitis.

# Detail Report

<b>CR Number:</b> 2024074003		<b>Implementation Date:</b> 21-Mar-24	<b>Related CR:</b> 2024074003	
<u>Change Requested</u>	Add a New PT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Coronary slow flow phenomenon	Approved Not as Requested	Proposed PT	
HLT primary	Coronary necrosis and vascular insufficiency		Coronary slow flow phenomenon	10090933
SOC primary	Vascular disorders		HLT primary	
			Ischaemic coronary artery disorders	10011085
			SOC primary	
			Cardiac disorders	10007541
			HLT secondary	
			Cardiac and vascular procedural complications	10007602
			SOC secondary	
			Injury, poisoning and procedural complications	10022117

**MSSO Comment:** The proposal to add a new PT Coronary slow flow phenomenon to primary HLT Coronary necrosis and vascular insufficiency in SOC Vascular disorders is approved but not as requested. Coronary slow flow phenomenon is the failure of blood to reperfuse a myocardial ischemic area after a physical obstruction has been removed or bypassed. The underlying mechanism is related to arterial microvasculature damage, which causes a reduced antegrade coronary blood flow despite proximal coronary artery patency. It is primarily seen during percutaneous coronary intervention in the setting of acute myocardial infarction. Coronary slow flow phenomenon will be added as a PT with a primary link to HLT Ischaemic coronary artery disorders and secondary HLT Cardiac and vascular procedural complications, secondary HLT Coronary necrosis and vascular insufficiency. In a related change, PT Coronary no-reflow phenomenon will also be linked to secondary HLT Cardiac and vascular procedural complications.

<b>CR Number:</b> 2024081001		<b>Implementation Date:</b> 21-Mar-24	<b>Related CR:</b> 2024074003	
<u>Change Requested</u>	Link a PT to a HLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Coronary slow flow phenomenon	Approved as Requested	Proposed PT	
To HLT	Coronary necrosis and vascular insufficiency		Coronary slow flow phenomenon	10090933
			To HLT	
			Coronary necrosis and vascular insufficiency	10065875

**MSSO Comment:**

# Detail Report

CR Number: 2024081002		Implementation Date: 21-Mar-24	Related CR: 2024074003	
<u>Change Requested</u>	Link a PT to a HLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Coronary no-reflow phenomenon	Approved as Requested	Proposed PT	
To HLT	Cardiac and vascular procedural complications		Coronary no-reflow phenomenon	10068534
			To HLT	
			Cardiac and vascular procedural complications	10007602

MSSO  
Comment:

CR Number: 2024074004		Implementation Date: 21-Mar-24	Related CR: 2024074004	
<u>Change Requested</u>	Add a New Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	Acute spontaneous subdural hematoma	Approved as Requested	Proposed LLT	
			Acute spontaneous subdural hematoma	10090941 Current
			To PT	
			Spontaneous subdural haematoma	10090938

MSSO  
Comment: The proposal to add a new term Acute spontaneous subdural hematoma is approved as requested. Although head trauma is the most common cause of subdural hematoma, subdural hematoma may be spontaneous or triggered by an inciting event. Risk factors for the development of spontaneous subdural hematoma include hypertension, vascular abnormalities and deficit of coagulation. Acute spontaneous subdural hematoma will be added as an LLT to a new PT Spontaneous subdural haematoma. In a related change, the American English spelled counterpart Spontaneous subdural hematoma and the British English spelled counterpart Acute spontaneous subdural haematoma will also be added as LLTs to the new PT Spontaneous subdural haematoma. In a further related change, new PT Spontaneous subdural haematoma will added be linked to primary HLT Central nervous system haemorrhages and cerebrovascular accidents and secondary HLT Nervous system haemorrhagic disorders.

# Detail Report

CR Number: 2024081005		Implementation Date: 21-Mar-24	Related CR: 2024074004	
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Spontaneous subdural haematoma</i>	Approved as Requested	Proposed PT	
HLT primary	<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		<i>Spontaneous subdural haematoma</i>	10090938
SOC primary	<i>Nervous system disorders</i>		HLT primary	
			<i>Central nervous system haemorrhages and cerebrovascular accidents</i>	10007948
			SOC primary	
			<i>Nervous system disorders</i>	10029205
			HLT secondary	
			<i>Nervous system haemorrhagic disorders</i>	10008206
		SOC secondary		
		<i>Vascular disorders</i>	10047065	

MSSO  
Comment:

CR Number: 2024081003		Implementation Date: 21-Mar-24	Related CR: 2024074004	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Spontaneous subdural hematoma	Approved as Requested	Proposed LLT	
To PT	Spontaneous subdural haematoma		Spontaneous subdural hematoma	10090940 Current
			To PT	
			Spontaneous subdural haematoma	10090938

MSSO  
Comment:

# Detail Report

CR Number: 2024081004		Implementation Date: 21-Mar-24	Related CR: 2024074004	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Acute spontaneous subdural haematoma	Approved as Requested	Proposed LLT	
To PT	Spontaneous subdural haematoma		Acute spontaneous subdural haematoma	10090939 Current
			To PT	
			Spontaneous subdural haematoma	10090938

MSSO  
Comment:

CR Number: 2024074005		Implementation Date: 21-Mar-24	Related CR: 2024074005	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	Cannabis-Drug Interaction	Approved Not as Requested	Proposed PT	
			Cannabis interaction	10090931
			HLT primary	
			Interactions	10022528
			SOC primary	
			General disorders and administration site conditions	10018065

MSSO  
Comment: The proposal to add a new term Cannabis-Drug Interaction is approved but not as requested. The interactions between cannabis and other drugs can vary depending on several factors, including the specific drugs involved, the individual's physiology, dosage, mode of administration, and frequency of use. The proposed term will be modified to be consistent with other interactions and added as PT Cannabis interaction to HLT Interactions.

CR Number: 2024074006		Implementation Date: 21-Mar-24	Related CR: 2024074006	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Anticholinergic effects	Approved Not as Requested	Proposed PT	
			Anticholinergic effect	10090930
			HLT primary	
			Autonomic nervous system disorders	10003839
			SOC primary	
			Nervous system disorders	10029205

MSSO  
Comment: The proposal to add a new LLT Anticholinergic effects is approved but not as requested. Anticholinergic effects refer to a group of physiological and neurological effects caused by drugs that block the action of acetylcholine, a neurotransmitter in the nervous system. Acetylcholine plays a crucial role in regulating various bodily functions, including muscle contraction, heart rate, glandular secretion, and cognition. The proposed term will be modified to its singular form and added as PT Anticholinergic effect to HLT Autonomic nervous system disorders.

# Detail Report

CR Number: 2024074007		Implementation Date: 21-Mar-24	Related CR: 2024074007		
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed PT	Cholesterol lowering therapy	Rejected			

MSSO Comment: The proposal to add a new PT Cholesterol lowering therapy is not approved. Cholesterol-lowering therapy refers to the use of medications or lifestyle changes to reduce levels of cholesterol in the blood. In general, the MSSO refrains from adding new terms related to specific drug therapies. Section 3.26 of the MedDRA Term Selection: Points to Consider Document provides guidance on different scenarios for coding indications.

CR Number: 2024074008		Implementation Date: 21-Mar-24	Related CR: 2024074008		
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed Term	Untreated infection	Rejected			

MSSO Comment: The proposal to add a new term Untreated infection is not approved. An untreated infection refers to an infectious condition in the body that has not been managed with appropriate medical treatment. When an infection is left untreated, it can potentially worsen and lead to complications. "Untreated" is a qualifier that usually is not included with specific terms because the combination of terms with all possible qualifiers would lead to an overpopulation of MedDRA.

CR Number: 2024074009		Implementation Date: 21-Mar-24	Related CR: 2024074009		
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed Term	Dry rash	Approved as Requested	Proposed LLT Dry rash	10090932	Current
			To PT Rash	10037844	

MSSO Comment: The proposal to add a new term Dry rash is approved as requested. A dry rash is a skin irritation that is characterized by dryness, scaling, and flaking of the skin. Dry rash will be added as an LLT to PT Rash.

# Detail Report

<b>CR Number:</b> 2024074010		<b>Implementation Date:</b> 25-Apr-24	<b>Related CR:</b> 2024074010	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Fibrose kystique</i>	Rejected After Suspension		
<b>MSSO Comment:</b> The proposal to add a new LLT Fibrose kystique is not approved after suspension. Instead of adding a new term, the translation of existing LLT Mucoviscidosis (code # 10028141) in the French translation of MedDRA will be changed from "Mucoviscidose" to "Fibrose kystique". Please see batch # 40118832; change request # 2024116012. This update was requested to facilitate comprehensive and standardized reporting of adverse events associated with Cystic Fibrosis in French-speaking regions, particularly in Quebec, Canada.				

<b>CR Number:</b> 2024075000		<b>Implementation Date:</b> 25-Mar-24	<b>Related CR:</b> 2024075000	
<a href="#">Change Requested</a>	Reassign Primary SOC	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Cavernous sinus thrombosis</i>	Approved as Requested	Proposed PT	
Old Primary SOC	<i>Infections and infestations</i>		<i>Cavernous sinus thrombosis</i>	10007830
New Primary SOC	<i>Nervous system disorders</i>		Old Primary SOC	
			<i>Infections and infestations</i>	10021881
			New Primary SOC	
			<i>Nervous system disorders</i>	10029205

**MSSO Comment:** The proposal to reassign the primary SOC of PT Cavernous sinus thrombosis from current SOC Infections and infestations to SOC Nervous system disorders is approved as requested. Although the association of a cavernous sinus thrombosis is usually in the setting of an infection, the term itself is a thrombotic condition. In a related change, the secondary HLT for PT Cavernous sinus thrombosis will be changed from HLT Central nervous system and spinal infections to HLT Inflammatory disorders following infection.

<b>CR Number:</b> 2024085003		<b>Implementation Date:</b> 25-Mar-24	<b>Related CR:</b> 2024075000	
<a href="#">Change Requested</a>	Link (move) a PT to another HLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Cavernous sinus thrombosis</i>	Approved as Requested	Proposed PT	
From HLT	<i>Central nervous system and spinal infections</i>		<i>Cavernous sinus thrombosis</i>	10007830
To HLT	<i>Inflammatory disorders following infection</i>		From HLT	
			<i>Central nervous system and spinal infections</i>	10007935
			To HLT	
			<i>Inflammatory disorders following infection</i>	10021982

**MSSO Comment:**



# Detail Report

<b>CR Number:</b> 2024078000		<b>Implementation Date:</b> 25-Mar-24	<b>Related CR:</b> 2024078000	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Laparoscopic promontofixation	Approved as Requested	Proposed LLT Laparoscopic promontofixation	10090944 Current
			To PT Pelvic floor repair	10034245
<b>MSSO Comment:</b> The proposal to add a new LLT Laparoscopic promontofixation is approved as requested. Laparoscopic promontofixation is a type of prolapse surgery in which a synthetic prosthesis is fixed between the bladder and the anterior wall of the vagina. A second prosthesis may be fixed between the rectum and the posterior wall of the vagina. Each prosthesis is then attached to a very strong ligament located in front of the spinal column, in front of the sacrum bone, at the promontory. Laparoscopic promontofixation will be added as an LLT to the PT Pelvic floor repair.				

<b>CR Number:</b> 2024078001		<b>Implementation Date:</b> 25-Mar-24	<b>Related CR:</b> 2024078001	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Surgical vaginal pessary removal	Approved as Requested	Proposed LLT Surgical vaginal pessary removal	10090945 Current
			To PT Vaginal pessary removal	10090942
<b>MSSO Comment:</b> The proposal to add a new LLT Surgical vaginal pessary removal is approved as requested. The proposed term represents the treatment for the serious complications arising from the use of pessaries and requiring surgical repair, such incontinence, entrapment, or fistulas. LLT Surgical vaginal pessary removal will be added under the new more general PT Vaginal pessary removal which will be added in a related change and linked to HLT Uterine therapeutic procedures, complementing the existing PT Vaginal pessary insertion.				

<b>CR Number:</b> 2024085001		<b>Implementation Date:</b> 25-Mar-24	<b>Related CR:</b> 2024078001	
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Vaginal pessary removal	Approved as Requested	Proposed PT Vaginal pessary removal	10090942
HLT primary	Uterine therapeutic procedures		HLT primary Uterine therapeutic procedures	10046808
SOC primary	Surgical and medical procedures		SOC primary Surgical and medical procedures	10042613
<b>MSSO Comment:</b>				

# Detail Report

<b>CR Number:</b> 2024078002		<b>Implementation Date:</b> 25-Mar-24	<b>Related CR:</b> 2024078002	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Macrocytic hypochromic anemia	Approved as Requested	Proposed LLT Macrocytic hypochromic anemia	10090946 Current
			To PT Hypochromic anaemia	10020969
<b>MSSO Comment:</b> The proposal to add a new LLT Macrocytic hypochromic anemia is approved as requested. In a macrocytic anemia, the larger red cells are always associated with insufficient numbers of cells and often also insufficient hemoglobin content per cell. Both of these factors work to the opposite effect of larger cell size, to finally result in a total blood hemoglobin concentration that is less than normal. Macrocytic hypochromic anemia will be added as LLT to PT Hypochromic anaemia. In a related change, the British counterpart Macrocytic hypochromic anaemia will also be added as LLT to PT Hypochromic anaemia.				

<b>CR Number:</b> 2024085002		<b>Implementation Date:</b> 25-Mar-24	<b>Related CR:</b> 2024078002	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Macrocytic hypochromic anaemia	Approved as Requested	Proposed LLT Macrocytic hypochromic anaemia	10090943 Current
To PT	Hypochromic anaemia		To PT Hypochromic anaemia	10020969

**MSSO Comment:**

<b>CR Number:</b> 2024078003		<b>Implementation Date:</b> 25-Mar-24	<b>Related CR:</b> 2024078003	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Adhesive plaster skin injury	Approved Not as Requested	Proposed LLT Adhesive plaster skin injury	10090949 Current
To PT	skin injury		To PT Skin injury	10061364

**MSSO Comment:** The proposal to add a new LLT Adhesive plaster skin injury to PT skin injury is approved but not as requested. An adhesive plaster skin injury is skin damage related to the use of medical adhesive products or devices such as tapes, wound dressings, stoma products, electrodes, medication patches and wound closure strips. Adhesive plaster skin injury will be added as sub-concept LLT to the corrected MedDRA capitalization PT Skin injury.

# Detail Report

<b>CR Number: 2024078004</b>		<b>Implementation Date:</b> 25-Mar-24	<b>Related CR:</b> 2024078004	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Adhesive tape skin injury</i>	Approved Not as Requested	Proposed LLT	
To PT	<i>skin injury</i>		<i>Adhesive tape skin injury</i>	10090950 Current
			To PT	
			<i>Skin injury</i>	10061364
<b>MSSO Comment:</b> The proposal to add a new LLT Adhesive tape skin injury to PT skin injury is approved but not as requested. An adhesive plaster (also known as adhesive tape, bandages or strips) skin injury is skin damage related to the use of medical adhesive products or devices such as tapes, wound dressings, stoma products, electrodes, medication patches and wound closure strips. Adhesive tape skin injury will be added as sub-concept LLT to the corrected MedDRA capitalization PT Skin injury.				

<b>CR Number: 2024079000</b>		<b>Implementation Date:</b> 25-Mar-24	<b>Related CR:</b> 2024079000	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Spinal cord lesion</i>	Rejected		
<b>MSSO Comment:</b> The proposal to add a new term Spinal cord lesion is not approved. As reflected in the "General word usage" paragraph of the Introductory Guide MedDRA Version 27.0, "Lesion terms may be considered for inclusion in MedDRA when the word "lesion" is part of a medical concept, e.g., PT Glomerulonephritis minimal lesion or a well-documented medical concept, e.g., LLT Brain lesion. However, the term will not be added when adding a broad "lesion" term only adds an additional imprecise term to existing "disorder" concepts, e.g., "renal lesion," when one could use for coding the existing LLT Renal disorder under PT Renal disorder." Please consider existing combinations terms LLT Multiple sclerosis spinal cord lesion and LLT Multiple sclerosis brain lesion or other based on your specific clinical scenario.				

<b>CR Number: 2024079001</b>		<b>Implementation Date:</b> 25-Mar-24	<b>Related CR:</b> 2024079001	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Traumatic pain</i>	Approved as Requested	Proposed LLT	
			<i>Traumatic pain</i>	10090951
			To PT	
			<i>Post-traumatic pain</i>	10065016 Current
<b>MSSO Comment:</b> The proposal to add a new term Traumatic pain is approved as requested to widen the window between the traumatic event and the appearance of associated pain (immediate, delayed, etc.). Traumatic pain will be added as an LLT to PT Post-traumatic pain. In a related change, PT Post-traumatic pain will be swapped with the new LLT Traumatic pain.				

# Detail Report

CR Number: 2024085004		Implementation Date: 25-Mar-24	Related CR: 2024079001		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Swap a PT with an LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed PT	Post-traumatic pain	Approved as Requested	Proposed PT		
With LLT	Traumatic pain		Post-traumatic pain	10065016	Current
			With LLT		
			Traumatic pain	10090951	
MSSO Comment:					

CR Number: 2024079002		Implementation Date: 25-Mar-24	Related CR: 2024079002		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed Term	GLUCURONOSYLTRANSFERASE DECREASED	Approved Not as Requested	Proposed PT		
			Glucuronosyltransferase decreased	10090952	
			HLT primary		
			Tissue enzyme analyses NEC	10043891	
			SOC primary		
			Investigations	10022891	
MSSO Comment: The proposal to add a new term GLUCURONOSYLTRANSFERASE DECREASED is approved but not as requested. Glucuronosyltransferase (UGT) is an enzyme responsible for glucuronidation, a process in which glucuronic acid is conjugated to substances, making them more water-soluble and easier to excrete from the body. When glucuronosyltransferase activity is decreased, it can lead to a decrease in the ability of the body to metabolize certain drugs and toxins, potentially resulting in higher levels of these substances circulating in the bloodstream for longer periods increasing the potential for toxicity. The proposed term will be modified for MedDRA capitalization rules to Glucuronosyltransferase decreased and added as PT to HLT Tissue enzyme analyses NEC.					

CR Number: 2024079003		Implementation Date: 25-Mar-24	Related CR: 2024079003		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed Term	Perineal itching	Rejected			
MSSO Comment: The proposal to add a new term Perineal itching is not approved. The requested concept is already represented by LLT Pruritus perineal.					

# Detail Report

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<b>CR Number:</b> 2024079004		<b>Implementation Date:</b> 25-Mar-24	<b>Related CR:</b> 2024079004		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed Term	Perineal irritation	Rejected			

**MSSO Comment:** The proposal to add a new term Perineal irritation is not approved. To avoid overpopulation of the terminology, MedDRA cannot add irritation terms (which besides are not medically specific) for every anatomical region. Please consider existing terms, such as LLT/PT Perineal erythema, LLT/PT Genital discomfort or other based on your specific clinical scenario.

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<b>CR Number:</b> 2024080000		<b>Implementation Date:</b> 25-Mar-24	<b>Related CR:</b> 2024080000		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed LLT	Lumbosciatica	Approved as Requested	Proposed LLT Lumbosciatica	10090953	Current
			To PT Sciatica	10039674	

**MSSO Comment:** The proposal to add a new LLT Lumbosciatica is approved as requested. Lumbosciatica is pain in the lumbar area that radiates to the lower extremity, sometimes even reaching the foot. For it to be called lumbosciatica, pain has to run from the buttock, through the back of the thigh, and further down the calf and foot, since pain that is limited to the lower back and buttocks is called lumbago. Lumbosciatica will be added as an LLT aligned with existing synonym LLT Lumbosciatalgia to PT Sciatica.

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<b>CR Number:</b> 2024080001		<b>Implementation Date:</b> 25-Mar-24	<b>Related CR:</b> 2024080001		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed LLT	Chronic secretory otitis media	Approved Not as Requested	Proposed LLT Chronic secretory otitis media	10090954	Current
To PT	otitis media chronic		To PT Otitis media chronic	10033081	

**MSSO Comment:** The proposal to add a new LLT Chronic secretory otitis media to PT otitis media chronic is approved but not as requested. Chronic serous (secretory) otitis media is common in young children. It can lead to hearing loss and formation of cholesteatoma. When conservative medical management fails, surgical drainage of accumulated fluid in the middle ear is indicated. Chronic secretory otitis media will be added as sub-concept LLT under the correctly capitalized PT Otitis media chronic.

# Detail Report

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<b>CR Number:</b> 2024080004		<b>Implementation Date:</b> 25-Mar-24	<b>Related CR:</b> 2024080004		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed Term	<i>Gastric emptying sensation</i>	Rejected			

**MSSO Comment:** The proposal to add a new term Gastric emptying sensation is not approved. This concept is vague and too unclear for inclusion in MedDRA. Please provide context and justification for the proposed concept term.

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<b>CR Number:</b> 2024080006		<b>Implementation Date:</b> 25-Mar-24	<b>Related CR:</b> 2024080006		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed Term	<i>Immune-mediated 3rd nerve palsy</i>	Rejected			

**MSSO Comment:** The proposal to add a new term Immune-mediated 3rd nerve palsy is not approved. The proposed term combines a medical concept with additional medical wording related to etiology and/or pathophysiology. Section 3.5 of the MedDRA Term Selection Points to Consider (MTS:PTC) document defines these as "combination terms". When considering the addition of such combination terms, MedDRA generally attempts to limit inclusion to those terms which describe important, distinct and robust medical concepts which are internationally recognized diagnostic entities. Examples include terms such as diabetic retinopathy, hypertensive cardiomegaly and eosinophilic pneumonia. Please consider LLTs Illrd nerve palsy and Immune-mediated neuropathy for your coding needs based on your specific clinical scenario.

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<b>CR Number:</b> 2024081000		<b>Implementation Date:</b> 25-Mar-24	<b>Related CR:</b> 2024081000		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed LLT	<i>Follicular variant of papillary thyroid carcinoma</i>	Approved as Requested	Proposed LLT		
To PT	<i>Papillary thyroid cancer</i>		<i>Follicular variant of papillary thyroid carcinoma</i>	10090955	Current
			To PT		
			<i>Papillary thyroid cancer</i>	10033701	

**MSSO Comment:** The proposal to add a new LLT Follicular variant of papillary thyroid carcinoma to PT Papillary thyroid cancer is approved as requested. Follicular variant of papillary thyroid carcinoma is a histological variant of papillary carcinoma thyroid. It has follicular architecture but with nuclear features of classical papillary carcinoma thyroid. It is associated with a higher incidence of extrathyroidal tumor invasion and regional lymphadenopathy.

# Detail Report

<b>CR Number: 2024082000</b>		<b>Implementation Date:</b> 01-Apr-24	<b>Related CR:</b> 2024082000	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Stent-graft endoleak type IIIC	Approved as Requested	Proposed LLT	
To PT	Stent-graft endoleak		Stent-graft endoleak type IIIC	10090962 Current
			To PT	
			Stent-graft endoleak	10064396
<b>MSSO Comment:</b> The proposal to add a new LLT Stent-graft endoleak type IIIC to PT Stent-graft endoleak is approved as requested. Endoleaks are complications where blood leaks into the aneurysm sac after the placement of a stent-graft for endovascular repair of an abdominal aortic aneurysm but before it has successfully sealed off the aneurysm. Type IIIC endoleaks specifically involve a persistent flow of blood into the aneurysm sac after placement of the stent-graft due to the failure of branches of the abdominal aorta to thrombose and seal off properly. Stent-graft endoleak type IIIC will be added as a new LLT to PT Stent-graft endoleak aligned with other specific types of stent-graft endoleaks.				
<b>CR Number: 2024082001</b>		<b>Implementation Date:</b> 01-Apr-24	<b>Related CR:</b> 2024082001	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Prosthesis site pain	Approved as Requested	Proposed LLT	
			Prosthesis site pain	10090958 Current
			To PT	
			Medical device site pain	10076133
<b>MSSO Comment:</b> The proposal to add a new LLT Prosthesis site pain is approved as requested. Four major categories (non ineffective, septic, other and idiopathic causes) have been identified as possible origin of persistent pain after prosthesis implantation. Prosthesis site pain will be added as sub-concept LLT under PT Medical device site pain.				
<b>CR Number: 2024082002</b>		<b>Implementation Date:</b> 01-Apr-24	<b>Related CR:</b> 2024082002	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Maculoschisis	Approved Not as Requested	Proposed LLT	
			Myopic maculoschisis	10090961 Current
			To PT	
			Myopic traction maculopathy	10080534
<b>MSSO Comment:</b> The proposal to add a new LLT Maculoschisis is approved but not as requested. In myopic maculoschisis, the macula seems to split because an area of the back of the eye develops an extra bulge backwards. This 'outpouching' is called a posterior staphyloma and can be progressive. The proposed term will be qualified and added as LLT Myopic maculoschisis as quasi synonym of existing LLT Myopic foveoschisis under PT Myopic traction maculopathy.				

# Detail Report

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<b>CR Number:</b> 2024082003		<b>Implementation Date:</b> 01-Apr-24	<b>Related CR:</b> 2024082003	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Nailbed pain</i>	Approved Not as Requested	Proposed LLT <i>Nail bed pain</i>	10090959 Current
			To PT <i>Onychalgia</i>	10064251
<b>MSSO</b> The proposal to add a new LLT Nailbed pain is approved but not as requested. Nail bed pain may be caused by a multitude of factors including injury or nail abnormality.				
<b>Comment:</b> The proposed term will be modified for MedDRA conventions and added as LLT Nail bed pain to PT Onychalgia.				

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<b>CR Number:</b> 2024082004		<b>Implementation Date:</b> 01-Apr-24	<b>Related CR:</b> 2024082004	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Iliac passion</i>	Rejected		
<b>MSSO</b> The proposal to add a new LLT Iliac passion is not approved. Iliac passion is the uncommon term for ileus which already exists in MedDRA. The term is rarely used and				
<b>Comment:</b> may cause challenges in other MedDRA language translations.				

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<b>CR Number:</b> 2024082005		<b>Implementation Date:</b> 01-Apr-24	<b>Related CR:</b> 2024082005	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Vaginal dysbiosis</i>	Approved as Requested	Proposed LLT <i>Vaginal dysbiosis</i>	10090960 Current
			To PT <i>Bacterial vaginosis</i>	10004055
<b>MSSO</b> The proposal to add a new LLT Vaginal dysbiosis is approved as requested. Vaginal dysbiosis is the disruption of the normal vaginal microbiome and may lead to an				
<b>Comment:</b> overgrowth of normal vaginal resident flora most often leading to bacterial vaginosis. Vaginal dysbiosis will be added as synonym LLT to existing LLT Vaginal flora imbalance and placed under PT Bacterial vaginosis.				

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# Detail Report

<b>CR Number:</b> 2024082006		<b>Implementation Date:</b> 01-Apr-24	<b>Related CR:</b> 2024082006	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Asymmetric periflexural exanthem of childhood</i>	Approved Not as Requested	Proposed PT	
			<i>Asymmetric periflexural exanthem of childhood</i>	10090956
			HLT primary	
			<i>Rashes, eruptions and exanthems NEC</i>	10052566
			SOC primary	
			<i>Skin and subcutaneous tissue disorders</i>	10040785

**MSSO Comment:** The proposal to add a new LLT Asymmetric periflexural exanthem of childhood is approved but not as requested. Asymmetric Periflexural Exanthem (APEC) is a distinctive and a self-limited exanthem which classically affects children and less frequently adults. The precise etiology of this condition is unknown, but the hypothesis of a viral cause seems to be plausible but remains unconfirmed. Asymmetric periflexural exanthem of childhood manifests as a unilateral papular exanthem with stereotypical morphology and distribution. Asymmetric periflexural exanthem of childhood will be added as a new PT under HLT Rashes, eruptions and exanthems NEC.

<b>CR Number:</b> 2024082007		<b>Implementation Date:</b> 01-Apr-24	<b>Related CR:</b> 2024082007	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Craniocervical instability</i>	Approved as Requested	Proposed LLT	
			<i>Craniocervical instability</i>	10090957 Current
			To PT	
			<i>Atlantoaxial instability</i>	10063580

**MSSO Comment:** The proposal to add a new LLT Craniocervical instability is approved as requested. Craniocervical instability is a medical condition where the strong ligaments that hold the head to the upper neck are loose or lax. The major ligaments involved are the alar, transverse and accessory ligaments. It is a medical condition with numerous names, including cranio-cervical instability, cranial instability, cranio-cervical syndrome, and occipitoatlantalaxial hypermobility. Craniocervical instability will be added as LLT to PT Atlantoaxial instability.

<b>CR Number:</b> 2024086000		<b>Implementation Date:</b> 01-Apr-24	<b>Related CR:</b> 2024086000	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Kidney disease</i>	Rejected		
To PT	<i>Nephropathy</i>			

**MSSO Comment:** The proposal to add a new LLT Kidney disease to PT Nephropathy is not approved. Kidney disease is a very broad synonym of existing LLT Renal disease. Since the word "disease" is used in several very different contexts in the kidney pathology, it is preferable to not continue adding broad and relatively ambiguous terms of this kind. In relation with this change request justification, it is recognized that, despite an undeniable relative overlap of the two concepts, Renal disease is more often used in the context of a functional or parenchymal derangement, whereas Renal disorder is a broader term that may include as well macroscopic morphological alterations of the kidneys, such as cysts, abscess, etc. Therefore, current placement of these two terms is considered adequate.

# Detail Report

<b>CR Number:</b> 2024087000		<b>Implementation Date:</b> 01-Apr-24	<b>Related CR:</b> 2024087000	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Perianal crohn's disease</i>	Approved Not as Requested	Proposed LLT <i>Perianal Crohn's disease</i>	10090963 Current
			To PT <i>Crohn's disease</i>	10011401
<b>MSSO Comment:</b> The proposal to add a new LLT Perianal crohn's disease is approved but not as requested. Perianal Crohn's disease is a manifestation of Crohn's disease that specifically affects the area around the anus and is able to cause complications such as perianal abscess, fistulas, fissures, pain and bleeding. The proposed term will be modified according to MedDRA capitalization rules and added as LLT Perianal Crohn's disease to PT Crohn's disease.				

<b>CR Number:</b> 2024087001		<b>Implementation Date:</b> 01-Apr-24	<b>Related CR:</b> 2024087001	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Speculoscopy</i>	Approved as Requested	Proposed LLT <i>Speculoscopy</i>	10090965 Current
			To PT <i>Colposcopy</i>	10010069
<b>MSSO Comment:</b> The proposal to add a new term Speculoscopy is approved as requested. Speculoscopy is a procedure in which light is provided by a chemiluminescent reaction occurring in a plastic-sealed tube (speculite) applied to the inside of the speculum. It is used to examine the cervix uteri for cancerous or pre-cancerous lesions. The proposed term will be added as LLT Speculoscopy to PT Colposcopy.				

<b>CR Number:</b> 2024087002		<b>Implementation Date:</b> 01-Apr-24	<b>Related CR:</b> 2024087002	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Magnified chemiluminescent examination (MCE)</i>	Approved Not as Requested	Proposed LLT <i>Magnified chemiluminescent examination of cervix</i>	10090964 Current
			To PT <i>Colposcopy</i>	10010069
<b>MSSO Comment:</b> The proposal to add a new term Magnified chemiluminescent examination (MCE) is approved but not as requested. The proposed term will be modified according to MedDRA conventions and qualified with anatomic location and added as LLT Magnified chemiluminescent examination of cervix, as synonym of LLT Speculoscopy (added in change request 2024087001) to PT Colposcopy.				

# Detail Report

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<b>CR Number:</b> 2024087003	<b>Implementation Date:</b> 01-Apr-24	<b>Related CR:</b> 2024087003	<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>
Proposed LLT	<i>Exercise induced reactive airway disease</i>	Rejected	

**MSSO Comment:** The proposal to add a new LLT Exercise induced reactive airway disease is not approved. Exercise induced reactive airway disease implies a causal relationship between two concepts, and therefore represents a combination term. The MSSO refrains from adding such terms as to avoid overpopulation of MedDRA.

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<b>CR Number:</b> 2024087004	<b>Implementation Date:</b> 01-Apr-24	<b>Related CR:</b> 2024087004	<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>
Proposed Term	<i>Compressive bandage for Hematoma</i>	Rejected	

**MSSO Comment:** The proposal to add a new term Compressive bandage for Hematoma is not approved. A compressive bandage for a hematoma is typically used to apply pressure to the affected area, which helps to reduce swelling and prevent further bleeding. To avoid the overpopulation of MedDRA, it is not feasible to accommodate terms relating to a combination of a therapy and its indication. Please consider other existing term(s) for compression treatment under SOC Surgical and medical procedures according to your specific needs.

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<b>CR Number:</b> 2024088020	<b>Implementation Date:</b> 04-Apr-24	<b>Related CR:</b> 2024088020	<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>
Proposed PT	<i>Retinal pigment changes</i>	Rejected	
HLT primary	<i>Retinal structural change, deposit and degeneration</i>		
SOC primary	<i>Eye disorders</i>		

**MSSO Comment:** The proposal to add a new PT Retinal pigment changes to primary HLT Retinal structural change, deposit and degeneration in SOC Eye disorders is not approved. Proposed concept name is incomplete as submitted and will be modified and added in change request 2024088021 as new PT Retinal pigment epithelium change.

# Detail Report

CR Number: 2024088021		Implementation Date: 04-Apr-24	Related CR: 2024088021	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Retinal pigment epithelium changes	Approved Not as Requested	Proposed PT	
			Retinal pigment epithelium change	10090967
			HLT primary	
			Retinal structural change, deposit and degeneration	10038896
			SOC primary	
			Eye disorders	10015919

MSSO Comment: The proposal to add a new LLT Retinal pigment epithelium changes is approved but not as requested. The retinal pigment epithelium is a single layer of cells tightly joined so that they form a barrier between the retina and the underlying choroid. As the retinal pigment epithelium ages or is affected by disease, a number of structural changes may occur. Proposed term will be modified into its singular form and added as new PT Retinal pigment epithelium change under HLT Retinal structural change, deposit and degeneration.

CR Number: 2024089000		Implementation Date: 04-Apr-24	Related CR: 2024089000	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Trichobezoars	Approved Not as Requested	Proposed LLT	
			Trichobezoar	10090968 Current
			To PT	
			Bezoar	10004542

MSSO Comment: The proposal to add a new LLT Trichobezoars is approved but not as requested. Trichobezoars are one of the types of bezoars and are composed of a conglomeration of hair and food particles. Proposed term will be modified into the singular form per MedDRA conventions and added as LLT Trichobezoar to PT Bezoar.

# Detail Report

CR Number: 2024089001		Implementation Date: 04-Apr-24	Related CR: 2024089001	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Hypothyroid cardiomyopathy</i>	Approved as Requested	Proposed PT <i>Hypothyroid cardiomyopathy</i>	10090970
			HLT primary <i>Cardiomyopathies</i>	10007635
			SOC primary <i>Cardiac disorders</i>	10007541
			HLT secondary <i>Metabolic disorders NEC</i>	10027428
			SOC secondary <i>Metabolism and nutrition disorders</i>	10027433

MSSO  
Comment: The proposal to add a new term Hypothyroid cardiomyopathy is approved as requested. A reversible form of dilated cardiomyopathy can be developed from alcohol drinking, pregnancy, chronic uncontrolled tachycardia, hypothyroidism, hyperthyroidism, drug use and other endocrine dysfunctions. Hypothyroid cardiomyopathy will be added as a new PT under primary HLT Cardiomyopathies, to secondary HLT Metabolic disorders NEC and to secondary HLT Thyroid hypofunction disorders.

CR Number: 2024095005		Implementation Date: 04-Apr-24	Related CR: 2024089001	
<a href="#">Change Requested</a>	Link a PT to a HLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Hypothyroid cardiomyopathy</i>	Approved as Requested	Proposed PT <i>Hypothyroid cardiomyopathy</i>	10090970
To HLT	<i>Thyroid hypofunction disorders</i>		To HLT <i>Thyroid hypofunction disorders</i>	10043741

MSSO  
Comment:

# Detail Report

<b>CR Number:</b> 2024090001		<b>Implementation Date:</b> 04-Apr-24	<b>Related CR:</b> 2024090001	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Spondyloptosis</i>	Approved as Requested	Proposed LLT <i>Spondyloptosis</i>	10090969 Current
			To PT <i>Spondylolisthesis</i>	10063550
<b>MSSO Comment:</b> The proposal to add a new LLT Spondyloptosis is approved as requested. Spondyloptosis is a term to denote grade V spondylolisthesis in the Meyerding classification: a vertebra having slipped so far with respect to the vertebra below that the two endplates are no longer congruent. Spondyloptosis will be added as a sub-concept LLT to PT Spondylolisthesis.				

<b>CR Number:</b> 2024093001		<b>Implementation Date:</b> 04-Apr-24	<b>Related CR:</b> 2024093001	
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Lead Inversion</i>	Approved Not as Requested	Proposed LLT <i>Lead inversion</i>	10090971 Current
HLT primary	<i>Device issues NEC</i>		To PT <i>Device inversion</i>	10070618
SOC primary	<i>Product issues</i>			
<b>MSSO Comment:</b> The proposal to add a new PT Lead Inversion to primary HLT Device issues NEC in SOC Product issues is approved but not as requested. In the epsilon designed leads of an extra vascular implantable cardioverter defibrillator, a change in orientation of the lead coils can occur in the sub-sternal space, a complication which is different to the move or migration of the lead from its initial location. This complication will be represented by the new term Lead inversion, which will be modified into lower case and added as an LLT to the PT Device inversion.				

<b>CR Number:</b> 2024094001		<b>Implementation Date:</b> 04-Apr-24	<b>Related CR:</b> 2024094001	
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Corneal guttata-like</i>	Approved Not as Requested	Proposed PT <i>Corneal pseudoguttata</i>	10090966
HLT primary	<i>Corneal disorders NEC</i>		HLT primary <i>Corneal structural change, deposit and degeneration</i>	10011049
SOC primary	<i>Eye disorders</i>		SOC primary <i>Eye disorders</i>	10015919
<b>MSSO Comment:</b> The proposal to add a new PT Corneal guttata-like to primary HLT Corneal disorders NEC in SOC Eye disorders is approved but not as requested. Corneal pseudoguttata, also known as pseudoguttae or secondary guttata, is a transient, reversible endothelial edema commonly associated with anterior segment pathology. Corneal pseudoguttata presents as dark lesions on slit-lamp exam with specular illumination, similar to primary corneal guttata. Corneal pseudoguttata is distinct from guttata because corneal pseudoguttata resolves over time and does not involve Descemet's membrane. Corneal pseudoguttata will be added as a PT to HLT Corneal structural change, deposit and degeneration.				

# Detail Report

<b>CR Number:</b> 2024094002		<b>Implementation Date:</b> 04-Apr-24	<b>Related CR:</b> 2024094002	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Immune mediated mucositis</i>	Approved Not as Requested	Proposed PT	
			<i>Immune-mediated mucositis</i>	10090972
			HLT primary	
			<i>Mucosal findings abnormal</i>	10028114
			SOC primary	
			<i>General disorders and administration site conditions</i>	10018065
			HLT secondary	
			<i>Immune and associated conditions NEC</i>	10027682
			SOC secondary	
			<i>Immune system disorders</i>	10021428

**MSSO Comment:** The proposal to add a new term Immune mediated mucositis is approved but not as requested. Immune mediated mucositis refers to mucositis in patients treated with immunotherapeutic agents, which might stimulate an immune response leading to immune-mediated adverse events. Proposed term will be modified and added as PT Immune-mediated mucositis to primary HLT Mucosal findings abnormal and to secondary HLT Immune and associated conditions NEC.

<b>CR Number:</b> 2024095000		<b>Implementation Date:</b> 12-Apr-24	<b>Related CR:</b> 2024095000	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Alpha-1 Antitrypsin Associated Liver Disease</i>	Rejected		

**MSSO Comment:** The proposal to add a new term Alpha-1 Antitrypsin Associated Liver Disease is not approved. Hepatic accumulation of abnormal alpha-1 antitrypsin can cause liver disease in both children and adults. This is an intrinsic feature of the disease which is already represented by the secondary link to HLT Hepatic metabolic disorders. With the same logic, and provided that the parenchymal lung damage of the disease is not yet represented, the PT Alpha-1 antitrypsin deficiency will receive an additional secondary link to HLT Parenchymal lung disorders NEC, since prognosis is related mainly to the degree of lung impairment.

# Detail Report

<b>CR Number:</b> 2024103001		<b>Implementation Date:</b> 12-Apr-24	<b>Related CR:</b> 2024095000	
<a href="#">Change Requested</a>	Link a PT to a HLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Alpha-1 antitrypsin deficiency</i>	Approved as Requested	Proposed PT	
To HLT	<i>Parenchymal lung disorders NEC</i>		<i>Alpha-1 antitrypsin deficiency</i>	10083869
			To HLT	
			<i>Parenchymal lung disorders NEC</i>	10033979

MSSO  
Comment:

<b>CR Number:</b> 2024095001		<b>Implementation Date:</b> 12-Apr-24	<b>Related CR:</b> 2024095001	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Postprandial blood glucose</i>	Approved as Requested	Proposed LLT	
			<i>Postprandial blood glucose</i>	10090976 Current
			To PT	
			<i>Blood glucose</i>	10005553

MSSO  
Comment: The proposal to add a new term Postprandial blood glucose is approved as requested. Postprandial glucose level is measured as an independent risk factor for cardiovascular disease that exerts effects greater than glucose levels at fasting state. Postprandial blood glucose will be added as LLT to PT Blood glucose in alignment with its counterpart LLT Fasting blood glucose.

<b>CR Number:</b> 2024095002		<b>Implementation Date:</b> 12-Apr-24	<b>Related CR:</b> 2024095002	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Death due to co-morbidities</i>	Rejected		

MSSO  
Comment: The proposal to add a new term Death due to co-morbidities is not approved. Even if some specific causes of death involving relevant system or organ failures (e.g., PT cardiac death) exist in MedDRA, not every circumstance leading or contributing to the outcome of death can be represented, as this would lead to the overpopulation of this area of MedDRA. Please review the LLT/PT Multimorbidity for your possible coding requirements.



# Detail Report

CR Number: 2024095003		Implementation Date: 12-Apr-24	Related CR: 2024095003	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	Endometriosis surgical removal	Approved as Requested	Proposed PT	
			Endometriosis surgical removal	10090975
			HLT primary	
			Gynaecological therapeutic procedures NEC	10052725
			SOC primary	
			Surgical and medical procedures	10042613
MSSO Comment:	The proposal to add a new term Endometriosis surgical removal is approved as requested. Endometriosis surgery (most often laparoscopic) aims to treat the structural causes of pain, infertility and other symptoms associated with endometriosis by destroying or removing all visible endometriotic lesions, performing adhesiolysis, and restoring the normal anatomy of damaged organs. Endometriosis surgical removal will be added as PT to the HLT Gynaecological therapeutic procedures NEC. In a related change, PT Endometriosis ablation will be demoted under new PT Endometriosis surgical removal.			

CR Number: 2024103002		Implementation Date: 12-Apr-24	Related CR: 2024095003	
<a href="#">Change Requested</a>	Demote a PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
PT to merge	Endometriosis ablation	Approved as Requested	PT to merge	
To PT	Endometriosis surgical removal		Endometriosis ablation	10057902 Current
			To PT	
			Endometriosis surgical removal	10090975
MSSO Comment:				

# Detail Report

CR Number: 2024095004		Implementation Date: 12-Apr-24	Related CR: 2024095004	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Myoepithelioma</i>	Approved Not as Requested	Proposed PT	
			<i>Salivary gland myoepithelioma</i>	10090974
			HLT primary	
			<i>Lip and oral cavity neoplasms benign</i>	10024531
			SOC primary	
			<i>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</i>	10029104
			HLT secondary	
			<i>Benign oral cavity neoplasms</i>	10030968
			SOC secondary	
			<i>Gastrointestinal disorders</i>	10017947
MSSO Comment:	The proposal to add a new term Myoepithelioma is approved but not as requested. Salivary gland myoepithelioma is a benign tumor of the oral cavity, arising predominantly from major and minor salivary glands, accounting for 1–1.5% of all glandular tumors, and mainly composed of myoepithelial cells located between the basal surface of acinar units, basement membrane, and surrounding intercalated duct. The proposed term will be modified for greater clarity and added as the PT Salivary gland myoepithelioma with a primary link to the HLT Lip and oral cavity neoplasms benign and a secondary link to HLT Benign oral cavity neoplasms.			

CR Number: 2024095006		Implementation Date: 19-Apr-24	Related CR: 2024095006	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Biopsy site infection</i>	Rejected After Suspension		
To PT	<i>Post procedural infection</i>			
MSSO Comment:	The proposal to add a new LLT Biopsy site infection to PT Post procedural infection is not approved after suspension. MedDRA cannot accommodate a specific term for every possible combination of anatomical site and condition. Therefore, a new PT Biopsy site complication was added in change request 2024102004 to facilitate coding of post-biopsy complications. Thus, the requested concept may be represented by associating this new LLT/PT with the type of complication occurrence, such as LLT/PT Post procedural infection in the case described.			

# Detail Report

CR Number: 2024096000		Implementation Date: 12-Apr-24	Related CR: 2024096000	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Type III Kounis syndrome	Approved Not as Requested	Proposed LLT Kounis syndrome type III	10090978 Current
			To PT Kounis syndrome	10069167

**MSSO Comment:** The proposal to add a new LLT Type III Kounis syndrome is approved but not as requested. Acute coronary syndrome occurs in conjunction with an allergic reaction in Kounis syndrome. This syndrome is categorized into three types, in which Type III is caused by thrombosis within a coronary artery stent. Proposed term will be modified for better alignment with existing LLT Kounis syndrome type I and LLT Kounis syndrome type II, and added as LLT Kounis syndrome type III under PT Kounis syndrome.

CR Number: 2024096001		Implementation Date: 12-Apr-24	Related CR: 2024096001	
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Coprophagia	Approved as Requested	Proposed PT Coprophagia	10090977
			HLT primary Stereotypies and automatisms	10042007
			SOC primary Psychiatric disorders	10037175
			HLT secondary Neurological signs and symptoms NEC	10029306
			SOC secondary Nervous system disorders	10029205

**MSSO Comment:** The proposal to add a new PT Coprophagia is approved as requested. Coprophagia is the compulsive, stereotyped use of obscene movements or gestures, seen in some cases of Gilles de la Tourette syndrome. Coprophagia will be added as new PT to primary HLT Stereotypies and automatisms and to secondary HLT Neurological signs and symptoms NEC. In a related change, the primary HLT for PT Coprolalia will be changed from primary HLT Speech articulation and rhythm disturbances to HLT Stereotypies and automatisms.

# Detail Report

<b>CR Number:</b> 2024103003		<b>Implementation Date:</b> 12-Apr-24	<b>Related CR:</b> 2024096001	
<a href="#">Change Requested</a>	Link (move) a PT to another HLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Coprolalia</i>	Approved as Requested	Proposed PT	
From HLT	<i>Speech articulation and rhythm disturbances</i>		<i>Coprolalia</i>	10010964
To HLT	<i>Stereotypies and automatisms</i>		From HLT	
			<i>Speech articulation and rhythm disturbances</i>	10041462
			To HLT	
			<i>Stereotypies and automatisms</i>	10042007

MSSO  
Comment:

<b>CR Number:</b> 2024096002		<b>Implementation Date:</b> 12-Apr-24	<b>Related CR:</b> 2024096002	
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Protracted COVID-19</i>	Rejected		

MSSO  
Comment: The proposal to add a new PT Protracted COVID-19 is not approved. Although it has become fairly evident that there are several protracting symptoms after microbiological recovery of SARS-CoV-2, such as neurological or cognitive disturbances or the presence of chronic post-infection fatigue, there is not yet a internationally well defined group of symptoms that, lasting over 6 months, may constitute the so called post-COVID syndrome. The terminology seems to vary but the most common one (and used by CDC) is Post-acute COVID-19 syndrome. Please review the PT Post-acute COVID-19 syndrome for your coding requirements.

<b>CR Number:</b> 2024097000		<b>Implementation Date:</b> 12-Apr-24	<b>Related CR:</b> 2024097000	
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Van Neck-Odelberg disease</i>	Approved as Requested	Proposed PT	
			<i>Van Neck-Odelberg disease</i>	10090979
			HLT primary	
			<i>Cartilage disorders</i>	10007709
			SOC primary	
			<i>Musculoskeletal and connective tissue disorders</i>	10028395

MSSO  
Comment: The proposal to add a new PT Van Neck-Odelberg disease is approved as requested. Van Neck-Odelberg disease or ischiopubic osteochondritis, is a rare cause of pain in the pediatric pelvis due to late closure in synchondrosis ischiopubic, whose main symptom is an asymmetric pain that can cause a limitation in movement or limp. Van Neck-Odelberg disease will be added as PT to HLT Cartilage disorders.

# Detail Report

<b>CR Number:</b> 2024097001		<b>Implementation Date:</b> 12-Apr-24		<b>Related CR:</b> 2024097001	
<a href="#">Change Requested</a>	Link (move) an LLT to another PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed LLT	<i>Port insertion</i>	Rejected			
From PT	<i>Central venous catheterisation</i>				
To PT	<i>Catheter placement</i>				
<b>MSSO Comment:</b>	The proposal to move the LLT Port insertion from PT Central venous catheterisation to PT Catheter placement is not approved. LLT Port insertion is an unqualified term which usually refers to vascular catheter insertion and thus is represented in MedDRA accordingly. For the less frequent sites, the term is offered usually in qualified form e.g. LLT Intraperitoneal access port insertion. Alignment of the terms would greatly impact legacy data.				

<b>CR Number:</b> 2024097002		<b>Implementation Date:</b> 12-Apr-24		<b>Related CR:</b> 2024097002	
<a href="#">Change Requested</a>	Link (move) an LLT to another PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed LLT	<i>Port removal</i>	Rejected			
From PT	<i>Central venous catheter removal</i>				
To PT	<i>Catheter removal</i>				
<b>MSSO Comment:</b>	The proposal to move the LLT Port removal from PT Central venous catheter removal to PT Catheter removal is not approved. LLT Port removal is an unqualified term which usually refers to vascular catheter removal and thus is represented in MedDRA accordingly. For the less frequent sites, the term is offered usually in qualified form or may be requested. Alignment of the terms would greatly impact legacy data.				

<b>CR Number:</b> 2024098000		<b>Implementation Date:</b> 12-Apr-24		<b>Related CR:</b> 2024098000	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed Term	<i>Acute exacerbation of chronic rhinosinusitis with nasal polyps</i>	Rejected			
<b>MSSO Comment:</b>	The proposal to add a new term Acute exacerbation of chronic rhinosinusitis with nasal polyps is not approved. This is a multiple concept term which can be coded using more than one MedDRA term, for example, LLT Chronic rhinosinusitis with nasal polyps and the recently added LLT Acute exacerbation of chronic rhinosinusitis (CR 2024060002). Please refer to Section 3.5 of the MedDRA Term Selection: Points to Consider Document regarding the coding of combination terms.				

# Detail Report

CR Number: 2024098001		Implementation Date: 12-Apr-24	Related CR: 2024098001	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	Renal perivascular epithelioid cell tumour	Approved Not as Requested	Proposed PT Renal perivascular epithelioid cell tumour	10090980
			HLT primary Renal neoplasms benign	10038487
			SOC primary Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10029104
			HLT secondary Renal neoplasms	10038486
			SOC secondary Renal and urinary disorders	10038359

MSSO Comment: The proposal to add a new term Renal perivascular epithelioid cell tumour is approved but not as requested. Renal perivascular epithelioid cell tumor (also called renal angiomyolipoma) is a benign mesenchymal tumour composed of variable proportions of adipose tissue, spindle and epithelioid smooth muscle cells, and thick-walled blood vessels. The proposed term will be modified for spelling and added as PT Renal perivascular epithelioid cell tumour with a primary link to HLT Renal neoplasms benign and a secondary link to HLT Renal neoplasms. In a related change, the American spelled counterpart LLT Renal perivascular epithelioid cell tumor will be added to PT Renal perivascular epithelioid cell tumour. Furthermore, the existing LLT Kidney angiomyolipoma and LLT Renal angioleiomyoma will be moved from PT Renal hamartoma to the new PT Renal perivascular epithelioid cell tumour.

CR Number: 2024103005		Implementation Date: 12-Apr-24	Related CR: 2024098001	
<a href="#">Change Requested</a>	Link (move) an LLT to another PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Kidney angiomyolipoma	Approved as Requested	Proposed LLT Kidney angiomyolipoma	10077284 Current
From PT	Renal hamartoma		From PT Renal hamartoma	10083207
To PT	Renal perivascular epithelioid cell tumour		To PT Renal perivascular epithelioid cell tumour	10090980

MSSO Comment:

# Detail Report

CR Number: 2024103004		Implementation Date: 12-Apr-24	Related CR: 2024098001		
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed LLT	Renal perivascular epithelioid cell tumor	Approved as Requested	Proposed LLT		
To PT	Renal perivascular epithelioid cell tumour		Renal perivascular epithelioid cell tumor	10090981	Current
			To PT		
			Renal perivascular epithelioid cell tumour	10090980	

MSSO  
Comment:

CR Number: 2024103006		Implementation Date: 12-Apr-24	Related CR: 2024098001		
<a href="#">Change Requested</a>	Link (move) an LLT to another PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed LLT	Renal angioleiomyoma	Approved as Requested	Proposed LLT		
From PT	Renal hamartoma		Renal angioleiomyoma	10087249	Current
To PT	Renal perivascular epithelioid cell tumour		From PT		
			Renal hamartoma	10083207	
			To PT		
			Renal perivascular epithelioid cell tumour	10090980	

MSSO  
Comment:

CR Number: 2024099000		Implementation Date: 12-Apr-24	Related CR: 2024099000		
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed LLT	Heterogeneously dense breast	Rejected			

MSSO  
Comment: The proposal to add a new LLT Heterogeneously dense breast is not approved. Please review existing terms LLT/PT Heterogeneously dense breasts which represent the requested concept.

# Detail Report

CR Number: 2024099001		Implementation Date: 12-Apr-24	Related CR: 2024099001	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Immune-mediated proctitis</i>	Approved as Requested	Proposed PT <i>Immune-mediated proctitis</i>	10090982
			HLT primary <i>Rectal inflammations NEC</i>	10036775
			SOC primary <i>Gastrointestinal disorders</i>	10017947
			HLT secondary <i>Immune and associated conditions NEC</i>	10027682
			SOC secondary <i>Immune system disorders</i>	10021428

MSSO Comment: The proposal to add a new term Immune-mediated proctitis is approved as requested. "Immune mediated" is defined as an inflammatory process caused by an unspecified immune reaction leading to dysregulation of the normal immune response. Immune related adverse events are often associated with immune checkpoint inhibitors therapies. Immune-mediated proctitis will be added as PT with a primary HLT Rectal inflammations NEC and to secondary HLT Immune and associated conditions NEC.

CR Number: 2024099003		Implementation Date: 12-Apr-24	Related CR: 2024099003	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Metabolic dysfunction-associated steatohepatitis (mash)</i>	Rejected		

MSSO Comment: The proposal to add a new LLT Metabolic dysfunction-associated steatohepatitis (mash) is not approved. This concept was added in change request 2024043055 of version 27.1, and will be available in September 2024.



# Detail Report

<b>CR Number:</b> 2024099006		<b>Implementation Date:</b> 12-Apr-24	<b>Related CR:</b> 2024099006	
<u>Change Requested</u>	Add a New Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	Cuffitis	Approved as Requested	Proposed PT Cuffitis	10090983
			HLT primary Gastrointestinal and hepatobiliary procedural complications	10017927
			SOC primary Injury, poisoning and procedural complications	10022117
			HLT secondary Gastrointestinal inflammatory disorders NEC	10017921
			SOC secondary Gastrointestinal disorders	10017947

**MSSO Comment:** The proposal to add a new term Cuffitis is approved as requested. Cuffitis is inflammation at the anal transition zone or "cuff" created as a result of ileal pouch-anal anastomosis. It is considered a variant form of ulcerative colitis that occurs in the rectal cuff. Cuffitis will be added as a new PT under primary HLT Gastrointestinal and hepatobiliary procedural complications and secondary HLT Gastrointestinal inflammatory disorders NEC. In a related change, the primary SOC for PT Pouchitis will be re-assigned from primary SOC Gastrointestinal disorders to SOC Injury, poisoning and procedural complications.

<b>CR Number:</b> 2024103007		<b>Implementation Date:</b> 12-Apr-24	<b>Related CR:</b> 2024099006	
<u>Change Requested</u>	Reassign Primary SOC	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Pouchitis	Approved as Requested	Proposed PT Pouchitis	10036463
Old Primary SOC	Gastrointestinal disorders		Old Primary SOC Gastrointestinal disorders	10017947
New Primary SOC	Injury, poisoning and procedural complications		New Primary SOC Injury, poisoning and procedural complications	10022117

**MSSO Comment:**

# Detail Report

<b>CR Number:</b> 2024099007		<b>Implementation Date:</b> 25-Apr-24		<b>Related CR:</b> 2024099007	
<a href="#">Change Requested</a>	Promote an LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed LLT	Lead inversion	Suspended			
From PT	Device inversion				
HLT primary	Device issues NEC				
<b>MSSO Comment:</b>	The proposal to promote the LLT Lead inversion from PT Device inversion to primary HLT Device issues NEC in SOC Product issues is suspended. The MSSO would like to take additional time to study this proposed change. You will be notified once a decision has been made on the disposition of your request.				

<b>CR Number: 2024099008</b>		<b>Implementation Date:</b> 12-Apr-24		<b>Related CR:</b> 2024099008	
<u>Change Requested</u>	Add a New PT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>	
Proposed PT	<i>Blood germanium increased</i>	Approved Not as Requested	Proposed PT		
HLT primary	<i>Toxicology laboratory analyses</i>		<i>Blood germanium radioisotope increased</i>	10090984	
SOC primary	<i>Investigations</i>		HLT primary		
			<i>Toxicology laboratory analyses</i>	10044261	
			SOC primary		
			<i>Investigations</i>	10022891	
<b>MSSO Comment:</b>	The proposal to add a new PT Blood germanium increased to primary HLT Toxicology laboratory analyses in SOC Investigations is approved but not as requested. Specific disease-targeting molecules radiolabeled with Germanium 68 can provide diagnostic images using positron emission tomography (PET), and when combined with a therapeutic agent, can enable targeted treatment planning. Proposed term will be modified and added as PT Blood germanium radioisotope increased to HLT Toxicology laboratory analyses.				

<b>CR Number:</b> 2024100000		<b>Implementation Date:</b> 25-Apr-24		<b>Related CR:</b> 2024100000	
<u>Change Requested</u>	Promote an LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>	
Proposed LLT	<i>Amyloid related imaging abnormality-microhaemorrhages</i>	Rejected After Suspension			
From PT	<i>Amyloid related imaging abnormality-microhaemorrhages and haemosiderin deposits</i>				
<b>MSSO Comment:</b>	The proposal to promote the LLT Amyloid related imaging abnormality-microhaemorrhages from PT Amyloid related imaging abnormality-microhaemorrhages and haemosiderin deposits is not approved after suspension. Increasing granularity at PT level may dilute signal detection. Other users' legacy data could also be heavily impacted. If the LLT terms are promoted, they would be closely related overlapping concepts with the current overarching PT Amyloid related imaging abnormality-microhaemorrhages and haemosiderin deposits. Challenges in analysis due to the term at LLT level may be addressed internally by organizations and not through structural changes in MedDRA.				

# Detail Report

CR Number: 2024100001		Implementation Date: 25-Apr-24	Related CR: 2024100001	
<a href="#">Change Requested</a>	Promote an LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Amyloid related imaging abnormality-haemosiderin deposits	Rejected After Suspension		
From PT	Amyloid related imaging abnormality-microhaemorrhages and haemosiderin deposits			
MSSO Comment:	The proposal to promote the LLT Amyloid related imaging abnormality-haemosiderin deposits from PT Amyloid related imaging abnormality-microhaemorrhages and haemosiderin deposits is not approved after suspension. Increasing granularity at PT level may dilute signal detection. Other users' legacy data could also be heavily impacted. If the LLT terms are promoted, they would be closely related overlapping concepts with the current overarching PT Amyloid related imaging abnormality-microhaemorrhages and haemosiderin deposits. Challenges in analysis due to the term at LLT level may be addressed internally by organizations and not through structural changes in MedDRA.			

CR Number: 2024100002		Implementation Date: 25-Apr-24	Related CR: 2024100002	
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Thalamic microhemorrhage	Approved Not as Requested	Proposed PT	
			Thalamic microhaemorrhage	10090985
			HLT primary	
			Central nervous system haemorrhages and cerebrovascular accidents	10007948
			SOC primary	
			Nervous system disorders	10029205
			HLT secondary	
			Nervous system haemorrhagic disorders	10008206
			SOC secondary	
			Vascular disorders	10047065
MSSO Comment:	The proposal to add a new PT Thalamic microhemorrhage is approved but not as requested. Thalamic microhaemorrhages can be seen in small vessel disease, after trauma (frequently also involving the corpus callosum, the midbrain, and/or the lobar white matter), secondary to initial infarction, or related to brain tumour. Proposed term will be modified for the British English spelling and added as new PT Thalamic microhaemorrhage under primary HLT Central nervous system haemorrhages and cerebrovascular accidents and secondary HLT Nervous system haemorrhagic disorders. In a related change, the American English spelled counterpart LLT Thalamic microhemorrhage will also be added under new PT Thalamic microhaemorrhage.			

# Detail Report

CR Number: 2024103008		Implementation Date: 12-Apr-24	Related CR: 2024100002	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Thalamic microhemorrhage	Approved as Requested	Proposed LLT	10090986 Current
To PT	Thalamic microhaemorrhage		Thalamic microhemorrhage	
			To PT	
			Thalamic microhaemorrhage	10090985

MSSO  
Comment:

CR Number: 2024101000		Implementation Date: 19-Apr-24	Related CR: 2024101000	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	Subungual exostosis	Approved as Requested	Proposed LLT	10090990 Current
			Subungual exostosis	
			To PT	
			Exostosis	10015688

MSSO  
Comment: The proposal to add a new term Subungual exostosis is approved as requested. Subungual exostosis is a benign bone tumor that occurs in the distal phalanges of the toes and rarely the hands and can be a source of pain and nail deformity. Subungual exostosis will be added as LLT to PT Exostosis.

# Detail Report

CR Number: 2024101001		Implementation Date: 19-Apr-24	Related CR: 2024101001	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Gower's sign	Approved Not as Requested	Proposed PT	
To PT	Muscular weakness		Gowers' sign	10090991
			HLT primary	
			Muscle weakness conditions	10062913
			SOC primary	
			Musculoskeletal and connective tissue disorders	10028395
			HLT secondary	
			Neuromuscular disorders NEC	10029318
			SOC secondary	
			Nervous system disorders	10029205

**MSSO Comment:** The proposal to add a new LLT Gower's sign to PT Muscular weakness is approved but not as requested. Gowers' sign is a clinical sign used in the diagnosis of certain neuromuscular disorders, particularly muscular dystrophy. It refers to the characteristic manner in which individuals with proximal muscle weakness rise from a seated or supine position by using their hands and arms to "walk" up their own body due to lack of hip and thigh muscle strength. The proposed term will be modified according to standard medical references to Gowers' sign and will be added as PT to primary HLT Muscle weakness conditions and secondary HLT Neuromuscular disorders NEC.

# Detail Report

CR Number: 2024101002		Implementation Date: 19-Apr-24	Related CR: 2024101002	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Pseudomembranous trachea</i>	Approved Not as Requested	Proposed PT <i>Tracheal pseudomembrane</i>	10090993
			HLT primary <i>Anaesthetic and allied procedural complications</i>	10080709
			SOC primary <i>Injury, poisoning and procedural complications</i>	10022117
			HLT secondary <i>Tracheal disorders (excl infections and neoplasms)</i>	10044288
			SOC secondary <i>Respiratory, thoracic and mediastinal disorders</i>	10038738

MSSO  
Comment: The proposal to add a new term Pseudomembranous trachea is approved but not as requested. Obstructive fibrinous tracheal pseudomembrane (often called tracheal pseudomembrane) is a rare, but potentially fatal complication associated with endotracheal intubation, whose formation is related with intracuff pressure during endotracheal intubation or infectious cause. The proposed concept will be renamed to its natural word order and more frequently found denomination in literature, and added as the PT Tracheal pseudomembrane to primary HLT Anaesthetic and allied procedural complications, to secondary HLT Tracheal disorders (excl infections and neoplasms) and to secondary HLT Inflammatory disorders following infection.

CR Number: 2024110004		Implementation Date: 19-Apr-24	Related CR: 2024101002	
<a href="#">Change Requested</a>	Link a PT to a HLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Tracheal pseudomembrane</i>	Approved as Requested	Proposed PT <i>Tracheal pseudomembrane</i>	10090993
To HLT	<i>Inflammatory disorders following infection</i>		To HLT <i>Inflammatory disorders following infection</i>	10021982

MSSO  
Comment:

# Detail Report

CR Number: 2024101003		Implementation Date: 19-Apr-24	Related CR: 2024101003	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	Metatarsal hypertrophy	Approved as Requested	Proposed LLT Metatarsal hypertrophy	10090995 Current
			To PT Bone hypertrophy	10005973
MSSO Comment:	The proposal to add a new term Metatarsal hypertrophy is approved as requested. First metatarsal bone can present different forms of hypertrophy located in the base, shaft or head. Each one of these forms of hypertrophy may be associated to different foot biomechanics alterations. Metatarsal hypertrophy will be added as LLT to PT Bone hypertrophy.			

CR Number: 2024101004		Implementation Date: 19-Apr-24	Related CR: 2024101004	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	Cannabinoid intoxication	Approved as Requested	Proposed LLT Cannabinoid intoxication	10090994 Current
			To PT Toxicity to various agents	10070863
MSSO Comment:	The proposal to add a new term Cannabinoid intoxication is approved as requested. Acute cannabis toxicity results in difficulty with coordination, decreased muscle strength, decreased hand steadiness, postural hypotension, lethargy, decreased concentration, slowed reaction time, slurred speech, and conjunctival injection. Subtle changes in attention and memory often occur with chronic use. Cannabinoid intoxication will be added as an LLT to PT Toxicity to various agents, in alignment with other substance intoxications.			

# Detail Report

CR Number: 2024101005		Implementation Date: 19-Apr-24	Related CR: 2024101005	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	Ileocecal valve lipoma	Approved as Requested	Proposed PT Ileocecal valve lipoma	10090992 Current
			HLT primary Lower gastrointestinal neoplasms benign	10024948
			SOC primary Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10029104
			HLT secondary Benign neoplasms gastrointestinal (excl oral cavity)	10017988
			SOC secondary Gastrointestinal disorders	10017947
MSSO Comment:	The proposal to add a new term Ileocecal valve lipoma is approved as requested. Lipomas of the ileocecal valve are a rarer entity than the more commonly occurring lipomatosis of the ileocecal valve. They can be differentiated from the latter as they have a demarcating capsule around the fatty tissue and are confined to only one of the ileocecal valve lips. Ileocecal valve lipoma will be added as PT with a primary link to HLT Lower gastrointestinal neoplasms benign and a secondary link to HLT Benign neoplasms gastrointestinal (excl oral cavity).			

CR Number: 2024101008		Implementation Date: 19-Apr-24	Related CR: 2024101008	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	Disseminated e. coli infection	Approved Not as Requested	Proposed PT Disseminated Escherichia infection	10090996
			HLT primary Escherichia infections	10015295
			SOC primary Infections and infestations	10021881
MSSO Comment:	The proposal to add a new term Disseminated e. coli infection is approved but not as requested. E. coli (Escherichia coli) are bacteria commonly found in the intestines of humans and animals. While most strains of E. coli are harmless, in unusual circumstances some can cause serious illness, particularly if they enter the bloodstream or infect other tissues. The proposed term will be modified to include the spelled-out pathogen genus and will be added as a new PT Disseminated Escherichia infection to HLT Escherichia infections. In addition, the species-specific term will be added in its spelled-out version as LLT Disseminated Escherichia coli infection to new PT Disseminated Escherichia infection.			



# Detail Report

CR Number: 2024110005		Implementation Date: 19-Apr-24	Related CR: 2024101008		
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed LLT	Disseminated Escherichia coli infection	Approved as Requested	Proposed LLT		
To PT	Disseminated Escherichia infection		Disseminated Escherichia coli infection	10090997	Current
			To PT		
			Disseminated Escherichia infection	10090996	

MSSO  
Comment:

CR Number: 2024102000		Implementation Date: 19-Apr-24	Related CR: 2024102000		
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed Term	Pathoglycemia	Rejected			

MSSO  
Comment: The proposal to add a new term Pathoglycemia is not approved. Pathoglycemia seems to be a term directly translated from Chinese indicating a pathologic blood sugar level. From scientific literature published in English, it is not completely clear, whether the term only refers to increased glucose levels, or also to decreases. Furthermore, the international applicability of the term is questionable.

CR Number: 2024102001		Implementation Date: 19-Apr-24	Related CR: 2024102001		
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed PT	HIV antigen/antibody	Approved Not as Requested	Proposed LLT		
			HIV antigen/antibody combination test	10090998	Current
			To PT		
			HIV test	10020185	

MSSO  
Comment: The proposal to add a new PT HIV antigen/antibody is approved but not as requested. An HIV antigen/antibody test looks for both HIV antibodies and antigens. The proposed term will be modified for greater clarity and added as sub-concept LLT HIV antigen/antibody combination test to PT HIV test. In a related change, the counterpart requested terms will be renamed and added as LLT HIV antigen/antibody combination test negative to PT HIV test negative and also LLT HIV antigen/antibody combination test positive will be added to PT HIV test positive.

# Detail Report

<b>CR Number:</b> 2024110006		<b>Implementation Date:</b> 19-Apr-24	<b>Related CR:</b> 2024102001	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>HIV antigen/antibody combination test positive</i>	Approved as Requested	Proposed LLT	
To PT	<i>HIV test positive</i>		<i>HIV antigen/antibody combination test positive</i>	10091000 Current
			To PT	
			<i>HIV test positive</i>	10020188

MSSO  
Comment:

<b>CR Number:</b> 2024110007		<b>Implementation Date:</b> 19-Apr-24	<b>Related CR:</b> 2024102001	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>HIV antigen/antibody combination test negative</i>	Approved as Requested	Proposed LLT	
To PT	<i>HIV test negative</i>		<i>HIV antigen/antibody combination test negative</i>	10090999 Current
			To PT	
			<i>HIV test negative</i>	10020187

MSSO  
Comment:

<b>CR Number:</b> 2024102002		<b>Implementation Date:</b> 19-Apr-24	<b>Related CR:</b> 2024102002	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>COVID induced myocarditis</i>	Rejected		

MSSO  
Comment: The proposal to add a new LLT COVID induced myocarditis is not approved. MedDRA cannot provide all possible symptoms reported associated with COVID-19 as combination terms. Based on your specific case, please consider split coding with LLT COVID-19 and LLT Myocarditis.

# Detail Report

CR Number: 2024102003		Implementation Date: 19-Apr-24	Related CR: 2024102003	
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Non-clear cell renal cell carcinoma	Approved as Requested	Proposed PT	
HLT primary	Renal neoplasms malignant		Non-clear cell renal cell carcinoma	10090987
SOC primary	Neoplasms benign, malignant and unspecified (incl cysts and polyps)		HLT primary	
			Renal neoplasms malignant	10068208
			SOC primary	
			Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10029104
			HLT secondary	
			Renal neoplasms	10038486
			SOC secondary	
			Renal and urinary disorders	10038359

**MSSO Comment:** The proposal to add a new PT Non-clear cell renal cell carcinoma to primary HLT Renal neoplasms malignant in SOC Neoplasms benign, malignant and unspecified (incl cysts and polyps) and secondary HLT Renal neoplasms in SOC Renal and urinary disorders is approved as requested. Non-clear cell renal cell carcinoma (ncRCC) is a heterogeneous group of diseases including a number of histological subtypes that are disparate in presentation, clinical course, and genetic basis. Survival of all subtypes of ncRCC in the metastatic setting is uniformly worse than the clear-cell counterpart.

CR Number: 2024102004		Implementation Date: 19-Apr-24	Related CR: 2024102004	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	Biopsy site cellulitis	Approved Not as Requested	Proposed PT	
			Biopsy site complication	10091001
			HLT primary	
			Non-site specific procedural complications	10029559
			SOC primary	
			Injury, poisoning and procedural complications	10022117

**MSSO Comment:** The proposal to add a new term Biopsy site cellulitis is approved but not as requested. MedDRA cannot accommodate a specific term for every possible combination of anatomical site and condition. Therefore, a new PT Biopsy site complication will be added to HLT Non-site specific procedural complications, to facilitate coding of post-biopsy complications. Thus, the requested concept may be represented by associating this new LLT/PT with the type of complication occurrence, such as LLT/PT Post procedural cellulitis in the case described.

# Detail Report

<b>CR Number:</b> 2024103000		<b>Implementation Date:</b> 19-Apr-24		<b>Related CR:</b> 2024103000	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed LLT	Cardioinhibitory syncope	Approved as Requested	Proposed LLT Cardioinhibitory syncope	10091002	Current
			To PT Syncope	10042772	
<b>MSSO Comment:</b> The proposal to add a new LLT Cardioinhibitory syncope is approved as requested. Reflex syncope refers to a neurally mediated response that gives rise to vasodilatation and/or bradycardia. According to the pattern of change in heart rate or blood pressure, reflex syncope can be classified as vasodepressor (vasodilatory hypotension), cardioinhibitory (bradycardia/asystole) or a mixture of the two main patterns. Cardioinhibitory syncope will be added as LLT to PT Syncope.					

<b>CR Number:</b> 2024107000		<b>Implementation Date:</b> 28-May-24		<b>Related CR:</b> 2024107000	
<a href="#">Change Requested</a>	Change term status in a SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed PT	Skin reaction	Approved Not as Requested	Proposed PT Skin reaction	10040914	
To SMQ	Hypersensitivity (SMQ)		To SMQ Hypersensitivity (SMQ)	20000214	
Status	I		Term scope Broad		

**MSSO Comment:** The proposal to change status of the term Skin reaction in Hypersensitivity (SMQ) to Inactive is approved but not as requested. PT Skin reaction will be moved from the narrow to the broad scope of the SMQ Hypersensitivity (SMQ). Based on the inclusion criteria this term is better placed in the broad scope for this SMQ.

<b>CR Number:</b> 2024107001		<b>Implementation Date:</b> 25-Apr-24		<b>Related CR:</b> 2024107001	
<a href="#">Change Requested</a>	Swap a PT with an LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed PT	Circumstance or information capable of leading to medication error	Rejected After Suspension			
With LLT	Potential for medication error				

**MSSO Comment:** The proposal to swap the PT Circumstance or information capable of leading to medication error with the LLT Potential for medication error is not approved after suspension. Due to the high frequency in regulatory databases, as well as the international acceptance and wide usage of the term in regulatory documentation, the term will remain at PT level. The term is appropriately broad to accommodate the various scenarios including contributing factors which may lead to medication errors.

# Detail Report

CR Number: 2024108000		Implementation Date: 19-Apr-24	Related CR: 2024108000	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Lymphocyte-activation gene 3 (LAG-3) expression	Approved Not as Requested	Proposed PT	
			LAG-3 expression	10091004
			HLT primary	
			Cell marker analyses	10072981
			SOC primary	
			Investigations	10022891
MSSO Comment:	The proposal to add a new LLT Lymphocyte-activation gene 3 (LAG-3) expression is approved but not as requested. LAG-3 is a cell-surface molecule expressed on T cells and other immune cells. LAG-3 reduces T-cell activation and proliferation, and may attenuate pro-inflammatory responses. Repeated exposure to tumor antigens is known to cause an increase in the expression of LAG-3. Increased LAG-3 expression leads to T-cell exhaustion and suppression of the anti-tumor activity of T cells. The proposed term will be modified to include the acronym and added as PT LAG-3 expression to HLT Cell marker analyses. In a related change, the spelled out expression will be added as LLT Lymphocyte-activation gene 3 expression to new PT LAG-3 expression.			

CR Number: 2024110008		Implementation Date: 19-Apr-24	Related CR: 2024108000	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Lymphocyte-activation gene 3 expression	Approved as Requested	Proposed LLT	
To PT	LAG-3 expression		Lymphocyte-activation gene 3 expression	10091007 Current
			To PT	
			LAG-3 expression	10091004
MSSO Comment:				

# Detail Report

<b>CR Number:</b> 2024108001		<b>Implementation Date:</b> 19-Apr-24	<b>Related CR:</b> 2024108001	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Lymphocyte-activation gene 3 (LAG-3) test</i>	Approved Not as Requested	Proposed PT	
			<i>LAG-3 test</i>	10091005
			HLT primary	
			<i>Cell marker analyses</i>	10072981
			SOC primary	
			<i>Investigations</i>	10022891

**MSSO Comment:** The proposal to add a new LLT Lymphocyte-activation gene 3 (LAG-3) test is approved but not as requested. LAG-3 is a cell-surface molecule expressed on T cells and other immune cells. LAG-3 reduces T-cell activation and proliferation, and may attenuate pro-inflammatory responses. Repeated exposure to tumor antigens is known to cause an increase in the expression of LAG-3. Increased LAG-3 expression leads to T-cell exhaustion and suppression of the anti-tumor activity of T cells. The proposed term will be modified to include the acronym and added as PT LAG-3 test to HLT Cell marker analyses. In a related change, the spelled out expression will be added as LLT Lymphocyte-activation gene 3 test to new PT LAG-3 test.

<b>CR Number:</b> 2024110009		<b>Implementation Date:</b> 19-Apr-24	<b>Related CR:</b> 2024108001	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Lymphocyte-activation gene 3 test</i>	Approved as Requested	Proposed LLT	
To PT	<i>LAG-3 test</i>		<i>Lymphocyte-activation gene 3 test</i>	10091010 Current
			To PT	
			<i>LAG-3 test</i>	10091005

**MSSO Comment:**

<b>CR Number:</b> 2024108002		<b>Implementation Date:</b> 19-Apr-24	<b>Related CR:</b> 2024108002	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Lymphocyte-activation gene 3 (LAG-3) test positive</i>	Approved Not as Requested	Proposed LLT	
			<i>Lymphocyte-activation gene 3 test positive</i>	10091006 Current
			To PT	
			<i>LAG-3 expression</i>	10091004

**MSSO Comment:** The proposal to add a new LLT Lymphocyte-activation gene 3 (LAG-3) test positive is approved but not as requested. LAG-3 is a cell-surface molecule expressed on T cells and other immune cells. LAG-3 reduces T-cell activation and proliferation, and may attenuate pro-inflammatory responses. Repeated exposure to tumor antigens is known to cause an increase in the expression of LAG-3. Increased LAG-3 expression leads to T-cell exhaustion and suppression of the anti-tumor activity of T cells. The proposed term will be modified without the acronym and added as LLT Lymphocyte-activation gene 3 test positive to PT LAG-3 expression. In a related change, the acronym will be added as LLT LAG-3 test positive to new PT LAG-3 expression added in change request 2024108000.

# Detail Report

<b>CR Number:</b> 2024110010		<b>Implementation Date:</b> 19-Apr-24	<b>Related CR:</b> 2024108002		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed LLT	LAG-3 test positive	Approved as Requested	Proposed LLT		
To PT	LAG-3 expression		LAG-3 test positive	10091008	Current
			To PT		
			LAG-3 expression	10091004	

MSSO  
Comment:

<b>CR Number:</b> 2024108003		<b>Implementation Date:</b> 19-Apr-24	<b>Related CR:</b> 2024108003		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed LLT	Lymphocyte-activation gene 3 (LAG-3) test negative	Approved Not as Requested	Proposed PT		
			LAG-3 test negative	10091003	
			HLT primary		
			Cell marker analyses	10072981	
			SOC primary		
			Investigations	10022891	

MSSO  
Comment: The proposal to add a new LLT Lymphocyte-activation gene 3 (LAG-3) test negative is approved but not as requested. LAG-3 is a cell-surface molecule expressed on T cells and other immune cells. LAG-3 reduces T-cell activation and proliferation, and may attenuate pro-inflammatory responses. Repeated exposure to tumor antigens is known to cause an increase in the expression of LAG-3. Increased LAG-3 expression leads to T-cell exhaustion and suppression of the anti-tumor activity of T cells. The proposed term will be modified to include the acronym and added as PT LAG-3 test negative to HLT Cell marker analyses. In a related change, the spelled out expression will be added as LLT Lymphocyte-activation gene 3 test negative to new PT LAG-3 test negative.

<b>CR Number:</b> 2024110011		<b>Implementation Date:</b> 19-Apr-24	<b>Related CR:</b> 2024108003		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed LLT	Lymphocyte-activation gene 3 test negative	Approved as Requested	Proposed LLT		
To PT	LAG-3 test negative		Lymphocyte-activation gene 3 test negative	10091009	Current
			To PT		
			LAG-3 test negative	10091003	

MSSO  
Comment:

# Detail Report

CR Number: 2024108004		Implementation Date: 19-Apr-24	Related CR: 2024108004		
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed LLT	Lymphocyte-activation gene 3 (LAG-3) cancer	Rejected			

MSSO Comment: The proposal to add a new LLT Lymphocyte-activation gene 3 (LAG-3) cancer is not approved. The current understanding is that LAG-3 is expressed on the immune-cell (and not in the tumour tissue). When a ligand on the tumor tissue (potentially galectin 3) binds to LAG-3 expressed on the T-cell/NK cell, this leads to down regulation of the T-cell immune response. Thus, adding this as a cancer characteristic is not adequate.

CR Number: 2024108005		Implementation Date: 24-Apr-24	Related CR: 2024108005		
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed Term	Melanoma oligometastatic recurrence	Approved Not as Requested	Proposed LLT		
			Oligometastatic neoplasm	10091011	Current
			To PT		
			Metastatic neoplasm	10061289	

MSSO Comment: The proposal to add a new term Melanoma oligometastatic recurrence is approved but not as requested. In oligometastatic cancer, the primary cancer has only spread to either one or a few sites in the body and is the more treatable type of "limited" metastatic cancer. Proposed term will be modified and broadened without qualifier and added as LLT Oligometastatic neoplasm to PT Metastatic neoplasm. The neoplasm specificity and recurrent nature may be captured with other case appropriate terms.



# Detail Report

<b>CR Number:</b> 2024108006		<b>Implementation Date:</b> 19-Apr-24	<b>Related CR:</b> 2024108006	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Hepatic artery-hepatic venous fistula</i>	Approved Not as Requested	Proposed PT <i>Hepatic vascular fistula</i>	10090988
			HLT primary <i>Hepatic vascular disorders</i>	10019712
			SOC primary <i>Hepatobiliary disorders</i>	10019805
			HLT secondary <i>Site specific vascular disorders NEC</i>	10057188
			SOC secondary <i>Vascular disorders</i>	10047065

**MSSO Comment:** The proposal to add a new LLT Hepatic artery-hepatic venous fistula is approved but not as requested. A hepatic artery-hepatic venous fistula is an abnormal connection between the hepatic artery and a hepatic vein. In addition, there are hepatic arteriportal fistula, which might be more frequent based on the close anatomical relation. Hepatic vascular fistula will be added as a new PT with primary HLT Hepatic vascular disorders and secondary HLT Site specific vascular disorders NEC. In a related change, PT Intrahepatic portal hepatic venous fistula will be demoted under to new PT Hepatic vascular fistula. Furthermore, LLT Hepatic artery-hepatic venous fistula will be added to new PT Hepatic vascular fistula.

<b>CR Number:</b> 2024110003		<b>Implementation Date:</b> 19-Apr-24	<b>Related CR:</b> 2024108006	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Hepatic artery-hepatic venous fistula</i>	Approved as Requested	Proposed LLT <i>Hepatic artery-hepatic venous fistula</i>	10090989 Current
To PT	<i>Hepatic vascular fistula</i>		To PT <i>Hepatic vascular fistula</i>	10090988

**MSSO Comment:**

# Detail Report

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<b>CR Number:</b> 2024110002		<b>Implementation Date:</b> 19-Apr-24	<b>Related CR:</b> 2024108006	
<a href="#">Change Requested</a>	Demote a PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
PT to merge	<i>Intrahepatic portal hepatic venous fistula</i>	Approved as Requested	PT to merge	
To PT	<i>Hepatic vascular fistula</i>		<i>Intrahepatic portal hepatic venous fistula</i>	10072629 Current
			To PT	
			<i>Hepatic vascular fistula</i>	10090988

MSSO  
Comment:

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<b>CR Number:</b> 2024108007		<b>Implementation Date:</b> 19-Apr-24	<b>Related CR:</b> 2024108007	
<a href="#">Change Requested</a>	Demote a PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
PT to merge	<i>Diabetic complication renal</i>	Approved as Requested	PT to merge	
To PT	<i>Diabetic nephropathy</i>		<i>Diabetic complication renal</i>	10086701 Current
			To PT	
			<i>Diabetic nephropathy</i>	10061835

MSSO  
Comment: The proposal to demote the PT Diabetic complication renal under PT Diabetic nephropathy is approved as requested. Renal diabetic complications are not clearly distinguished from diabetic nephropathy. Diabetic nephropathy is a continuum of renal changes from hyperfiltration to end-stage renal disease.

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<b>CR Number:</b> 2024108008		<b>Implementation Date:</b> 24-Apr-24	<b>Related CR:</b> 2024108008	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Lymphocytes decreased</i>	Approved as Requested	Proposed LLT	
			<i>Lymphocytes decreased</i>	10091012 Current
			To PT	
			<i>Lymphocyte count decreased</i>	10025256

MSSO  
Comment: The proposal to add a new term Lymphocytes decreased is approved as requested. For more specific coding, Lymphocytes decreased will be added as synonym LLT under PT Lymphocyte count decreased in alignment with corresponding LLT Lymphocytes raised under PT Lymphocyte count increased.

# Detail Report

<b>CR Number:</b> 2024108012		<b>Implementation Date:</b> 24-Apr-24	<b>Related CR:</b> 2024108012	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Hypoamylasemia</i>	Approved as Requested	Proposed LLT <i>Hypoamylasemia</i>	10091014 Current
			To PT <i>Hypoamylasaemia</i>	10091013
<b>MSSO Comment:</b> The proposal to add a new term Hypoamylasemia is approved as requested. Low serum amylase (hypoamylasemia) has been reported in certain common cardiometabolic conditions such as obesity, diabetes (regardless of type), and metabolic syndrome, all of which appear to have a common aetiology of insufficient insulin action due to insulin resistance and/or diminished insulin secretion. Hypoamylasemia will be added as an LLT under the British spelled new PT Hypoamylasaemia, which will be added, in a related change, and linked to HLT Metabolic disorders NEC.				

<b>CR Number:</b> 2024115007		<b>Implementation Date:</b> 24-Apr-24	<b>Related CR:</b> 2024108012	
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Hypoamylasaemia</i>	Approved as Requested	Proposed PT <i>Hypoamylasaemia</i>	10091013
HLT primary	<i>Metabolic disorders NEC</i>		HLT primary <i>Metabolic disorders NEC</i>	10027428
SOC primary	<i>Metabolism and nutrition disorders</i>		SOC primary <i>Metabolism and nutrition disorders</i>	10027433
<b>MSSO Comment:</b>				

<b>CR Number:</b> 2024108015		<b>Implementation Date:</b> 24-Apr-24	<b>Related CR:</b> 2024108015	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Stoma site fibroma</i>	Approved Not as Requested	Proposed PT <i>Stoma site complication</i>	10091015
			HLT primary <i>Stoma complications</i>	10074475
			SOC primary <i>Injury, poisoning and procedural complications</i>	10022117

**MSSO Comment:** The proposal to add a new term Stoma site fibroma is approved but not as requested. Stoma sites can be subject to multiple specific complications for which MedDRA cannot add a specific stoma site combined term. To overcome the problem described in the justification, a new PT named Stoma site complication will be added under HLT Stoma complications.

# Detail Report

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<b>CR Number:</b> 2024108016		<b>Implementation Date:</b> 24-Apr-24	<b>Related CR:</b> 2024108016		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed Term	<i>Stoma site crust</i>	Rejected			

**MSSO Comment:** The proposal to add a new term Stoma site crust is not approved. Stoma sites can be subject to multiple specific complications for which MedDRA cannot add a specific stoma site combined term. The proposed concept can be represented through combined coding with the LLT/PT Stoma site complication added in change request 2024108015 and LLT/PT Stoma site wound added in change request 2024108017. Section 3.5 of the MedDRA Term Selection Points to Consider (MTS:PTC) document defines these as "combination terms".

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<b>CR Number:</b> 2024108017		<b>Implementation Date:</b> 24-Apr-24	<b>Related CR:</b> 2024108017		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed Term	<i>Stoma site wound</i>	Approved as Requested	Proposed PT		
			<i>Stoma site wound</i>		10091016
			HLT primary		
			<i>Stoma complications</i>		10074475
			SOC primary		
			<i>Injury, poisoning and procedural complications</i>		10022117
			HLT secondary		
			<i>Skin injuries and mechanical dermatoses</i>		10040877
			SOC secondary		
			<i>Skin and subcutaneous tissue disorders</i>		10040785

**MSSO Comment:** The proposal to add a new term Stoma site wound is approved as requested. The skin around the edges of a stoma and underneath the stoma appliance can get easily irritated and wounds may develop. Stoma site wound is a common specific complication of stomas. Stoma site wound will be added as a PT with a primary link to HLT Stoma complications and a secondary link to HLT Skin injuries and mechanical dermatoses.

# Detail Report

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<b>CR Number:</b> 2024108018		<b>Implementation Date:</b> 24-Apr-24	<b>Related CR:</b> 2024108018		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed Term	<i>Stoma site discolored</i>	Rejected			

**MSSO Comment:** The proposal to add a new term Stoma site discolored is not approved. Stoma sites can be subject to multiple specific complications for which MedDRA cannot add a specific stoma site combined term. The proposed concept can be represented through combined coding with the PT Stoma site complication added in change request 2024108015. Section 3.5 of the MedDRA Term Selection Points to Consider (MTS:PTC) document defines these as "combination terms".

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<b>CR Number:</b> 2024109000		<b>Implementation Date:</b> 24-Apr-24	<b>Related CR:</b> 2024109000		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed LLT	<i>Tendon retraction</i>	Approved as Requested	Proposed LLT		
To PT	<i>Tendon rupture</i>		<i>Tendon retraction</i>	10091017	Current
			To PT		
			<i>Tendon rupture</i>	10043248	

**MSSO Comment:** The proposal to add a new LLT Tendon retraction to PT Tendon rupture is approved as requested. Acute proximal full-thickness tendon injury (ie, tendon avulsion or rupture) is a severe injury that often results in abnormal reduction in tendon length called tendon retraction.

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<b>CR Number:</b> 2024109001		<b>Implementation Date:</b> 24-Apr-24	<b>Related CR:</b> 2024109001		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed LLT	<i>Hypomimia</i>	Approved as Requested	Proposed LLT		
To PT	<i>Reduced facial expression</i>		<i>Hypomimia</i>	10091018	Current
			To PT		
			<i>Reduced facial expression</i>	10078576	

**MSSO Comment:** The proposal to add a new LLT Hypomimia to PT Reduced facial expression is approved as requested. Hypomimia is a symptom of various neuro-psychiatric disorders - such as Parkinson's disease or psychological/ psychiatric factors with emotional expression impediment - that limits the accurate expression of emotion in the face due to a decrease in the speed and coordination with which the facial musculature is activated.

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# Detail Report

<b>CR Number:</b> 2024109002		<b>Implementation Date:</b> 24-Apr-24	<b>Related CR:</b> 2024109002		
<a href="#">Change Requested</a>	Link a PT to a HLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed PT	Depression suicidal	Rejected			
To HLT	Suicidal and self-injurious behaviour				

**MSSO Comment:** The proposal to link the PT Depression suicidal to the HLT Suicidal and self-injurious behaviour is not approved. The additional requested HLT Suicidal and self-injurious behaviour and the existing HLT Depressive disorders both link to SOC Psychiatric disorders. A SOC may only be represented once for a term.

<b>CR Number:</b> 2024109003		<b>Implementation Date:</b> 24-Apr-24	<b>Related CR:</b> 2024109003		
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed LLT	Type 5 long QT syndrome (LQT5)	Approved Not as Requested	Proposed LLT Long QT syndrome 5	10091020	Current
			To PT Long QT syndrome congenital	10057926	

**MSSO Comment:** The proposal to add a new LLT Type 5 long QT syndrome (LQT5) is approved but not as requested. Long QT syndrome type 5 is an uncommon variant of Long QT syndrome (LQTS) caused by mutations in the KCNE1 gene: it accounts for approximately 2–3% of all genotyped LQTS patients. Mutations in the KCNE1 gene cause both Romano-Ward (LQT5) and Jervell and Lange-Nielsen syndromes. Proposed term will be modified for removal of acronym and for better alignment and added as LLT Long QT syndrome 5 under PT Long QT syndrome congenital (aligned with existing synonym LLT Romano Ward syndrome).

<b>CR Number:</b> 2024109004		<b>Implementation Date:</b> 24-Apr-24	<b>Related CR:</b> 2024109004		
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed LLT	Linear IgA bullous dermatosis (LABD)	Rejected			

**MSSO Comment:** The proposal to add a new LLT Linear IgA bullous dermatosis (LABD) is not approved. Proposed concept already exists as LLT Linear IgA bullous dermatosis under PT Linear IgA disease.

# Detail Report

CR Number: 2024109005		Implementation Date: 24-Apr-24	Related CR: 2024109005	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Minamata disease	Approved Not as Requested	Proposed PT	
			Minamata disease	10091019
			HLT primary	
			Poisoning and toxicity	10035777
			SOC primary	
			Injury, poisoning and procedural complications	10022117
			HLT secondary	
			Nervous system disorders NEC	10057185
			SOC secondary	
			Nervous system disorders	10029205
MSSO Comment:	The proposal to add a new LLT Minamata disease is approved but not as requested. Minamata disease is methylmercury poisoning that leads to neurological symptoms such as sensory disturbance in the distal portions of four extremities, cerebellar ataxia and bilateral concentric contraction of the visual field. The condition develops after a person has been eating heavily contaminated seafood daily. It is established that the disease differs from inorganic mercury poisoning which damages kidneys. Minamata disease will be added as a new PT under primary HLT Poisoning and toxicity and secondary HLT Nervous system disorders NEC.			

CR Number: 2024109006		Implementation Date: 24-Apr-24	Related CR: 2024109006	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	Mammary duct dilatation	Rejected		
MSSO Comment:	The proposal to add a new term Mammary duct dilatation is not approved. The proposed concept exists in LLT Mammary duct ectasia.			

# Detail Report

<b>CR Number:</b> 2024110000		<b>Implementation Date:</b> 24-Apr-24	<b>Related CR:</b> 2024110000	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Cardiogenic brain embolism	Approved Not as Requested	Proposed LLT Cardiogenic embolism To PT Embolism arterial	10091021 Current  10014513
<b>MSSO Comment:</b> The proposal to add a new LLT Cardiogenic brain embolism is approved but not as requested. The main sources of embolism from the heart are thrombus from within the cardiac chambers and debris shedding off valves. Cardiac embolism can produce infarctions in any vascular distribution. The proposed term will be modified without the anatomic site combination and added as LLT Cardiogenic embolism to PT Embolism arterial.				

<b>CR Number:</b> 2024110012		<b>Implementation Date:</b> 25-Apr-24	<b>Related CR:</b> 2024110012	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Diverticula of the larynx	Rejected		
<b>MSSO Comment:</b> The proposal to add a new LLT Diverticula of the larynx is not approved. Diverticula, in a general sense, refer to abnormal outpouchings or sac-like protrusions that can occur in various parts of the body. Laryngocele is the specific type of an outpouching of the mucous membrane occurring in the larynx and is represented by existing LLT/PT Laryngocele or LLT/PT Acquired laryngocele. Either of these may be considered to meet coding needs, depending upon reported scenario.				

<b>CR Number:</b> 2024110013		<b>Implementation Date:</b> 25-Apr-24	<b>Related CR:</b> 2024110013	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Fitzpatrick skin phototype	Approved Not as Requested	Proposed PT Fitzpatrick skin phototype HLT primary Physical examination procedures and organ system status SOC primary Investigations	10091022  10071941  10022891
<b>MSSO Comment:</b> The proposal to add a new LLT Fitzpatrick skin phototype is approved but not as requested. The Fitzpatrick skin type classification system is a scale used to categorize human skin complexion based on the response to ultraviolet light. The classification system takes into account factors such as genetic disposition, reaction to sun exposure, and tanning habits. Fitzpatrick skin phototype will be added as PT to HLT Physical examination procedures and organ system status.				



# Detail Report

<b>CR Number:</b> 2024110014		<b>Implementation Date:</b> 25-Apr-24	<b>Related CR:</b> 2024110014	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Fitzpatrick skin phototype I</i>	Approved as Requested	Proposed LLT <i>Fitzpatrick skin phototype I</i>	10091029
			To PT <i>Fitzpatrick skin phototype</i>	10091022
<b>MSSO</b> The proposal to add a new LLT Fitzpatrick skin phototype I is approved as requested. Fitzpatrick skin phototype I describes skin that often burns easily and rarely tans. <b>Comment:</b> Examples include people with very fair or pale skin, red or blonde hair, and blue or green eyes. Fitzpatrick skin phototype I will be added as LLT to the new PT Fitzpatrick skin phototype added in change request 2024110013.				
<b>CR Number:</b> 2024110015		<b>Implementation Date:</b> 25-Apr-24	<b>Related CR:</b> 2024110015	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Fitzpatrick skin phototype II</i>	Approved as Requested	Proposed LLT <i>Fitzpatrick skin phototype II</i>	10091023
			To PT <i>Fitzpatrick skin phototype</i>	10091022
<b>MSSO</b> The proposal to add a new LLT Fitzpatrick skin phototype II is approved as requested. Fitzpatrick skin phototype II describes skin that usually burns easily and sometimes <b>Comment:</b> tans. People with light skin, blonde or light brown hair, and blue, hazel, or green eyes typically fall into this category. Fitzpatrick skin phototype II will be added as LLT to the new PT Fitzpatrick skin phototype added in change request 2024110013.				
<b>CR Number:</b> 2024110016		<b>Implementation Date:</b> 25-Apr-24	<b>Related CR:</b> 2024110016	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Fitzpatrick skin phototype III</i>	Approved as Requested	Proposed LLT <i>Fitzpatrick skin phototype III</i>	10091024
			To PT <i>Fitzpatrick skin phototype</i>	10091022
<b>MSSO</b> The proposal to add a new LLT Fitzpatrick skin phototype III is approved as requested. Fitzpatrick skin phototype III describes skin that may burn moderately and tans <b>Comment:</b> gradually. Individuals with medium-toned skin, light to medium brown hair, and brown or hazel eyes are often classified as type III. Fitzpatrick skin phototype III will be added as LLT to the new PT Fitzpatrick skin phototype added in change request 2024110013.				

# Detail Report

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<b>CR Number:</b> 2024110017		<b>Implementation Date:</b> 25-Apr-24	<b>Related CR:</b> 2024110017	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Fitzpatrick skin phototype IV</i>	Approved as Requested	Proposed LLT <i>Fitzpatrick skin phototype IV</i>	10091025
			To PT <i>Fitzpatrick skin phototype</i>	10091022

**MSSO** The proposal to add a new LLT Fitzpatrick skin phototype IV is approved as requested. Fitzpatrick skin phototype IV describes skin that rarely burns and tans with ease.  
**Comment:** This category includes individuals with olive or light brown skin, dark brown hair, and brown eyes. Fitzpatrick skin phototype IV will be added as LLT to the new PT Fitzpatrick skin phototype added in change request 2024110013.

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<b>CR Number:</b> 2024110018		<b>Implementation Date:</b> 25-Apr-24	<b>Related CR:</b> 2024110018	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Fitzpatrick skin phototype VI</i>	Approved as Requested	Proposed LLT <i>Fitzpatrick skin phototype VI</i>	10091026
			To PT <i>Fitzpatrick skin phototype</i>	10091022

**MSSO** The proposal to add a new LLT Fitzpatrick skin phototype VI is approved as requested. Fitzpatrick skin phototype VI describes skin that almost never burns and is deeply pigmented. Individuals with very dark brown to black skin, black hair, and brown eyes are typically classified as type VI. Fitzpatrick skin phototype VI will be added as LLT to the new PT Fitzpatrick skin phototype added in change request 2024110013.

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<b>CR Number:</b> 2024110019		<b>Implementation Date:</b> 25-Apr-24	<b>Related CR:</b> 2024110019	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Fitzpatrick skin phototype V</i>	Approved as Requested	Proposed LLT <i>Fitzpatrick skin phototype V</i>	10091028
			To PT <i>Fitzpatrick skin phototype</i>	10091022

**MSSO** The proposal to add a new LLT Fitzpatrick skin phototype V is approved as requested. Fitzpatrick skin phototype V describes skin that rarely burns and tans easily. People with dark brown skin, black hair, and brown eyes usually fall into this category. Fitzpatrick skin phototype V will be added as LLT to the new PT Fitzpatrick skin phototype added in change request 2024110013.

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# Detail Report

CR Number: 2024110020		Implementation Date: 25-Apr-24	Related CR: 2024110020		MedDRA Code #
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed LLT	Alloplasty	Rejected			

MSSO Comment: The proposal to add a new LLT Alloplasty is not approved. The term is an ambiguous term and may refer to concepts in psychoanalytic theory as well as alloplastic material used in surgery and as such is not well defined uniformly.

CR Number: 2024110021		Implementation Date: 25-Apr-24	Related CR: 2024110021		MedDRA Code #
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed LLT	Hypocythemia	Rejected			

MSSO Comment: The proposal to add a new LLT Hypocythemia is not approved. Hypocythemia is not a generally used term in medical literature. Please consider existing terms relating to either the specific type of cytopenia, or general term cytopenia depending on your specific scenario.

CR Number: 2024110022		Implementation Date: 25-Apr-24	Related CR: 2024110022		MedDRA Code #
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed LLT	Thoracic disc disease	Approved as Requested	Proposed LLT		
To PT	Intervertebral disc disorder		Thoracic disc disease	10091027	Current
			To PT		
			Intervertebral disc disorder	10061521	

MSSO Comment: The proposal to add a new LLT Thoracic disc disease to PT Intervertebral disc disorder is approved as requested. Thoracic disc disease refers to a condition where the discs between the vertebrae in the thoracic region of the spine deteriorate or become damaged. The proposed term will be added to supplement the specific terms available for the cervical and lumbar spine locations.

# Detail Report

CR Number: 2024112000		Implementation Date: 30-Apr-24	Related CR: 2024112000	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Atypical Stevens-Johnson Syndrome</i>	Approved Not as Requested	Proposed PT <i>Atypical Stevens-Johnson syndrome</i>	10091034
			HLT primary <i>Stomatitis and ulceration</i>	10042129
			SOC primary <i>Gastrointestinal disorders</i>	10017947
			HLT secondary <i>Bullous conditions</i>	10006555
			SOC secondary <i>Skin and subcutaneous tissue disorders</i>	10040785

MSSO Comment: The proposal to add a new LLT Atypical Stevens-Johnson Syndrome is approved but not as requested. Atypical Stevens-Johnson Syndrome (Atypical SJS) is a rare variation of SJS with a complete absence of or only a few cutaneous manifestations. It is usually seen in children infected by M. pneumoniae, but it is also found with other infective pathogens as well as certain drugs. The proposed term will be modified in accordance with MedDRA capitalization standards to PT Atypical Stevens-Johnson syndrome and added to primary HLT Stomatitis and ulceration and to secondary links to HLT Bullous conditions, HLT Inflammatory disorders following infection and HLT Poisoning and toxicity.

CR Number: 2024121003		Implementation Date: 30-Apr-24	Related CR: 2024112000	
<a href="#">Change Requested</a>	Link a PT to a HLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Atypical Stevens-Johnson Syndrome</i>	Approved as Requested	Proposed PT <i>Atypical Stevens-Johnson syndrome</i>	10091034
To HLT	<i>Poisoning and toxicity</i>		To HLT <i>Poisoning and toxicity</i>	10035777

MSSO Comment: Lower case "s" in syndrome

# Detail Report

<b>CR Number:</b> 2024121002		<b>Implementation Date:</b> 30-Apr-24	<b>Related CR:</b> 2024112000	
<a href="#">Change Requested</a>	Link a PT to a HLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Atypical Stevens-Johnson Syndrome</i>	Approved as Requested	Proposed PT	
To HLT	<i>Inflammatory disorders following infection</i>		<i>Atypical Stevens-Johnson syndrome</i>	10091034
			To HLT	
			<i>Inflammatory disorders following infection</i>	10021982

MSSO Comment: Lower case "s" in syndrome

<b>CR Number:</b> 2024112001		<b>Implementation Date:</b> 24-Apr-24	<b>Related CR:</b> 2024112001	
<a href="#">Change Requested</a>	Rename PT/LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Term to modify	<i>Aplasia pure red cell</i>	Rejected		
Replacement term	<i>Pure red cell aplasia</i>			

MSSO Comment: The proposal to rename PT/LLT Aplasia pure red cell to Pure red cell aplasia is not approved. The natural word order for this concept would be Pure red cell aplasia. Inverted word order in many old MedDRA terms was favored to facilitate the adjacency of similar conditions in alphabetic order tabulations. This practice is no longer followed, provided the higher flexibility and retrieval capacity of modern data-bases; however, the MSSO does not commit to turn into natural word order all the concepts which were added in the past favoring the alphabetic order facilitation, because this would overpopulate the terminology and may prompt users to re-code legacy data unnecessarily.

<b>CR Number:</b> 2024113000		<b>Implementation Date:</b> 24-Apr-24	<b>Related CR:</b> 2024113000	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>ARID1A gene mutation</i>	Approved Not as Requested	Proposed PT	
			<i>ARID1A gene mutation</i>	10091033
			HLT primary	
			<i>Gene mutations and other alterations NEC</i>	10083625
			SOC primary	
			<i>Congenital, familial and genetic disorders</i>	10010331

MSSO Comment: The proposal to add a new LLT ARID1A gene mutation is approved but not as requested. Mutations in the AT-interacting domain-rich protein 1A (ARID1A) gene, a critical component of the switch/sucrose nonfermentable (SWI/SNF) complex, are frequently found in most human cancers. Approximately 5–10% of lung cancers carry ARID1A gene mutations. ARID1A gene mutation will be added as a new PT under HLT Gene mutations and other alterations NEC.

# Detail Report

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<b>CR Number:</b> 2024113001		<b>Implementation Date:</b> 25-Apr-24	<b>Related CR:</b> 2024113001	
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Prosthetic aortic valve thrombosis</i>	Approved as Requested	Proposed LLT	
To PT	<i>Prosthetic cardiac valve thrombosis</i>		<i>Prosthetic aortic valve thrombosis</i>	10091040 Current
			To PT	
			<i>Prosthetic cardiac valve thrombosis</i>	10063176
<b>MSSO Comment:</b> The proposal to add a new LLT Prosthetic aortic valve thrombosis to PT Prosthetic cardiac valve thrombosis is approved as requested. Prosthetic valve thrombosis is a rare but serious complication of valve replacement, most often encountered with mechanical prostheses. Valve complication (stenosis/thrombosis) can occur with prosthetic valves in any location but may present with varying clinical manifestations depending on the specific valve involved, necessitating different management and treatment. The possibility of concise coding and data retrieval are important to ensure adequate monitoring and risk management.				

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<b>CR Number:</b> 2024113002		<b>Implementation Date:</b> 30-Apr-24	<b>Related CR:</b> 2024113002	
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Prosthetic mitral valve thrombosis</i>	Approved as Requested	Proposed LLT	
To PT	<i>Prosthetic cardiac valve thrombosis</i>		<i>Prosthetic mitral valve thrombosis</i>	10091036 Current
			To PT	
			<i>Prosthetic cardiac valve thrombosis</i>	10063176
<b>MSSO Comment:</b> The proposal to add a new LLT Prosthetic mitral valve thrombosis to PT Prosthetic cardiac valve thrombosis is approved as requested. Valve complication (stenosis/thrombosis) can occur with prosthetic valves in any location but may present with varying clinical manifestations depending on the specific valve involved, necessitating different management and treatment. The possibility of concise coding and data retrieval are important to ensure adequate monitoring and risk management.				

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<b>CR Number:</b> 2024113003		<b>Implementation Date:</b> 30-Apr-24	<b>Related CR:</b> 2024113003	
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Prosthetic pulmonary valve thrombosis</i>	Approved as Requested	Proposed LLT	
To PT	<i>Prosthetic cardiac valve thrombosis</i>		<i>Prosthetic pulmonary valve thrombosis</i>	10091038 Current
			To PT	
			<i>Prosthetic cardiac valve thrombosis</i>	10063176
<b>MSSO Comment:</b> The proposal to add a new LLT Prosthetic pulmonary valve thrombosis to PT Prosthetic cardiac valve thrombosis is approved as requested. Valve complication (stenosis/thrombosis) can occur with prosthetic valves in any location but may present with varying clinical manifestations depending on the specific valve involved, necessitating different management and treatment. The possibility of concise coding and data retrieval are important to ensure adequate monitoring and risk management. Mechanical prosthetic valves are rarely implanted in the right heart, mainly because of their important thrombogenicity.				

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# Detail Report

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<b>CR Number:</b> 2024113004		<b>Implementation Date:</b> 30-Apr-24	<b>Related CR:</b> 2024113004	
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Prosthetic tricuspid valve thrombosis</i>	Approved as Requested	Proposed LLT	
To PT	<i>Prosthetic cardiac valve thrombosis</i>		<i>Prosthetic tricuspid valve thrombosis</i>	10091041 Current
			To PT	
			<i>Prosthetic cardiac valve thrombosis</i>	10063176

**MSSO Comment:** The proposal to add a new LLT Prosthetic tricuspid valve thrombosis to PT Prosthetic cardiac valve thrombosis is approved as requested. Valve complication (stenosis/thrombosis) can occur with prosthetic valves in any location but may present with varying clinical manifestations depending on the specific valve involved, necessitating different management and treatment. The possibility of concise coding and data retrieval are important to ensure adequate monitoring and risk management. The incidence of right sided prosthetic valve thrombosis is higher than left-sided.

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<b>CR Number:</b> 2024113005		<b>Implementation Date:</b> 25-Apr-24	<b>Related CR:</b> 2024113005	
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Prosthetic pulmonary valve stenosis</i>	Approved as Requested	Proposed LLT	
To PT	<i>Prosthetic cardiac valve stenosis</i>		<i>Prosthetic pulmonary valve stenosis</i>	10091037 Current
			To PT	
			<i>Prosthetic cardiac valve stenosis</i>	10080073

**MSSO Comment:** The proposal to add a new LLT Prosthetic pulmonary valve stenosis to PT Prosthetic cardiac valve stenosis is approved as requested. Valve complication (stenosis/thrombosis) can occur with prosthetic valves in any location but may present with varying clinical manifestations depending on the specific valve involved, necessitating different management and treatment. The possibility of concise coding and data retrieval are important to ensure adequate monitoring and risk management.

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<b>CR Number:</b> 2024113006		<b>Implementation Date:</b> 25-Apr-24	<b>Related CR:</b> 2024113006	
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Prosthetic aortic valve stenosis</i>	Approved as Requested	Proposed LLT	
To PT	<i>Prosthetic cardiac valve stenosis</i>		<i>Prosthetic aortic valve stenosis</i>	10091039 Current
			To PT	
			<i>Prosthetic cardiac valve stenosis</i>	10080073

**MSSO Comment:** The proposal to add a new LLT Prosthetic aortic valve stenosis to PT Prosthetic cardiac valve stenosis is approved as requested. Valve complication (stenosis/thrombosis) can occur with prosthetic valves in any location but may present with varying clinical manifestations depending on the specific valve involved, necessitating different management and treatment. The possibility of concise coding and data retrieval are important to ensure adequate monitoring and risk management.

# Detail Report

<b>CR Number:</b> 2024113007		<b>Implementation Date:</b> 30-Apr-24	<b>Related CR:</b> 2024113007	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Prosthetic mitral valve stenosis</i>	Approved as Requested	Proposed LLT	
To PT	<i>Prosthetic cardiac valve stenosis</i>		<i>Prosthetic mitral valve stenosis</i>	10091042 Current
			To PT	
			<i>Prosthetic cardiac valve stenosis</i>	10080073
<b>MSSO Comment:</b> The proposal to add a new LLT Prosthetic mitral valve stenosis to PT Prosthetic cardiac valve stenosis is approved as requested. Valve complication (stenosis/thrombosis) can occur with prosthetic valves in any location but may present with varying clinical manifestations depending on the specific valve involved, necessitating different management and treatment. The possibility of concise coding and data retrieval are important to ensure adequate monitoring and risk management. For mitral prosthetic valves, a peak transvalvular velocity >2.5 m/s, mean gradient >10 mmHg or pressure half-time >200 ms provides a strong argument for significant obstruction.				

<b>CR Number:</b> 2024113008		<b>Implementation Date:</b> 25-Apr-24	<b>Related CR:</b> 2024113008	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Prosthetic tricuspid valve stenosis</i>	Approved as Requested	Proposed LLT	
To PT	<i>Prosthetic cardiac valve stenosis</i>		<i>Prosthetic tricuspid valve stenosis</i>	10091035 Current
			To PT	
			<i>Prosthetic cardiac valve stenosis</i>	10080073
<b>MSSO Comment:</b> The proposal to add a new LLT Prosthetic tricuspid valve stenosis to PT Prosthetic cardiac valve stenosis is approved as requested. Valve complication (stenosis/thrombosis) can occur with prosthetic valves in any location but may present with varying clinical manifestations depending on the specific valve involved, necessitating different management and treatment. The possibility of concise coding and data retrieval are important to ensure adequate monitoring and risk management.				

<b>CR Number:</b> 2024113009		<b>Implementation Date:</b> 30-Apr-24	<b>Related CR:</b> 2024113009	
<a href="#">Change Requested</a>	Link (move) an LLT to another PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Maxillectomy</i>	Rejected		
From PT	<i>Maxillofacial operation</i>			
To PT	<i>Jaw operation</i>			
<b>MSSO Comment:</b> The proposal to move the LLT Maxillectomy from PT Maxillofacial operation to PT Jaw operation is not approved. Maxillectomy is better placed under the more specific PT Maxillofacial operation. Generally, in common clinical usage, the 'jaw' is used to refer to the mandible. Thus, all mandibular terms are under PT Jaw operation and when referring to maxilla, they are linked to PT Maxillofacial operation.				



# Detail Report

<b>CR Number:</b> 2024113010		<b>Implementation Date:</b> 30-Apr-24	<b>Related CR:</b> 2024113010	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Pain in joint involving foot</i>	Approved Not as Requested	Proposed LLT	
To PT	<i>Arthralgia</i>		<i>Foot joint pain</i>	10091043 Current
			To PT	
			<i>Arthralgia</i>	10003239
<b>MSSO Comment:</b> The proposal to add a new LLT Pain in joint involving foot to PT Arthralgia is approved but not as requested. Foot joint pain can arise from various causes including injury, overuse, arthritis, or structural issues. Symptoms may include discomfort, swelling, stiffness, or limited range of motion. The proposed term will be modified to its natural word order and added as an LLT Foot joint pain to PT Arthralgia.				
<b>CR Number:</b> 2024115004		<b>Implementation Date:</b> 16-May-24	<b>Related CR:</b> 2024115004	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Nonvalvular atrial fibrillation</i>	Approved Not as Requested After Suspension	Proposed LLT	
To PT	<i>Atrial Fibrillation</i>		<i>Nonvalvular atrial fibrillation</i>	10091141 Current
			To PT	
			<i>Atrial fibrillation</i>	10003658
<b>MSSO Comment:</b> The proposal to add a new LLT Nonvalvular atrial fibrillation to PT Atrial Fibrillation is approved but not as requested after suspension. There are two main types of atrial fibrillation: valvular and non-valvular. Nonvalvular atrial fibrillation is atrial fibrillation in the absence of moderate-to-severe mitral stenosis or a mechanical heart valve. Nonvalvular atrial fibrillation will be added as an LLT to the corrected PT Atrial fibrillation.				
<b>CR Number:</b> 2024115005		<b>Implementation Date:</b> 30-Apr-24	<b>Related CR:</b> 2024115005	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Cervical fibroid removal</i>	Approved Not as Requested	Proposed LLT	
			<i>Cervix fibroid removal</i>	10091044 Current
			To PT	
			<i>Cervix tumour excision</i>	10080988
<b>MSSO Comment:</b> The proposal to add a new LLT Cervical fibroid removal is approved but not as requested. Cervical fibroids are benign smooth muscle tumors of the cervix. If the cervical fibroids become symptomatic the treatment is removal. The proposed term will be modified according to MedDRA conventions and added as LLT Cervix fibroid removal to PT Cervix tumour excision.				

# Detail Report

<b>CR Number:</b> 2024115006		<b>Implementation Date:</b> 30-Apr-24	<b>Related CR:</b> 2024115006	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Tenex Procedure</i>	Approved Not as Requested	Proposed LLT <i>Ultrasound-guided percutaneous needle tenotomy</i>	10091045 Current
			To PT <i>Tenotomy</i>	10043263
<b>MSSO Comment:</b> The proposal to add a new LLT Tenex Procedure is approved but not as requested. TENEX™ is a minimally invasive procedure (trademarked) that removes scar tissue from a tendon. It is an ultrasound-guided percutaneous needle tenotomy for treating tendinopathy. Proposed trademark term will not be added as MedDRA conventions do not include proprietary names. Instead, the non-trademark procedure itself which is Ultrasound-guided percutaneous needle tenotomy will be added as LLT under PT Tenotomy.				

<b>CR Number:</b> 2024115009		<b>Implementation Date:</b> 01-May-24	<b>Related CR:</b> 2024115009	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Hyperlipidemia aggravated</i>	Rejected		
To PT	<i>Hyperlipidaemia</i>			
<b>MSSO Comment:</b> The proposal to add a new LLT Hyperlipidemia aggravated to PT Hyperlipidaemia is not approved. The MSSO refrains from adding new terms with a qualifier of aggravation, worsening, or exacerbation unless such a term represents an internationally accepted unique medical concept. Please refer to the MedDRA Term Selection Points to Consider document providing coding approaches in Section 3.9 Modification of Pre-existing Conditions.				

<b>CR Number:</b> 2024115010		<b>Implementation Date:</b> 01-May-24	<b>Related CR:</b> 2024115010	
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Tracheal aspirate culture positive</i>	Approved as Requested	Proposed PT <i>Tracheal aspirate culture positive</i>	10091047
HLT primary	<i>Microbiology and serology tests NEC</i>		HLT primary <i>Microbiology and serology tests NEC</i>	10027530
SOC primary	<i>Investigations</i>		SOC primary <i>Investigations</i>	10022891
<b>MSSO Comment:</b> The proposal to add a new PT Tracheal aspirate culture positive to primary HLT Microbiology and serology tests NEC in SOC Investigations is approved as requested. A tracheal aspirate culture is a test performed to identify any bacteria, fungi, or viruses present in the tracheal secretions of a patient. The proposed term will be added as the positive result in addition to the existing non-qualified test term name. In a related change the negative test result will also be added as PT Tracheal aspirate culture negative to HLT Microbiology and serology tests NEC as requested in the initial justification.				

# Detail Report

<b>CR Number:</b> 2024122001		<b>Implementation Date:</b> 01-May-24	<b>Related CR:</b> 2024115010	
<u>Change Requested</u>	Add a New PT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Tracheal aspirate culture negative	Approved as Requested	Proposed PT	
HLT primary	Microbiology and serology tests NEC		Tracheal aspirate culture negative	10091053
SOC primary	Investigations		HLT primary	
			Microbiology and serology tests NEC	10027530
			SOC primary	
			Investigations	10022891

MSSO  
Comment:

<b>CR Number:</b> 2024115011		<b>Implementation Date:</b> 01-May-24	<b>Related CR:</b> 2024115011	
<u>Change Requested</u>	Add a New PT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Ureter biopsy normal	Approved as Requested	Proposed PT	
HLT primary	Urinary tract histopathology procedures		Ureter biopsy normal	10091046
SOC primary	Investigations		HLT primary	
			Urinary tract histopathology procedures	10046569
			SOC primary	
			Investigations	10022891

MSSO  
Comment: The proposal to add a new PT Ureter biopsy normal to primary HLT Urinary tract histopathology procedures in SOC Investigations is approved as requested. A ureter biopsy is a medical procedure in which a small sample of tissue is taken from the ureter for microscopic examination. The proposed term will be added as the normal qualified counterpart term to existing PT Ureter biopsy. In a related change, Ureter biopsy abnormal will also be added as PT to HLT Urinary tract histopathology procedures representing the abnormal qualified counterpart term as requested in the initial justification.

# Detail Report

<b>CR Number:</b> 2024122002		<b>Implementation Date:</b> 01-May-24	<b>Related CR:</b> 2024115011		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed PT	<i>Ureter biopsy abnormal</i>	Approved as Requested	Proposed PT		
HLT primary	<i>Urinary tract histopathology procedures</i>		<i>Ureter biopsy abnormal</i>		10091054
SOC primary	<i>Investigations</i>		HLT primary		
			<i>Urinary tract histopathology procedures</i>		10046569
			SOC primary		
			<i>Investigations</i>		10022891

MSSO  
Comment:

<b>CR Number:</b> 2024115012		<b>Implementation Date:</b> 01-May-24	<b>Related CR:</b> 2024115012		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed PT	<i>Ultrasound liver elastography</i>	Approved as Requested	Proposed PT		
HLT primary	<i>Hepatobiliary imaging procedures</i>		<i>Ultrasound liver elastography</i>		10091050
SOC primary	<i>Investigations</i>		HLT primary		
			<i>Hepatobiliary imaging procedures</i>		10019808
			SOC primary		
			<i>Investigations</i>		10022891

MSSO  
Comment: The proposal to add a new PT Ultrasound liver elastography to primary HLT Hepatobiliary imaging procedures in SOC Investigations is approved as requested. Ultrasound liver elastography is a non-invasive imaging technique used to assess the stiffness or elasticity of liver tissue. It is particularly useful in diagnosing liver conditions such as fibrosis and cirrhosis. There are different methods of liver elastography, including transient elastography and vibration-controlled transient elastography. In a related change, PT Transient elastography will be demoted under new PT Ultrasound liver elastography.

<b>CR Number:</b> 2024122003		<b>Implementation Date:</b> 01-May-24	<b>Related CR:</b> 2024115012		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Demote a PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
PT to merge	<i>Transient elastography</i>	Approved as Requested	PT to merge		
To PT	<i>Ultrasound liver elastography</i>		<i>Transient elastography</i>		10070321 Current
			To PT		
			<i>Ultrasound liver elastography</i>		10091050

MSSO  
Comment:

# Detail Report

<b>CR Number:</b> 2024115013		<b>Implementation Date:</b> 01-May-24	<b>Related CR:</b> 2024115013	
<u>Change Requested</u>	Add a New PT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Chronic prostatitis/chronic pelvic pain syndrome (CP/CPPS)	Approved Not as Requested	Proposed PT	
			Chronic prostatitis/chronic pelvic pain syndrome	10091051
			HLT primary	
			Reproductive tract signs and symptoms NEC	10040674
			SOC primary	
			Reproductive system and breast disorders	10038604
			HLT secondary	
			Urinary tract signs and symptoms NEC	10046591
			SOC secondary	
			Renal and urinary disorders	10038359

**MSSO Comment:** The proposal to add a new PT Chronic prostatitis/chronic pelvic pain syndrome (CP/CPPS) is approved but not as requested. Chronic prostatitis/chronic pelvic pain syndrome is a clinical syndrome in males defined by pain or discomfort in the pelvic region, often accompanied by urologic symptoms or sexual dysfunction. Despite the use of the term "prostatitis," it is unclear to what degree the prostate is the source of symptoms. Chronic prostatitis/chronic pelvic pain syndrome will be added as a PT to primary HLT Reproductive tract signs and symptoms NEC and to secondary HLT Urinary tract signs and symptoms NEC.

<b>CR Number:</b> 2024115014		<b>Implementation Date:</b> 01-May-24	<b>Related CR:</b> 2024115014	
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Amyopathic dermatomyositis	Approved as Requested	Proposed LLT	
To PT	Dermatomyositis		Amyopathic dermatomyositis	10091057 Current
			To PT	
			Dermatomyositis	10012503

**MSSO Comment:** The proposal to add a new LLT Amyopathic dermatomyositis to PT Dermatomyositis is approved as requested. Amyopathic dermatomyositis is a form of dermatomyositis characterized by the presence of typical skin findings without muscle weakness.

# Detail Report

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<b>CR Number:</b> 2024115015		<b>Implementation Date:</b> 01-May-24	<b>Related CR:</b> 2024115015	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Total rhinectomy	Approved as Requested	Proposed LLT	
To PT	Rhinectomy		Total rhinectomy	10091058 Current
			To PT	
			Rhinectomy	10075071

**MSSO Comment:** The proposal to add a new LLT Total rhinectomy to PT Rhinectomy is approved as requested. Total rhinectomy is an uncommon procedure for the treatment of nasal malignancies, usually reserved for locally advanced tumors.

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<b>CR Number:</b> 2024115016		<b>Implementation Date:</b> 01-May-24	<b>Related CR:</b> 2024115016	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Partial rhinectomy	Approved as Requested	Proposed LLT	
To PT	Rhinectomy		Partial rhinectomy	10091059 Current
			To PT	
			Rhinectomy	10075071

**MSSO Comment:** The proposal to add a new LLT Partial rhinectomy to PT Rhinectomy is approved as requested. A rhinectomy is the surgical removal of the nose. If only part of the nose is removed it is called a partial rhinectomy, while entire nose removal is called a total rhinectomy.

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<b>CR Number:</b> 2024115017		<b>Implementation Date:</b> 01-May-24	<b>Related CR:</b> 2024115017	
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Traumatic skin ulcer	Rejected		

**MSSO Comment:** The proposal to add a new PT Traumatic skin ulcer is not approved. In order to avoid over-granularity at PT level it is not possible to have a "traumatic" counterpart for every anatomic site ulcer term. Please refer to Section 3.5 of the MedDRA Term Selection: Points to Consider Document regarding coding approaches/considerations.

# Detail Report

<b>CR Number:</b> 2024115018		<b>Implementation Date:</b> 01-May-24	<b>Related CR:</b> 2024115018	
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Gastric occult blood</i>	Approved Not as Requested	Proposed PT	
			<i>Gastric occult blood test</i>	10091052
			HLT primary	
			<i>Gastrointestinal histopathology procedures</i>	10017962
			SOC primary	
			<i>Investigations</i>	10022891

**MSSO Comment:** The proposal to add a new PT Gastric occult blood is approved but not as requested. A gastric occult blood test is used for detecting the presence of occult blood in gastric aspirate or vomitus. Analysis of gastric content can aid physicians in diagnosing and treating a number of conditions. After reconsideration, the proposed term will be modified for clarity and added as new PT Gastric occult blood test under HLT Gastrointestinal histopathology procedures. In a related change, the negative counterpart will also be added as new PT Gastric occult blood test negative under HLT Gastrointestinal histopathology procedures.

<b>CR Number:</b> 2024122004		<b>Implementation Date:</b> 01-May-24	<b>Related CR:</b> 2024115018	
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Gastric occult blood test negative</i>	Approved as Requested	Proposed PT	
HLT primary	<i>Gastrointestinal histopathology procedures</i>		<i>Gastric occult blood test negative</i>	10091055
SOC primary	<i>Investigations</i>		HLT primary	
			<i>Gastrointestinal histopathology procedures</i>	10017962
			SOC primary	
			<i>Investigations</i>	10022891

**MSSO Comment:**

<b>CR Number:</b> 2024115019		<b>Implementation Date:</b> 01-May-24	<b>Related CR:</b> 2024115019	
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Photoradiotherapy</i>	Approved Not as Requested	Proposed LLT	
			<i>Photoradiation therapy</i>	10091056 Current
			To PT	
			<i>Photodynamic therapy</i>	10034942

**MSSO Comment:** The proposal to add a new PT Photoradiotherapy is approved but not as requested. Photoradiation therapy is achieved when a photosensitizing drug is activated by light to form products that are lethal to tumor cells. The most commonly used drug is hematoporphyrin derivative, which is preferentially taken up and retained by malignant tissue. Proposed term will be modified to the most commonly referenced nomenclature and added as LLT Photoradiation therapy under PT Photodynamic therapy.

# Detail Report

<b>CR Number:</b> 2024115020		<b>Implementation Date:</b> 01-May-24	<b>Related CR:</b> 2024115020		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed Term	Cancer anorexia	Rejected			

**MSSO Comment:** The proposal to add a new term Cancer anorexia is not approved. The proposed term combines a medical concept with additional medical wording related to etiology and/or pathophysiology. Section 3.5 of the MedDRA Term Selection Points to Consider (MTS:PTC) document defines these as "combination terms" and provides coding guidance. When considering the addition of such combination terms, MedDRA generally attempts to limit inclusion to those terms which describe important, distinct and robust medical concepts which are internationally recognized diagnostic entities. Examples include terms such as diabetic retinopathy, hypertensive cardiomegaly and eosinophilic pneumonia.

<b>CR Number:</b> 2024115021		<b>Implementation Date:</b> 01-May-24	<b>Related CR:</b> 2024115021		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed LLT	Exposure to communicable disease during pregnancy	Rejected			
To PT	Exposure during pregnancy				

**MSSO Comment:** The proposal to add a new LLT Exposure to communicable disease during pregnancy to PT Exposure during pregnancy is not approved. This is a multiple concept term which can be coded using more than one MedDRA term. Section 3.5 of the MedDRA Term Selection Points to Consider (MTS:PTC) document defines "combination terms". Depending on your scenario, please consider PT Exposed to maternal infection in utero added in change request 2024057002 added for version 27.1.

<b>CR Number:</b> 2024115022		<b>Implementation Date:</b> 01-May-24	<b>Related CR:</b> 2024115022		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed PT	Intestinal neoplasm surgery	Approved as Requested	Proposed PT		
			Intestinal neoplasm surgery		10091049
			HLT primary		
			Gastrointestinal therapeutic procedures NEC		10018013
			SOC primary		
			Surgical and medical procedures		10042613

**MSSO Comment:** The proposal to add a new PT Intestinal neoplasm surgery is approved as requested. Surgery is one of the main treatments for intestinal neoplasms. In some cases, it might be the only treatment from which to expect a curative outcome of an intestinal cancer. Intestinal neoplasm surgery will be added as a PT to HLT Gastrointestinal therapeutic procedures NEC.



# Detail Report

<b>CR Number:</b> 2024115023		<b>Implementation Date:</b> 01-May-24	<b>Related CR:</b> 2024115023		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed PT	<i>Large intestinal neoplasm surgery</i>	Rejected			

**MSSO Comment:** The proposal to add a new PT Large intestinal neoplasm surgery is not approved. The proposed term combines a medical concept with additional medical wording related to etiology and/or pathophysiology. Section 3.5 of the MedDRA Term Selection Points to Consider (MTS:PTC) document defines these as "combination terms" and provides coding guidance. When considering the addition of such combination terms, MedDRA generally attempts to limit inclusion to those terms which describe important, distinct and robust medical concepts which are internationally recognized diagnostic entities. Examples include terms such as diabetic retinopathy, hypertensive cardiomegaly and eosinophilic pneumonia. The proposed concept can be represented by existing MedDRA terms, including the PT Intestinal neoplasm surgery added in change request 2024115022, in association with the type of neoplasm.

<b>CR Number:</b> 2024115024		<b>Implementation Date:</b> 01-May-24	<b>Related CR:</b> 2024115024		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed LLT	<i>Pressure ulcer treatment</i>	Approved Not as Requested	Proposed PT		
To PT	<i>Wound treatment</i>		<i>Decubitus ulcer treatment</i>		10091048
			HLT primary		
			<i>Skin and subcutaneous tissue therapeutic procedures NEC</i>		10040794
			SOC primary		
			<i>Surgical and medical procedures</i>		10042613

**MSSO Comment:** The proposal to add a new LLT Pressure ulcer treatment to PT Wound treatment is approved but not as requested. Generally, pressure injuries are cleaned with saline or saltwater to remove dead tissue. The injury may also be covered with a special bandage or the use of special dressings and therapies that speed up skin healing. In some cases, surgery is required to remove the dead tissue. The proposed term will be renamed to the most frequently used concept in literature and added as PT Decubitus ulcer treatment to HLT Skin and subcutaneous tissue therapeutic procedures NEC.

# Detail Report

<b>CR Number:</b> 2024115025		<b>Implementation Date:</b> 01-May-24	<b>Related CR:</b> 2024115025		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed PT	<i>Increased lower respiratory tract secretion</i>	Rejected			

**MSSO Comment:** The proposal to add a new PT Increased lower respiratory tract secretion is not approved. The requested concept can be represented by PT Increased bronchial secretion or any of its LLTs, including LLT Airway secretion excessive. When the level of the respiratory tract is not specified (such as in LLT Airway secretion excessive) it is generally used in the context of lower respiratory conditions (as seen by link to HLT Lower respiratory tract signs and symptoms), such as COPD, asthma or lower respiratory infections. Secretions resulting from conditions in the upper respiratory tract are better represented with terms qualified with anatomical location, such as PT Increased upper airway secretion or LLT Throat secretion increased. In addition, please consider resubmitting the second part ("tracheal" codes) of your change request as a complex change request for MedDRA 28.0 in relation to HLT Tracheal disorders (excl infections and neoplasms).

<b>CR Number:</b> 2024116000		<b>Implementation Date:</b> 02-May-24	<b>Related CR:</b> 2024116000		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed LLT	<i>Hernia of the loins</i>	Rejected			

**MSSO Comment:** The proposal to add a new LLT Hernia of the loins is not approved. The loin, also called regio lumbalis, is a broad region typically referring to the part of the body between the lower ribs and the pelvis. It is often associated with the lower back and upper hips. Hernias in the loin region are not generally referred as such in scientific medical literature. The provided reference equating spinal disc herniation with hernia of the loins is considered colloquial and not following general English language use.

<b>CR Number:</b> 2024116001		<b>Implementation Date:</b> 02-May-24	<b>Related CR:</b> 2024116001		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed LLT	<i>Chronic Kidney Disease–Associated Pruritus</i>	Approved Not as Requested	Proposed LLT		
To PT	<i>Chronic kidney disease</i>		<i>Chronic kidney disease-associated pruritus</i>	10091062	
			To PT		
			<i>Uraemic pruritus</i>	10060875	Current

**MSSO Comment:** The proposal to add a new LLT Chronic Kidney Disease-Associated Pruritus to PT Chronic kidney disease is approved but not as requested. Pruritus is a common symptom among patients on maintenance dialysis that in many cases substantially impairs quality of life. Although often referred to as "uremic pruritus," the itching in this setting often occurs in adequately dialyzed patients or, in patients not on dialysis, in the absence of other symptoms associated with uremia. Thus, the preferred term is chronic kidney disease-associated pruritus. The proposed term will be modified according to MedDRA capitalization rules and added as LLT Chronic kidney disease-associated pruritus to PT Uraemic pruritus. In a related change, PT Uraemic pruritus will be swapped with newly added LLT Chronic kidney disease-associated pruritus.

# Detail Report

CR Number: 2024123001		Implementation Date: 02-May-24	Related CR: 2024116001		
<a href="#">Change Requested</a>	Swap a PT with an LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed PT	<i>Uraemic pruritus</i>	Approved as Requested	Proposed PT		
With LLT	<i>Chronic kidney disease-associated pruritus</i>		<i>Uraemic pruritus</i>	10060875	Current
			With LLT		
			<i>Chronic kidney disease-associated pruritus</i>	10091062	

MSSO  
Comment:

CR Number: 2024116002		Implementation Date: 02-May-24	Related CR: 2024116002		
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed LLT	<i>Actinomyces bacteremia</i>	Approved as Requested	Proposed LLT		
			<i>Actinomyces bacteremia</i>	10091068	Current
			To PT		
			<i>Actinomyces bacteraemia</i>	10091066	

MSSO  
Comment: The proposal to add a new LLT Actinomyces bacteremia is approved as requested. Actinomycosis is an uncommon, chronic granulomatous disease caused by filamentous, gram-positive, anaerobic bacteria. Actinomycetes are commensal inhabitants of the oral cavity and intestinal tract but acquire pathogenicity through invasion. Actinomyces bacteremia will be added as LLT to a new PT Actinomyces bacteraemia added with British English spelling in a related change under HLT Actinomycotic infectious disorders.

CR Number: 2024123003		Implementation Date: 02-May-24	Related CR: 2024116002		
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed PT	<i>Actinomyces bacteraemia</i>	Approved as Requested	Proposed PT		
HLT primary	<i>Actinomycotic infectious disorders</i>		<i>Actinomyces bacteraemia</i>	10091066	
SOC primary	<i>Infections and infestations</i>		HLT primary		
			<i>Actinomycotic infectious disorders</i>	10000627	
			SOC primary		
			<i>Infections and infestations</i>	10021881	

MSSO  
Comment:

# Detail Report

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<b>CR Number:</b> 2024116003		<b>Implementation Date:</b> 02-May-24	<b>Related CR:</b> 2024116003	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	CT-CAP	Approved Not as Requested	Proposed LLT CT of chest, abdomen and pelvis	10091071 Current
			To PT Computerised tomogram	10010234

**MSSO Comment:** The proposal to add a new LLT CT-CAP is approved but not as requested. CT scans of the chest, abdomen, and pelvis are commonly used for various diagnostic purposes, including cancer staging and trauma diagnosis. After reconsideration, the concept will be added, however the proposed term will be modified to a partially spelled out version and added as LLT CT of chest, abdomen and pelvis to PT Computerised tomogram aligned with LLT Whole body CAT.

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<b>CR Number:</b> 2024116004		<b>Implementation Date:</b> 02-May-24	<b>Related CR:</b> 2024116004	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Satellite tumor	Approved as Requested	Proposed LLT Satellite tumor	10091069 Current
			To PT Neoplasm	10028980

**MSSO Comment:** The proposal to add a new LLT Satellite tumor is approved as requested. A satellite tumor is a minor, or attendant, tumor situated near a larger one. Although the development of satellite tumors suggests that the cancer has become more aggressive and has the ability to invade surrounding areas and therefore commonly occur in the context of advanced or metastatic cancer, satellite tumors can also occur in benign conditions. Satellite tumor and its British English spelled counterpart Satellite tumour will both be added as LLTs to PT Neoplasm.

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<b>CR Number:</b> 2024123004		<b>Implementation Date:</b> 02-May-24	<b>Related CR:</b> 2024116004	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Satellite tumour	Approved as Requested	Proposed LLT Satellite tumour	10091067 Current
To PT	Neoplasm		To PT Neoplasm	10028980

**MSSO Comment:**

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# Detail Report

<b>CR Number:</b> 2024116005		<b>Implementation Date:</b> 02-May-24	<b>Related CR:</b> 2024116005		
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed LLT	Satellite lesion	Rejected			

**MSSO** The proposal to add a new LLT Satellite lesion is not approved. A "satellite lesion" typically refers to a secondary lesion that develops near or adjacent to a primary lesion.  
**Comment:** Generally, a broad "lesion" term only adds an additional imprecise term to existing "disorder" concepts and the MSSO generally refrains from adding new unspecific lesion concepts.

<b>CR Number:</b> 2024116006		<b>Implementation Date:</b> 02-May-24	<b>Related CR:</b> 2024116006		
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed LLT	PITUITARY ADENOMA removal	Approved Not as Requested	Proposed LLT Pituitary adenoma removal	10091070	Current
			To PT Pituitary tumour removal	10035108	

**MSSO** The proposal to add a new LLT PITUITARY ADENOMA removal is approved but not as requested. A pituitary adenoma is a non-cancerous tumor that develops in the pituitary gland. Depending on its size and location, it can cause hormonal imbalances and exert pressure on nearby structures in the brain. It can be removed through a surgical procedure. The proposed term will be modified for MedDRA capitalization rules and added as LLT Pituitary adenoma removal to PT Pituitary tumour removal.

<b>CR Number:</b> 2024116007		<b>Implementation Date:</b> 01-May-24	<b>Related CR:</b> 2024116007		
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed LLT	MIXED VENOUS BLOOD GASOMETRY	Rejected			

**MSSO** The proposal to add a new LLT MIXED VENOUS BLOOD GASOMETRY is not approved. The requested term is available as LLT Mixed venous blood saturation under PT Venous oxygen saturation.

# Detail Report

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<b>CR Number:</b> 2024116008		<b>Implementation Date:</b> 02-May-24	<b>Related CR:</b> 2024116008		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed LLT	<i>IFOBT test</i>	Rejected			

**MSSO Comment:** The proposal to add a new LLT IFOBT test is not approved. The proposed term can be represented by existing LLT Faecal immunochemical test under PT Occult blood.

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<b>CR Number:</b> 2024116013		<b>Implementation Date:</b> 02-May-24	<b>Related CR:</b> 2024116013		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed PT	<i>Pericardiodesis</i>	Approved as Requested	Proposed PT <i>Pericardiodesis</i>		10091072
			HLT primary <i>Cardiac therapeutic procedures NEC</i>		10027660
			SOC primary <i>Surgical and medical procedures</i>		10042613

**MSSO Comment:** The proposal to add a new PT Pericardiodesis is approved as requested. Pericardiodesis is a procedure performed to obliterate the pericardial space by means of induced pericardial sclerosis in order to prevent recurrent pericardial effusions. Pericardiodesis will be added as a new PT to HLT Cardiac therapeutic procedures NEC.

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<b>CR Number:</b> 2024116015		<b>Implementation Date:</b> 02-May-24	<b>Related CR:</b> 2024116015		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed PT	<i>Labia swelling</i>	Approved Not as Requested	Proposed LLT <i>Labia swelling</i>		10091073 Current
HLT primary	<i>Vulvovaginal signs and symptoms</i>		To PT <i>Vulvovaginal swelling</i>		10071211
SOC primary	<i>Reproductive system and breast disorders</i>				

**MSSO Comment:** The proposal to add a new PT Labia swelling to primary HLT Vulvovaginal signs and symptoms in SOC Reproductive system and breast disorders is approved but not as requested. Swelling of the labia may be a sign of an infection, an imbalance of vaginal bacteria, or allergy. Labia swelling will be added as sub-concept LLT under PT Vulvovaginal swelling.

# Detail Report

CR Number: 2024116016		Implementation Date: 02-May-24	Related CR: 2024116016		
<a href="#">Change Requested</a>	Rename PT/LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Term to modify	<i>Skin candida</i>	Rejected			
Replacement term	<i>Skin candidiasis</i>				

MSSO Comment: The proposal to rename PT/LLT Skin candida to Skin candidiasis is not approved. The use of the name of the genus (Candida) in association with a concrete anatomical region or system can be understood as an infection. The use of the Genus name and anatomic site versus the site and "candidiasis" term are used interchangeably in medical literature and thus also in MedDRA.

CR Number: 2024117000		Implementation Date: 02-May-24	Related CR: 2024117000		
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed Term	<i>Cervicothoracic wound dehiscence</i>	Rejected			

MSSO Comment: The proposal to add a new term Cervicothoracic wound dehiscence is not approved. To avoid the overpopulation of MedDRA the MSSO refrains from adding an anatomically qualified term for every procedural complication.

# Detail Report

<b>CR Number:</b> 2024117001		<b>Implementation Date:</b> 02-May-24	<b>Related CR:</b> 2024117001	
<u>Change Requested</u>	Add a New PT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Saccadic eye movement disorder</i>	Approved as Requested	Proposed PT	
HLT primary	<i>Coordination and balance disturbances</i>		<i>Saccadic eye movement disorder</i>	10091076
SOC primary	<i>Nervous system disorders</i>		HLT primary	
			<i>Coordination and balance disturbances</i>	10072984
			SOC primary	
			<i>Nervous system disorders</i>	10029205
			HLT secondary	
			<i>Ocular nerve and muscle disorders</i>	10030059
			SOC secondary	
			<i>Eye disorders</i>	10015919

**MSSO Comment:** The proposal to add a new PT Saccadic eye movement disorder to primary HLT Coordination and balance disturbances in SOC Nervous system disorders and secondary HLT Ocular nerve and muscle disorders in SOC Eye disorders is approved as requested. New PT Saccadic eye movement disorder will be added to clarify the concept as a disorder versus the existing term PT Saccadic eye movement which could be interpreted as normal saccadic eye movement. LLT/PT Saccadic eye movement will be made non-current in change request 2024117003.

<b>CR Number:</b> 2024117002		<b>Implementation Date:</b> 02-May-24	<b>Related CR:</b> 2024117002	
<u>Change Requested</u>	Demote a PT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
PT to merge	<i>Saccadic eye movement</i>	Approved as Requested	PT to merge	
To PT	<i>Saccadic eye movement disorder</i>		<i>Saccadic eye movement</i>	10053694 Non-Current
			To PT	
			<i>Saccadic eye movement disorder</i>	10091076

**MSSO Comment:** The proposal to demote the PT Saccadic eye movement under PT Saccadic eye movement disorder is approved as requested. Existing PT Saccadic eye movement could be interpreted as normal saccadic eye movement and therefore, will be demoted under newly added PT Saccadic eye movement disorder. In a related change, existing LLT Deficiencies of saccadic eye movements will be moved from PT Eye movement disorder to the new PT Saccadic eye movement disorder.



# Detail Report

CR Number: 2024123005		Implementation Date: 02-May-24	Related CR: 2024117002	
<a href="#">Change Requested</a>	Link (move) an LLT to another PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Deficiencies of saccadic eye movements	Approved as Requested	Proposed LLT	
From PT	Eye movement disorder		Deficiencies of saccadic eye movements	10012127 Non-Current
To PT	Saccadic eye movement disorder		From PT	
			Eye movement disorder	10061129
			To PT	
			Saccadic eye movement disorder	10091076

MSSO  
Comment:

CR Number: 2024117003		Implementation Date: 02-May-24	Related CR: 2024117003	
<a href="#">Change Requested</a>	Change Status of LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
LLT to change	Saccadic eye movement	Approved as Requested	LLT to change	
Status	non-current		Saccadic eye movement	10053694 Non-Current
			Status	
			non-current	

MSSO  
Comment: The proposal to change status of LLT Saccadic eye movement to non-current is approved as requested. Saccadic eye movement could be interpreted as normal saccadic eye movement verses a disorder. Therefore, a change in status to non-current is warranted.

# Detail Report

<b>CR Number:</b> 2024117004		<b>Implementation Date:</b> 01-May-24	<b>Related CR:</b> 2024117004	
<u>Change Requested</u>	Promote an LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Menopausal acne</i>	Approved as Requested	Proposed LLT	
From PT	<i>Acne</i>		<i>Menopausal acne</i>	10090033
HLT primary	<i>Acnes</i>		From PT	
			<i>Acne</i>	10000496
			HLT primary	
			<i>Acnes</i>	10000497
			SOC primary	
			<i>Skin and subcutaneous tissue disorders</i>	10040785
			HLT secondary	
			<i>Menopausal effects NEC</i>	10027299
			SOC secondary	
			<i>Reproductive system and breast disorders</i>	10038604

**MSSO Comment:** The proposal to promote the LLT Menopausal acne from PT Acne to primary HLT Acnes in SOC Skin and subcutaneous tissue disorders and secondary HLT Menopausal effects NEC in SOC Reproductive system and breast disorders is approved as requested to better capture the 'menopausal' aspects of the concept, Menopausal acne.

<b>CR Number:</b> 2024117005		<b>Implementation Date:</b> 01-May-24	<b>Related CR:</b> 2024117005	
<u>Change Requested</u>	Promote an LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Electrocardiogram ST-T change</i>	Approved as Requested	Proposed LLT	
From PT	<i>Electrocardiogram ST-T segment abnormal</i>		<i>Electrocardiogram ST-T change</i>	10061117
HLT primary	<i>ECG investigations</i>		From PT	
			<i>Electrocardiogram ST-T segment abnormal</i>	10052333
			HLT primary	
			<i>ECG investigations</i>	10053104
			SOC primary	
			<i>Investigations</i>	10022891

**MSSO Comment:** The proposal to promote the LLT Electrocardiogram ST-T change from PT Electrocardiogram ST-T segment abnormal to primary HLT ECG investigations in SOC Investigations is approved as requested because a change in ST-T segment is not necessarily abnormal.

# Detail Report

<b>CR Number:</b> 2024117006		<b>Implementation Date:</b> 01-May-24	<b>Related CR:</b> 2024117006	
<u>Change Requested</u>	Link (move) an LLT to another PT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>ECG Nonspecific ST-T change</i>	Approved as Requested	Proposed LLT	
From PT	<i>Electrocardiogram ST-T segment abnormal</i>		<i>ECG Nonspecific ST-T change</i>	10057502 Current
To PT	<i>Electrocardiogram ST-T change</i>		From PT	
			<i>Electrocardiogram ST-T segment abnormal</i>	10052333
			To PT	
			<i>Electrocardiogram ST-T change</i>	10061117
<b>MSSO Comment:</b> The proposal to move the LLT ECG Nonspecific ST-T change from PT Electrocardiogram ST-T segment abnormal to PT Electrocardiogram ST-T change is approved as requested. A change in ST-T segment is not necessarily abnormal, therefore, LLT ECG Nonspecific ST-T change will be moved to newly promoted PT Electrocardiogram ST-T change.				

<b>CR Number:</b> 2024117007		<b>Implementation Date:</b> 01-May-24	<b>Related CR:</b> 2024117007	
<u>Change Requested</u>	Link (move) an LLT to another PT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Electrocardiogram ST-T change NOS</i>	Approved as Requested	Proposed LLT	
From PT	<i>Electrocardiogram ST-T segment abnormal</i>		<i>Electrocardiogram ST-T change NOS</i>	10050179 Current
To PT	<i>Electrocardiogram ST-T change</i>		From PT	
			<i>Electrocardiogram ST-T segment abnormal</i>	10052333
			To PT	
			<i>Electrocardiogram ST-T change</i>	10061117
<b>MSSO Comment:</b> The proposal to move the LLT Electrocardiogram ST-T change NOS from PT Electrocardiogram ST-T segment abnormal to PT Electrocardiogram ST-T change is approved as requested. A change in ST-T segment is not necessarily abnormal, therefore, LLT Electrocardiogram ST-T change NOS will be moved to newly promoted PT Electrocardiogram ST-T change.				

# Detail Report

CR Number: 2024117008		Implementation Date: 02-May-24	Related CR: 2024117008	
<u>Change Requested</u>	Add a New PT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Uterine cervix agenesis</i>	Approved as Requested	Proposed PT	
HLT primary	<i>Female reproductive tract disorders congenital</i>		<i>Uterine cervix agenesis</i>	10091075
SOC primary	<i>Congenital, familial and genetic disorders</i>		HLT primary	
			<i>Female reproductive tract disorders congenital</i>	10016416
			SOC primary	
			<i>Congenital, familial and genetic disorders</i>	10010331
			HLT secondary	
			<i>Congenital female reproductive tract disorders</i>	10010446
			SOC secondary	
			<i>Reproductive system and breast disorders</i>	10038604

**MSSO Comment:** The proposal to add a new PT Uterine cervix agenesis to primary HLT Female reproductive tract disorders congenital in SOC Congenital, familial and genetic disorders and secondary HLT Congenital female reproductive tract disorders in SOC Reproductive system and breast disorders is approved as requested. To avoid potential ambiguity between the neck verses the cervix with existing term "cervical agenesis", the MSSO proposes to add new PT Uterine cervix agenesis to primary to HLT Female reproductive tract disorders congenital, secondary to HLT Congenital female reproductive tract disorders. See related change requests in this batch to demote existing PT Cervical agenesis to an LLT under newly proposed PT Uterine cervix agenesis and change its status to non-current.

CR Number: 2024117009		Implementation Date: 02-May-24	Related CR: 2024117009	
<u>Change Requested</u>	Demote a PT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
PT to merge	<i>Cervical agenesis</i>	Approved as Requested	PT to merge	
To PT	<i>Uterine cervix agenesis</i>		<i>Cervical agenesis</i>	10090480 Non-Current
			To PT	
			<i>Uterine cervix agenesis</i>	10091075

**MSSO Comment:** The proposal to demote the PT Cervical agenesis under PT Uterine cervix agenesis is approved as requested. To avoid potential ambiguity between the neck verses the cervix with existing term "cervical agenesis", the MSSO proposes to demote existing PT Cervical agenesis to an LLT under new PT Uterine cervix agenesis. See related change requests in this batch to add new PT Uterine cervix agenesis and change the status of demoted PT Cervical agenesis to non-current.

# Detail Report

<b>CR Number:</b> 2024117010		<b>Implementation Date:</b> 02-May-24	<b>Related CR:</b> 2024117010	
<a href="#">Change Requested</a>	Change Status of LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
LLT to change	<i>Cervical agenesis</i>	Approved as Requested	LLT to change	
Status	<i>non-current</i>		<i>Cervical agenesis</i>	10090480 Non-Current
			Status	
			<i>non-current</i>	

**MSSO Comment:** The proposal to change status of LLT Cervical agenesis to non-current is approved as requested. To avoid potential ambiguity between the neck verses the cervix with existing term "cervical agenesis", the MSSO proposes change the status of LLT Cervical agenesis to non-current. See related changes in this batch to add new PT Uterine cervix agenesis and demote existing PT Cervical agenesis to an LLT under new PT Uterine cervix agenesis.

<b>CR Number:</b> 2024117011		<b>Implementation Date:</b> 01-May-24	<b>Related CR:</b> 2024117011	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Refetoff syndrome</i>	Approved as Requested	Proposed LLT	
To PT	<i>Resistance to thyroid hormone</i>		<i>Refetoff syndrome</i>	10091074 Current
			To PT	
			<i>Resistance to thyroid hormone</i>	10090554

**MSSO Comment:** The proposal to add a new LLT Refetoff syndrome to PT Resistance to thyroid hormone is approved as requested. In some cases, patients have syndromes of hypothyroidism despite high thyroid hormone levels. Thyroid hormone resistance (also called Refetoff syndrome) describes a rare syndrome in which the thyroid hormone levels are elevated but the thyroid stimulating hormone level is not suppressed, or not completely suppressed as would be expected.

<b>CR Number:</b> 2024117012		<b>Implementation Date:</b> 01-May-24	<b>Related CR:</b> 2024117012	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Streptococcal nephropathy</i>	Rejected		

**MSSO Comment:** The proposal to add a new term Streptococcal nephropathy is not approved. The term is represented by existing PT Post streptococcal glomerulonephritis. If this term does not meet your specific needs, please consider Section 3.8 of the MedDRA Term Selection: Points to Consider document for coding of Location-Specific vs. Microorganism-Specific Infection.

# Detail Report

CR Number: 2024120000		Implementation Date: 02-May-24	Related CR: 2024120000	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	13C urea breath test	Approved as Requested	Proposed LLT 13C urea breath test	10091064 Current
			To PT Helicobacter test	10070400
<div>MSSO</div> <div>Comment:</div> <div>The proposal to add a new LLT 13C urea breath test is approved as requested. Even though the 14C-UBT (urea breath test) is safe, the current preference is for the 13C isotope used in the 13C urea breath test. This test is non-radioactive, and used especially in children, women of childbearing age and during pregnancy. 13C urea breath test will be added as an LLT to PT Helicobacter test.</div>				

CR Number: 2024120001		Implementation Date: 02-May-24	Related CR: 2024120001	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Bladder neck elevation	Rejected		
<div>MSSO</div> <div>Comment:</div> <div>The proposal to add a new LLT Bladder neck elevation is not approved. The term Bladder neck elevation is ambiguous as it can refer to a surgical procedure in which the bladder neck is lifted to address urinary incontinence issues (particularly stress urinary incontinence in women), or an investigation outcome of bladder ultrasound which might be related to urodynamic bladder outlet obstruction in referenced study.</div>				

# Detail Report

CR Number: 2024120002		Implementation Date: 02-May-24	Related CR: 2024120002	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	MELTUMP	Approved Not as Requested	Proposed PT <i>Melanocytic tumour of uncertain malignant potential</i>	10091063
			HLT primary <i>Skin melanomas (excl ocular)</i>	10027156
			SOC primary <i>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</i>	10029104
			HLT secondary <i>Skin melanomas (excl ocular)</i>	10027156
			SOC secondary <i>Skin and subcutaneous tissue disorders</i>	10040785

MSSO  
Comment: The proposal to add a new LLT MELTUMP is approved but not as requested. Although most melanocytic lesions can be diagnosed by histopathologists as benign or malignant with high confidence, a subset of morphologically ambiguous lesions does exist and still represents a significant problem for pathologists. These lesions have been defined as MELTUMP, i.e. melanocytic tumors of uncertain malignant potential. The proposed term will be modified to its' spelled-out version and in the British English spelling added as a PT Melanocytic tumour of uncertain malignant potential to bi-axial HLT Skin melanomas (excl ocular) with primary SOC Neoplasms benign, malignant and unspecified (incl cysts and polyps) and secondary SOC Skin and subcutaneous tissue disorders. In a related change, the American English spelled counterpart LLT Melanocytic tumor of uncertain malignant potential to PT Melanocytic tumour of uncertain malignant potential.

CR Number: 2024123002		Implementation Date: 02-May-24	Related CR: 2024120002	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Melanocytic tumor of uncertain malignant potential</i>	Approved as Requested	Proposed LLT <i>Melanocytic tumor of uncertain malignant potential</i>	10091065 Current
To PT	<i>Melanocytic tumour of uncertain malignant potential</i>		To PT <i>Melanocytic tumour of uncertain malignant potential</i>	10091063

MSSO  
Comment:

# Detail Report

CR Number: 2024120003		Implementation Date: 08-May-24	Related CR: 2024120003	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	Serotherapy	Approved Not as Requested	Proposed PT	
			Haematologic serotherapy	10091082
			HLT primary	
			Haematological therapeutic procedures NEC	10052724
			SOC primary	
			Surgical and medical procedures	10042613
MSSO Comment:	The proposal to add a new term Serotherapy is approved but not as requested. Serotherapy the treatment of disease by the injection of serum containing antibodies to the disease. The proposed term will be modified for clarity to distinguish from cosmetic context and added as PT Haematologic serotherapy under HLT Haematological therapeutic procedures NEC. In a related change, the American English spelled LLT Hematologic serotherapy will be added to PT Haematologic serotherapy.			

CR Number: 2024129012		Implementation Date: 08-May-24	Related CR: 2024120003	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Hematologic serotherapy	Approved as Requested	Proposed LLT	
To PT	Haematologic serotherapy		Hematologic serotherapy	10091096 Current
			To PT	
			Haematologic serotherapy	10091082
MSSO Comment:				



# Detail Report

CR Number: 2024120004		Implementation Date: 08-May-24	Related CR: 2024120004	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Hereditary Sensory and Autonomic Neuropathy</i>	Approved Not as Requested	Proposed PT <i>Hereditary sensory and autonomic neuropathy</i>	10091083
			HLT primary <i>Peripheral nervous system disorders congenital NEC</i>	10052632
			SOC primary <i>Congenital, familial and genetic disorders</i>	10010331
			HLT secondary <i>Inherited neuropathies</i>	10022031
			SOC secondary <i>Nervous system disorders</i>	10029205

**MSSO Comment:** The proposal to add a new term Hereditary Sensory and Autonomic Neuropathy is approved but not as requested. Hereditary sensory and autonomic neuropathy (HSAN1, previously known as HSN1) is a rare inherited peripheral neuropathy. HSAN1 patients develop severe loss of sensation to temperature, pressure, and pain. The loss starts in the extremities, usually beginning in the feet. The proposed term will be modified for MedDRA capitalization standards and added as PT Hereditary sensory and autonomic neuropathy to primary HLT Peripheral nervous system disorders congenital NEC and to secondary HLT Inherited neuropathies.

CR Number: 2024120005		Implementation Date: 08-May-24	Related CR: 2024120005	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Dysmelia</i>	Approved as Requested	Proposed LLT <i>Dysmelia</i>	10091090 Current
			To PT <i>Congenital musculoskeletal disorder of limbs</i>	10086689

**MSSO Comment:** The proposal to add a new term Dysmelia is approved as requested. Dysmelia is the anomaly of a limb or limbs resulting from a disturbance in embryonic development; the term includes defects of excessive development as well as reduction deformities. Dysmelia will be added as LLT under PT Congenital musculoskeletal disorder of limbs.

# Detail Report

<b>CR Number:</b> 2024120006		<b>Implementation Date:</b> 08-May-24	<b>Related CR:</b> 2024120006		
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed Term	Radioactive seed localization (RSL)	Approved Not as Requested	Proposed LLT	Radioactive seed localization	10091086 Current
			To PT	Radioactive seed localisation	10091085

**MSSO Comment:** The proposal to add a new term Radioactive seed localization (RSL) is approved but not as requested. The radioactive seed localization is an intraoperative localization technique used in many types of cancer surgery such as breast cancer conservative surgery. The technique uses a radioactive seed placed in the center of the target prior to removal surgery. When the removal occurs, the physician uses a radiation detector to locate and remove the seed and surrounding tissue. Proposed term will be modified by removal of acronym and added as LLT Radioactive seed localization under new PT Radioactive seed localisation. In a related change, the counterpart British English spelled new PT Radioactive seed localisation will be added under HLT Therapeutic procedures NEC.

<b>CR Number:</b> 2024129013		<b>Implementation Date:</b> 08-May-24	<b>Related CR:</b> 2024120006		
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed PT	Radioactive seed localisation	Approved as Requested	Proposed PT	Radioactive seed localisation	10091085
HLT primary	Therapeutic procedures NEC		HLT primary	Therapeutic procedures NEC	10027700
SOC primary	Surgical and medical procedures		SOC primary	Surgical and medical procedures	10042613

**MSSO Comment:**

<b>CR Number:</b> 2024120007		<b>Implementation Date:</b> 08-May-24	<b>Related CR:</b> 2024120007		
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed Term	Tracheobronchial tree tumor	Rejected			

**MSSO Comment:** The proposal to add a new term Tracheobronchial tree tumor is not approved. The proposed term is a grouping term. It is uncommon for tumors to simultaneously develop in both the trachea and the bronchi. Typically, tumors will arise in one location and may spread to other nearby areas or distant parts of the body.

# Detail Report

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<b>CR Number:</b> 2024120008		<b>Implementation Date:</b> 08-May-24	<b>Related CR:</b> 2024120008	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Interarterial course of the left coronary artery</i>	Approved as Requested	Proposed LLT <i>Interarterial course of the left coronary artery</i>	10091091 Current
			To PT <i>Congenital coronary artery malformation</i>	10061060
<b>MSSO Comment:</b> The proposal to add a new term Interarterial course of the left coronary artery is approved as requested. An interarterial course of the left coronary artery is defined as the origination of the left main or left anterior descending coronary artery from the right coronary sinus of Valsalva, with a course between the ascending aorta and the pulmonary artery trunk. Interarterial course of the left coronary artery will be added as subconcept LLT under PT Congenital coronary artery malformation.				

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<b>CR Number:</b> 2024120009		<b>Implementation Date:</b> 08-May-24	<b>Related CR:</b> 2024120009	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>MAXILLARY ANTROSTOMY</i>	Approved Not as Requested	Proposed LLT <i>Maxillary antrostomy</i>	10091088 Current
			To PT <i>Sinus antrostomy</i>	10066911
<b>MSSO Comment:</b> The proposal to add a new term MAXILLARY ANTROSTOMY is approved but not as requested. Maxillary antrostomy is a surgical procedure involving the creation of an opening or passage into the maxillary sinus. The proposed term will be modified for MedDRA capitalization rules and added as LLT Maxillary antrostomy to PT Sinus antrostomy.				

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<b>CR Number:</b> 2024120010		<b>Implementation Date:</b> 08-May-24	<b>Related CR:</b> 2024120010	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Dropsy</i>	Rejected		
<b>MSSO Comment:</b> The proposal to add a new term Dropsy is not approved. There are potential variations in the meaning of the term and it has potential for ambiguity.				

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# Detail Report

<b>CR Number:</b> 2024120011		<b>Implementation Date:</b> 08-May-24	<b>Related CR:</b> 2024120011	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Suprasellar cistern lipoma</i>	Approved as Requested	Proposed LLT <i>Suprasellar cistern lipoma</i>	10091092 Current
			To PT <i>Intracranial lipoma</i>	10072288
<b>MSSO Comment:</b> The proposal to add a new term Suprasellar cistern lipoma is approved as requested. A suprasellar cistern lipoma is a benign tumor composed of fatty tissue that occurs in the region of the suprasellar cistern. These lipomas are typically slow-growing and are often discovered incidentally during brain imaging scans performed for other reasons. They are usually asymptomatic and do not require treatment unless they cause symptoms due to compression of nearby structures. The proposed term will be added as a location-qualified LLT Suprasellar cistern lipoma to PT Intracranial lipoma.				
<b>CR Number:</b> 2024120012		<b>Implementation Date:</b> 08-May-24	<b>Related CR:</b> 2024120012	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Amenia</i>	Rejected		
<b>MSSO Comment:</b> The proposal to add a new term Amenia is not approved. Although a rarely used synonym for amenorrhoe, the MSSO refrains from adding this term as it is very similar to the much more frequently reported term Anemia (low hemoglobin). There may be a risk that autoencoders or synonym lists will address this as a misspelled form of anemia. Also in manual coding, the term may require querying.				
<b>CR Number:</b> 2024120013		<b>Implementation Date:</b> 08-May-24	<b>Related CR:</b> 2024120013	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Extracapsular Cataract Extraction</i>	Approved Not as Requested	Proposed LLT <i>Extracapsular cataract extraction</i>	10091087 Current
			To PT <i>Cataract operation</i>	10063797
<b>MSSO Comment:</b> The proposal to add a new term Extracapsular Cataract Extraction is approved but not as requested. Extracapsular cataract extraction is a surgical procedure for cataract surgery. It leaves the posterior capsule of the lens intact, removing the nucleus and cortex of the lens. Extracapsular cataract extraction was a common cataract surgery technique before the advent of phacoemulsification, a more modern and less invasive technique, but is still a popular method in the developing world. The proposed term will be modified according to MedDRA capitalization rules and added as LLT Extracapsular cataract extraction to PT Cataract operation.				

# Detail Report

<b>CR Number:</b> 2024120014		<b>Implementation Date:</b> 08-May-24	<b>Related CR:</b> 2024120014	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	SALMONELLA ENTERICA INFECTION	Approved Not as Requested	Proposed LLT Salmonella enterica infection	10091093 Current
			To PT Salmonellosis	10039447
<b>MSSO Comment:</b> The proposal to add a new term SALMONELLA ENTERICA INFECTION is approved but not as requested. Subspecies of Salmonella enterica are responsible for almost all Salmonella infections of warm-blooded animals. Only a few serovars are responsible for most Salmonella infections in humans and domestic animals. The proposed term will be modified in accordance with MedDRA capitalization conventions and added as the LLT Salmonella enterica infection to the PT Salmonellosis.				

<b>CR Number:</b> 2024120015		<b>Implementation Date:</b> 08-May-24	<b>Related CR:</b> 2024120015	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	Retinectomy	Approved as Requested	Proposed PT Retinectomy	10091084
			HLT primary Retinal therapeutic procedures	10038890
			SOC primary Surgical and medical procedures	10042613
<b>MSSO Comment:</b> The proposal to add a new term Retinectomy is approved as requested. Retinectomy refers to the excision of the retina. During retinectomy, the complete peripheral retina may be excised, leaving the central retina untouched. Excising only the peripheral retina also prevents postoperative proliferation and traction. Retinectomy will be added as PT to the HLT Retinal therapeutic procedures.				

<b>CR Number:</b> 2024120016		<b>Implementation Date:</b> 08-May-24	<b>Related CR:</b> 2024120016	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	ICE score abnormal	Rejected		
<b>MSSO Comment:</b> The proposal to add a new term ICE score abnormal is not approved. The supporting justification article refers to prioritizing features, initiatives, and rollouts related to product management. Product management aspects are not within the scope of MedDRA.				

# Detail Report

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<b>CR Number:</b> 2024120017		<b>Implementation Date:</b> 08-May-24	<b>Related CR:</b> 2024120017	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Cryobiopsy</i>	Approved as Requested	Proposed LLT <i>Cryobiopsy</i>	10091094 Current
			To PT <i>Biopsy</i>	10004720
<b>MSSO</b> <b>Comment:</b> The proposal to add a new term Cryobiopsy is approved as requested. Cryobiopsy involves subjecting tissue to cryofixation by a liquid cryogen to preserve the tissue for subsequent morphologic and immunohistochemical analysis. Cryobiopsy will be added as LLT under PT Biopsy.				

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<b>CR Number:</b> 2024120018		<b>Implementation Date:</b> 08-May-24	<b>Related CR:</b> 2024120018	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Cryorecanalization</i>	Approved as Requested	Proposed LLT <i>Cryorecanalization</i>	10091089 Current
			To PT <i>Cryotherapy</i>	10011483
<b>MSSO</b> <b>Comment:</b> The proposal to add a new term Cryorecanalization is approved as requested. Cryorecanalization uses a cryoprobe to relieve obstructions in tubular passages, such as the bronchial tree or the esophagus, often through constricting tumor debulking. Cryorecanalization will be added as an LLT to PT Cryotherapy. In a related change, the British English spelled counterpart will also be added as LLT Cryorecanalisation to PT Cryotherapy.				

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<b>CR Number:</b> 2024129014		<b>Implementation Date:</b> 08-May-24	<b>Related CR:</b> 2024120018	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Cryorecanalisation</i>	Approved as Requested	Proposed LLT <i>Cryorecanalisation</i>	10091095 Current
To PT	<i>Cryotherapy</i>		To PT <i>Cryotherapy</i>	10011483
<b>MSSO</b> <b>Comment:</b>				

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# Detail Report

CR Number: 2024120019		Implementation Date: 08-May-24	Related CR: 2024120019	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Internal hydrocephalus	Approved as Requested	Proposed LLT Internal hydrocephalus	10091098 Current
			To PT Hydrocephalus	10020508
<div>MSSO</div> <div>Comment:</div> <div>The proposal to add a new LLT Internal hydrocephalus is approved as requested. Hydrocephalus is often divided based on several categories including obstruction, communication and increases in intracranial pressure, as well as ventriculomegaly. Internal hydrocephalus is sometimes used to describe obstruction of the foramina of Luschka and Magendie leading to obstruction within the ventricular system. The proposed term will be added as LLT Internal hydrocephalus to PT Hydrocephalus.</div>				
CR Number: 2024120020		Implementation Date: 08-May-24	Related CR: 2024120020	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Hydrocephalus malresorptivus	Approved as Requested	Proposed LLT Hydrocephalus malresorptivus	10091097 Current
			To PT Hydrocephalus	10020508
<div>MSSO</div> <div>Comment:</div> <div>The proposal to add a new LLT Hydrocephalus malresorptivus is approved as requested. Malresorptive hydrocephalus, a synonym of Hydrocephalus communicative, is a subtype of hydrocephalus characterized by impaired absorption of cerebrospinal fluid (CSF) within the brain's ventricular system. In malresorptive hydrocephalus, there is a dysfunction in the mechanism responsible for CSF absorption, leading to an accumulation of fluid within the ventricular system and an increase in intracranial pressure. Hydrocephalus malresorptivus will be added as LLT to PT Hydrocephalus.</div>				

# Detail Report

<b>CR Number:</b> 2024120021		<b>Implementation Date:</b> 02-May-24	<b>Related CR:</b> 2024120021	
<u>Change Requested</u>	Add a New PT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Psychogenic pruritus</i>	Approved Not as Requested	Proposed PT	
HLT primary	<i>Pruritus NEC</i>		<i>Psychogenic pruritus</i>	10091060
SOC primary	<i>Skin and subcutaneous tissue disorders</i>		HLT primary	
			<i>Somatic symptom disorders</i>	10077547
			SOC primary	
			<i>Psychiatric disorders</i>	10037175
			HLT secondary	
			<i>Pruritus NEC</i>	10049293
			SOC secondary	
			<i>Skin and subcutaneous tissue disorders</i>	10040785

**MSSO** The proposal to add a new PT Psychogenic pruritus to primary HLT Pruritus NEC in SOC Skin and subcutaneous tissue disorders is approved but not as requested.  
**Comment:** Psychogenic pruritus, also known as psychogenic itch or functional itch disorder is pruritus not associated with a dermatologic or systemic cause. More often than not, it is attributed to a psychiatric cause. Psychogenic pruritus will be added as new PT under primary HLT Somatic symptom disorders and secondary HLT Pruritus NEC.

<b>CR Number:</b> 2024120022		<b>Implementation Date:</b> 02-May-24	<b>Related CR:</b> 2024120022	
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Coronary calcium score high</i>	Approved as Requested	Proposed LLT	
To PT	<i>Computerised tomogram heart abnormal</i>		<i>Coronary calcium score high</i>	10091061 Current
			To PT	
			<i>Computerised tomogram heart abnormal</i>	10088902

**MSSO** The proposal to add a new LLT Coronary calcium score high to PT Computerised tomogram heart abnormal is approved as requested. Individuals with coronary artery calcium (CAC)  $\geq 1000$  constitute a unique population at substantially higher risk for cardiovascular disease events, non-cardiovascular disease outcomes, and mortality than those with lower CAC. LLT Coronary calcium score high is added as synonym of existing LLT Cardiac calcium score high.



# Detail Report

CR Number: 2024121001		Implementation Date: 07-May-24	Related CR: 2024121001	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Neuroendocrine tumor of the thymus	Approved as Requested	Proposed LLT Neuroendocrine tumor of the thymus	10091080 Current
			To PT Neuroendocrine tumour of the thymus	10091079
MSSO Comment:	The proposal to add a new LLT Neuroendocrine tumor of the thymus is approved as requested. Thymic neuroendocrine tumors, otherwise known as thymic carcinoid tumors, are uncommon primary thymic neoplasms with neuroendocrine differentiation that generally present as a mass within the anterior mediastinum. Neuroendocrine tumor of the thymus will be added as an LLT to a new PT representing the British English counterpart term Neuroendocrine tumour of the thymus, which will be added with a primary link to HLT Mediastinal neoplasms malignant and secondary links to HLT Thymus disorders, HLT Mediastinal disorders and to HLT Endocrine neoplasms NEC.			

CR Number: 2024128006		Implementation Date: 07-May-24	Related CR: 2024121001	
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Neuroendocrine tumour of the thymus	Approved as Requested	Proposed PT Neuroendocrine tumour of the thymus	10091079
HLT primary	Mediastinal neoplasms malignant		HLT primary Mediastinal neoplasms malignant	10027081
SOC primary	Neoplasms benign, malignant and unspecified (incl cysts and polyps)		SOC primary Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10029104
			HLT secondary Thymus disorders	10043677
			SOC secondary Blood and lymphatic system disorders	10005329
MSSO Comment:				

# Detail Report

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<b>CR Number:</b> 2024128008		<b>Implementation Date:</b> 07-May-24	<b>Related CR:</b> 2024121001	
<a href="#">Change Requested</a>	Link a PT to a HLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Neuroendocrine tumour of the thymus	Approved as Requested	Proposed PT	
To HLT	Endocrine neoplasms NEC		Neuroendocrine tumour of the thymus	10091079
			To HLT	
			Endocrine neoplasms NEC	10014714

MSSO  
Comment:

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<b>CR Number:</b> 2024128007		<b>Implementation Date:</b> 07-May-24	<b>Related CR:</b> 2024121001	
<a href="#">Change Requested</a>	Link a PT to a HLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Neuroendocrine tumour of the thymus	Approved as Requested	Proposed PT	
To HLT	Mediastinal disorders		Neuroendocrine tumour of the thymus	10091079
			To HLT	
			Mediastinal disorders	10027072

MSSO  
Comment:

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<b>CR Number:</b> 2024122000		<b>Implementation Date:</b> 07-May-24	<b>Related CR:</b> 2024122000	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Freezing of gait	Approved as Requested	Proposed LLT	
To PT	Freezing phenomenon		Freezing of gait	10091081 Current
			To PT	
			Freezing phenomenon	10060904

MSSO  
Comment: The proposal to add a new LLT Freezing of gait to PT Freezing phenomenon is approved as requested. Freezing of gait is a unique and disabling clinical phenomenon characterised by brief episodes of inability to step or by extremely short steps that typically occur on initiating gait or on turning while walking. In a related change, non-current LLT Frozen gait will be moved from PT Parkinsonian gait to PT Freezing phenomenon for consistency.

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# Detail Report

CR Number: 2024128009		Implementation Date: 07-May-24	Related CR: 2024122000	
<a href="#">Change Requested</a>	Link (move) an LLT to another PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Frozen gait</i>	Approved as Requested	Proposed LLT	10017390 Non-Current
From PT	<i>Parkinsonian gait</i>		<i>Frozen gait</i>	
To PT	<i>Freezing phenomenon</i>		From PT	10056242
			<i>Parkinsonian gait</i>	
			To PT	
			<i>Freezing phenomenon</i>	10060904

MSSO  
Comment:

CR Number: 2024122005		Implementation Date: 09-May-24	Related CR: 2024122005	
<a href="#">Change Requested</a>	Promote an LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Fitzpatrick skin phototype I</i>	Approved After Suspension	Proposed LLT	10091029
From PT	<i>Fitzpatrick skin phototype</i>		<i>Fitzpatrick skin phototype I</i>	
			From PT	10091022
			<i>Fitzpatrick skin phototype</i>	
			HLT primary	
			<i>Physical examination procedures and organ system status</i>	10071941
			SOC primary	
			<i>Investigations</i>	10022891

MSSO  
Comment: The proposal to promote the LLT Fitzpatrick skin phototype I from PT Fitzpatrick skin phototype is approved as requested after suspension. After careful reconsideration, the MSSO has opted for placement on the PT level, aligned with the approach for blood group terms. The Fitzpatrick skin phototype comprises a finite set of categorical values that defy classification into normal/abnormal or increased/decreased categories. LLT Fitzpatrick skin phototype I will be promoted from PT Fitzpatrick skin phototype to HLT Physical examination procedures and organ system status.

# Detail Report

CR Number: 2024122006		Implementation Date: 09-May-24	Related CR: 2024122006	
<u>Change Requested</u>	Promote an LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Fitzpatrick skin phototype II</i>	Approved After Suspension	Proposed LLT	
From PT	<i>Fitzpatrick skin phototype</i>		<i>Fitzpatrick skin phototype II</i>	10091023
			From PT	
			<i>Fitzpatrick skin phototype</i>	10091022
			HLT primary	
			<i>Physical examination procedures and organ system status</i>	10071941
			SOC primary	
			<i>Investigations</i>	10022891

**MSSO Comment:** The proposal to promote the LLT Fitzpatrick skin phototype II from PT Fitzpatrick skin phototype is approved as requested after suspension. After careful reconsideration, the MSSO has opted for placement on the PT level, aligned with the approach for blood group terms. The Fitzpatrick skin phototype comprises a finite set of categorical values that defy classification into normal/abnormal or increased/decreased categories. LLT Fitzpatrick skin phototype II will be promoted from PT Fitzpatrick skin phototype to HLT Physical examination procedures and organ system status.

CR Number: 2024122007		Implementation Date: 09-May-24	Related CR: 2024122007	
<u>Change Requested</u>	Promote an LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Fitzpatrick skin phototype III</i>	Approved After Suspension	Proposed LLT	
From PT	<i>Fitzpatrick skin phototype</i>		<i>Fitzpatrick skin phototype III</i>	10091024
			From PT	
			<i>Fitzpatrick skin phototype</i>	10091022
			HLT primary	
			<i>Physical examination procedures and organ system status</i>	10071941
			SOC primary	
			<i>Investigations</i>	10022891

**MSSO Comment:** The proposal to promote the LLT Fitzpatrick skin phototype III from PT Fitzpatrick skin phototype is approved as requested after suspension. After careful reconsideration, the MSSO has opted for placement on the PT level, aligned with the approach for blood group terms. The Fitzpatrick skin phototype comprises a finite set of categorical values that defy classification into normal/abnormal or increased/decreased categories. LLT Fitzpatrick skin phototype III will be promoted from PT Fitzpatrick skin phototype to HLT Physical examination procedures and organ system status.

# Detail Report

<b>CR Number:</b> 2024122008		<b>Implementation Date:</b> 09-May-24	<b>Related CR:</b> 2024122008	
<u>Change Requested</u>	Promote an LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Fitzpatrick skin phototype IV</i>	Approved After Suspension	Proposed LLT	
From PT	<i>Fitzpatrick skin phototype</i>		<i>Fitzpatrick skin phototype IV</i>	10091025
			From PT	
			<i>Fitzpatrick skin phototype</i>	10091022
			HLT primary	
			<i>Physical examination procedures and organ system status</i>	10071941
			SOC primary	
			<i>Investigations</i>	10022891

**MSSO Comment:** The proposal to promote the LLT Fitzpatrick skin phototype IV from PT Fitzpatrick skin phototype is approved as requested after suspension. After careful reconsideration, the MSSO has opted for placement on the PT level, aligned with the approach for blood group terms. The Fitzpatrick skin phototype comprises a finite set of categorical values that defy classification into normal/abnormal or increased/decreased categories. LLT Fitzpatrick skin phototype IV will be promoted from PT Fitzpatrick skin phototype to HLT Physical examination procedures and organ system status.

<b>CR Number:</b> 2024122009		<b>Implementation Date:</b> 09-May-24	<b>Related CR:</b> 2024122009	
<u>Change Requested</u>	Promote an LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Fitzpatrick skin phototype V</i>	Approved After Suspension	Proposed LLT	
From PT	<i>Fitzpatrick skin phototype</i>		<i>Fitzpatrick skin phototype V</i>	10091028
			From PT	
			<i>Fitzpatrick skin phototype</i>	10091022
			HLT primary	
			<i>Physical examination procedures and organ system status</i>	10071941
			SOC primary	
			<i>Investigations</i>	10022891

**MSSO Comment:** The proposal to promote the LLT Fitzpatrick skin phototype V from PT Fitzpatrick skin phototype is approved as requested after suspension. After careful reconsideration, the MSSO has opted for placement on the PT level, aligned with the approach for blood group terms. The Fitzpatrick skin phototype comprises a finite set of categorical values that defy classification into normal/abnormal or increased/decreased categories. LLT Fitzpatrick skin phototype V will be promoted from PT Fitzpatrick skin phototype to HLT Physical examination procedures and organ system status.

# Detail Report

<b>CR Number:</b> 2024122010		<b>Implementation Date:</b> 09-May-24	<b>Related CR:</b> 2024122010	
<u>Change Requested</u>	Promote an LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Fitzpatrick skin phototype VI</i>	Approved After Suspension	Proposed LLT	
From PT	<i>Fitzpatrick skin phototype</i>		<i>Fitzpatrick skin phototype VI</i>	10091026
			From PT	
			<i>Fitzpatrick skin phototype</i>	10091022
			HLT primary	
			<i>Physical examination procedures and organ system status</i>	10071941
			SOC primary	
			<i>Investigations</i>	10022891

**MSSO Comment:** The proposal to promote the LLT Fitzpatrick skin phototype VI from PT Fitzpatrick skin phototype is approved as requested after suspension. After careful reconsideration, the MSSO has opted for placement on the PT level, aligned with the approach for blood group terms. The Fitzpatrick skin phototype comprises a finite set of categorical values that defy classification into normal/abnormal or increased/decreased categories. LLT Fitzpatrick skin phototype VI will be promoted from PT Fitzpatrick skin phototype to HLT Physical examination procedures and organ system status.

<b>CR Number:</b> 2024124000		<b>Implementation Date:</b> 08-May-24	<b>Related CR:</b> 2024124000	
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Correction of Rickets</i>	Approved Not as Requested	Proposed PT	
			<i>Bone correction brace treatment</i>	10091099
			HLT primary	
			<i>Limb therapeutic procedures</i>	10024502
			SOC primary	
			<i>Surgical and medical procedures</i>	10042613

**MSSO Comment:** The proposal to add a new LLT Correction of Rickets is approved but not as requested. Children with a bone deformity, such as caused by rickets, may need braces to reposition the bones as they grow. The proposed term will be modified for alignment with the justification and added as PT Bone correction brace treatment to HLT Limb therapeutic procedures.

# Detail Report

<b>CR Number:</b> 2024124001		<b>Implementation Date:</b> 09-May-24	<b>Related CR:</b> 2024124001	
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Drug administered at a compromised administration site</i>	Approved Not as Requested	Proposed LLT	
HLT primary	<i>Product administration errors and issues</i>		<i>Product administered at compromised administration site</i>	10091108 Current
SOC primary	<i>Injury, poisoning and procedural complications</i>		To PT	
			<i>Product administered at inappropriate site</i>	10080753
<b>MSSO Comment:</b> The proposal to add a new PT Drug administered at a compromised administration site to primary HLT Product administration errors and issues in SOC Injury, poisoning and procedural complications is approved but not as requested. There are products that need to be applied to administration sites with certain conditions, e.g., proper amount of subcutaneous fat, undamaged skin. The proposed term will be modified to replace drug by the more general word product and added as LLT Product administered at compromised administration site under PT Product administered at inappropriate site.				

<b>CR Number:</b> 2024127000		<b>Implementation Date:</b> 09-May-24	<b>Related CR:</b> 2024127000	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Sinus dryness</i>	Rejected		
<b>MSSO Comment:</b> The proposal to add a new term Sinus dryness is not approved. The proposed concept may be represented by existing LLT Paranasal sinus dryness, based on the scenario.				

<b>CR Number:</b> 2024127003		<b>Implementation Date:</b> 09-May-24	<b>Related CR:</b> 2024127003	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Renal small vessel disease</i>	Rejected		
<b>MSSO Comment:</b> The proposal to add a new LLT Renal small vessel disease is not approved. This is merely a descriptive term that can be used in any organ in the differentiation between large versus small vessel involvement. Please use the several existing broad terms in MedDRA if no additional information after querying is received.				

# Detail Report

<b>CR Number:</b> 2024127004		<b>Implementation Date:</b> 09-May-24	<b>Related CR:</b> 2024127004		
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed LLT	Paroxysmal dystonia and psychotic exacerbation	Rejected			

**MSSO Comment:** The proposal to add a new LLT Paroxysmal dystonia and psychotic exacerbation is not approved. Paroxysmal dystonia and psychotic exacerbation is a multiple concept term which can be coded using more than one existing MedDRA term. Please refer to Section 3.5 of the MedDRA Term Selection: Points to Consider Document regarding the coding of combination terms. Although referenced and mentioned in several literature articles, the concept is not yet fully matured as a standalone disease concept.

<b>CR Number:</b> 2024127005		<b>Implementation Date:</b> 09-May-24	<b>Related CR:</b> 2024127005		
<a href="#">Change Requested</a>	Swap a PT with an LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed PT	Endocardial fibroelastosis	Approved Not as Requested	Proposed LLT		
With LLT	Idiopathic cardiomegaly		Idiopathic cardiomegaly	10052650	Current
			From PT		
			Endocardial fibroelastosis	10014663	
			To PT		
			Cardiomegaly	10007632	

**MSSO Comment:** The proposal to swap the PT Endocardial fibroelastosis with the LLT Idiopathic cardiomegaly is approved but not as requested. Endocardial fibroelastosis is characterized by diffuse thickening of the left ventricular endocardium secondary to proliferation of fibrous and elastic tissue. It exists in a dilated and contracted form. Idiopathic cardiomegaly on the other hand, refers to an enlarged heart of unknown cause. Idiopathic cardiomegaly will be moved from under PT Endocardial fibroelastosis to PT Cardiomegaly.

<b>CR Number:</b> 2024127006		<b>Implementation Date:</b> 09-May-24	<b>Related CR:</b> 2024127006		
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed PT	Hypertransferrinaemia	Approved Not as Requested	Proposed PT		
HLT primary	Mineral and electrolyte analyses		Hypertransferrinaemia	10091104	
SOC primary	Investigations		HLT primary		
			Anaemia deficiencies	10002042	
			SOC primary		
			Blood and lymphatic system disorders	10005329	

**MSSO Comment:** The proposal to add a new PT Hypertransferrinaemia to primary HLT Mineral and electrolyte analyses in SOC Investigations is approved but not as requested. Hypertransferrinaemia occurs in patients with iron deficiency anaemia in an attempt of the body to enhance its iron stores by producing large amounts of transferrin, which can serve to increase iron absorption from the gastrointestinal tract. Hypertransferrinaemia will be added as new PT under HLT Anaemia deficiencies. In a related change, the American English spelled counterpart LLT Hypertransferrinemia will also be added under PT Hypertransferrinaemia.



# Detail Report

<b>CR Number:</b> 2024130009		<b>Implementation Date:</b> 09-May-24	<b>Related CR:</b> 2024127006	<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	
Proposed LLT	<i>Hypertransferrinemia</i>	Approved as Requested	Proposed LLT	
To PT	<i>Hypertransferrinaemia</i>		<i>Hypertransferrinemia</i>	10091106 Current
			To PT	
			<i>Hypertransferrinaemia</i>	10091104

MSSO  
Comment:

<b>CR Number:</b> 2024127007		<b>Implementation Date:</b> 09-May-24	<b>Related CR:</b> 2024127007	<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	
Proposed PT	<i>IgG4 related ophthalmic disease</i>	Approved Not as Requested	Proposed LLT	
HLT primary	<i>Ocular infections, inflammations and associated manifestations</i>		<i>IgG4 related ophthalmic disease</i>	10091105 Current
			To PT	
SOC primary	<i>Eye disorders</i>		<i>Immunoglobulin G4 related disease</i>	10077271

MSSO  
Comment: The proposal to add a new PT IgG4 related ophthalmic disease to primary HLT Ocular infections, inflammations and associated manifestations in SOC Eye disorders and secondary HLT Autoimmune disorders NEC in SOC Immune system disorders is approved but not as requested. When IgG4-related disease manifests in the eye or orbit, it is referred to as IgG4-related ophthalmic disease (IgG4-ROD), which most commonly causes painless swelling of the lacrimal gland(s). Other commonly affected parts of the eye and orbit include the extraocular muscles, orbital fat, infraorbital nerve, eyelid, and the nasolacrimal duct system. The proposed term will be added as LLT IgG4 related ophthalmic disease to PT Immunoglobulin G4 related disease. In a related change, PT Immunoglobulin G4 related disease will also be linked to HLT Ocular infections, inflammations and associated manifestations and also to HLT Pancreatic disorders NEC to represent some of the common manifestations of the disease.

<b>CR Number:</b> 2024130011		<b>Implementation Date:</b> 09-May-24	<b>Related CR:</b> 2024127007	<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Link a PT to a HLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	
Proposed PT	<i>Immunoglobulin G4 related disease</i>	Approved as Requested	Proposed PT	
To HLT	<i>Pancreatic disorders NEC</i>		<i>Immunoglobulin G4 related disease</i>	10077271
			To HLT	
			<i>Pancreatic disorders NEC</i>	10027692

MSSO  
Comment:

# Detail Report

<b>CR Number:</b> 2024130010		<b>Implementation Date:</b> 09-May-24	<b>Related CR:</b> 2024127007	
<u>Change Requested</u>	Link a PT to a HLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Immunoglobulin G4 related disease</i>	Approved as Requested	Proposed PT	
To HLT	<i>Ocular infections, inflammations and associated manifestations</i>		<i>Immunoglobulin G4 related disease</i>	10077271
			To HLT	
			<i>Ocular infections, inflammations and associated manifestations</i>	10030045

MSSO  
Comment:

<b>CR Number:</b> 2024127008		<b>Implementation Date:</b> 09-May-24	<b>Related CR:</b> 2024127008	
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Lung tightness</i>	Approved as Requested	Proposed LLT	
To PT	<i>Chest discomfort</i>		<i>Lung tightness</i>	10091100 Current
			To PT	
			<i>Chest discomfort</i>	10008469

MSSO  
Comment: The proposal to add a new LLT Lung tightness to PT Chest discomfort is approved as requested. Lung tightness refers to a sensation of constriction or pressure in the chest area, often accompanied by difficulty breathing. "Lung tightness" and "chest tightness" are often used interchangeably to describe the sensation of constriction or pressure in the chest area. The proposed term will be added in parallel to LLT Chest tightness under PT Chest discomfort.

<b>CR Number:</b> 2024127009		<b>Implementation Date:</b> 09-May-24	<b>Related CR:</b> 2024127009	
<u>Change Requested</u>	Add a New Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	<i>Nikolsky's sign positive</i>	Approved as Requested	Proposed PT	
			<i>Nikolsky's sign positive</i>	10091102
			HLT primary	
			<i>Skin histopathology and skin investigations NEC</i>	10087056
			SOC primary	
			<i>Investigations</i>	10022891

MSSO  
Comment: The proposal to add a new term Nikolsky's sign positive is approved as requested. Nikolsky's sign is a clinical dermatological examination technique used to diagnose certain skin conditions, particularly pemphigus vulgaris and other blistering disorders. When Nikolsky's sign is positive, gentle lateral pressure on apparently normal-looking skin causes separation of the epidermis from the dermis. Nikolsky's sign positive will be added as PT to HLT Skin histopathology and skin investigations NEC. In a related change, PT Nikolsky's sign will be demoted under new PT Nikolsky's sign positive and made non-current. Furthermore, new PT Nikolsky's sign test will be added under HLT Skin histopathology and skin investigations NEC to represent the unqualified test name.

# Detail Report

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<b>CR Number:</b> 2024130002		<b>Implementation Date:</b> 09-May-24	<b>Related CR:</b> 2024127009		
<a href="#">Change Requested</a>	Demote a PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
PT to merge	<i>Nikolsky's sign</i>	Approved as Requested	PT to merge		
To PT	<i>Nikolsky's sign positive</i>		<i>Nikolsky's sign</i>	10029415	Non-Current
			To PT		
			<i>Nikolsky's sign positive</i>	10091102	

MSSO  
Comment:

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<b>CR Number:</b> 2024130003		<b>Implementation Date:</b> 09-May-24	<b>Related CR:</b> 2024127009		
<a href="#">Change Requested</a>	Change Status of LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
LLT to change	<i>Nikolsky's sign</i>	Approved as Requested	LLT to change		
Status	<i>Non-current</i>		<i>Nikolsky's sign</i>	10029415	Non-Current
			Status		
			<i>Non-current</i>		

MSSO  
Comment:

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<b>CR Number:</b> 2024130005		<b>Implementation Date:</b> 09-May-24	<b>Related CR:</b> 2024127009		
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed PT	<i>Nikolsky's sign test</i>	Approved as Requested	Proposed PT		
HLT primary	<i>Skin histopathology and skin investigations NEC</i>		<i>Nikolsky's sign test</i>	10091101	
SOC primary	<i>Investigations</i>		HLT primary		
			<i>Skin histopathology and skin investigations NEC</i>	10087056	
			SOC primary		
			<i>Investigations</i>	10022891	

MSSO  
Comment:

# Detail Report

<b>CR Number:</b> 2024127010		<b>Implementation Date:</b> 09-May-24	<b>Related CR:</b> 2024127010	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Nikolsky's sign negative</i>	Approved as Requested	Proposed PT <i>Nikolsky's sign negative</i>	10091103
			HLT primary <i>Skin histopathology and skin investigations NEC</i>	10087056
			SOC primary <i>Investigations</i>	10022891

**MSSO Comment:** The proposal to add a new term Nikolsky's sign negative is approved as requested. The absence of a positive Nikolsky's sign suggests that the structural integrity of the skin layers is preserved and there is no significant loss of cohesion, when gentle lateral pressure is applied. An absence of Nikolsky's sign provides reassurance in the differential diagnosis of certain skin diseases. New PT Nikolsky's sign negative will be added to HLT Skin histopathology and skin investigations NEC.

<b>CR Number:</b> 2024128000		<b>Implementation Date:</b> 09-May-24	<b>Related CR:</b> 2024128000	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Cardiac stent placement</i>	Approved as Requested	Proposed LLT <i>Cardiac stent placement</i>	10091109 Current
To PT	<i>Coronary arterial stent insertion</i>		To PT <i>Coronary arterial stent insertion</i>	10052086

**MSSO Comment:** The proposal to add a new LLT Cardiac stent placement to PT Coronary arterial stent insertion is approved as requested. A cardiac stent is used to treat narrowed or blocked coronary arteries.

<b>CR Number:</b> 2024128001		<b>Implementation Date:</b> 09-May-24	<b>Related CR:</b> 2024128001	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Broken back</i>	Rejected		

**MSSO Comment:** The proposal to add a new LLT Broken back is not approved. Proposed term may be represented more accurately with existing medical terminology such as LLT Spinal fracture, depending on clinical scenario. In colloquial terms, "back" may be broader and refer to additional components.

# Detail Report

<b>CR Number:</b> 2024128002		<b>Implementation Date:</b> 13-May-24	<b>Related CR:</b> 2024128002	<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	
Proposed PT	HTLV-2 test negative	Approved as Requested	Proposed PT HTLV-2 test negative	10091111
			HLT primary Virus identification and serology	10047490
			SOC primary Investigations	10022891

**MSSO Comment:** The proposal to add a new PT HTLV-2 test negative is approved as requested. The body responds to an HTLV-I or HTLV-II infection by producing antibodies. The presence of antibodies to HTLV-I or HTLV-II indicates that a person is infected with the virus. HTLV-2 test negative will be added as new PT under HLT Virus identification and serology to complement the existing positive counterpart PT HTLV-2 test positive.

<b>CR Number:</b> 2024128003		<b>Implementation Date:</b> 13-May-24	<b>Related CR:</b> 2024128003	<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	
Proposed Term	Tibial tuberosity transfer	Approved as Requested	Proposed PT Tibial tuberosity transfer	10091112
			HLT primary Joint therapeutic procedures	10023221
			SOC primary Surgical and medical procedures	10042613

**MSSO Comment:** The proposal to add a new term Tibial tuberosity transfer is approved as requested. Tibial tuberosity transfer, also called bony realignment or osteotomy, is a surgical treatment option for instability, arthritis or cartilage defects affecting the patellofemoral joint (kneecap and femur). Tibial tuberosity transfer will be added as new PT under HLT Joint therapeutic procedures.

<b>CR Number:</b> 2024128004		<b>Implementation Date:</b> 09-May-24	<b>Related CR:</b> 2024128004	<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	
Proposed LLT	ETDRS test	Approved Not as Requested	Proposed LLT ETDRS acuity test	10091110 Current
To PT	Visual acuity tests		To PT Visual acuity tests	10047533

**MSSO Comment:** The proposal to add a new LLT ETDRS test to PT Visual acuity tests is approved but not as requested. ETDRS acuity testing has become the worldwide standard for visual acuity testing, replacing the Snellen and Sloan acuity tests. ETDRS stands for Early Treatment Diabetic Retinopathy Study. The proposed term will be modified for clarity and added as LLT ETDRS acuity test to PT Visual acuity tests.

# Detail Report

<b>CR Number:</b> 2024128005		<b>Implementation Date:</b> 09-May-24	<b>Related CR:</b> 2024128005	
<u>Change Requested</u>	Add a New PT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Congenital thrombotic thrombocytopenic purpura</i>	Approved as Requested	Proposed PT	
			<i>Congenital thrombotic thrombocytopenic purpura</i>	10091107
			HLT primary	
			<i>Haematological disorders congenital NEC</i>	10018848
			SOC primary	
			<i>Congenital, familial and genetic disorders</i>	10010331
			HLT secondary	
			<i>Thrombocytopenias</i>	10043555
			SOC secondary	
			<i>Blood and lymphatic system disorders</i>	10005329

MSSO Comment: The proposal to add a new PT Congenital thrombotic thrombocytopenic purpura is approved as requested. Congenital thrombotic thrombocytopenic purpura (cTTP) is a rare autosomal recessive microangiopathic disorder caused by inherited mutations in the ADAMTS13 gene. The prophylactic transfusion of fresh frozen plasma has been linked to significant improvements in symptoms and outcomes. Congenital thrombotic thrombocytopenic purpura will be added as new PT under primary HLT Haematological disorders congenital NEC and secondary HLT Thrombocytopenias, HLT Purpura and related conditions and HLT Bruising, ecchymosis and purpura.

<b>CR Number:</b> 2024130012		<b>Implementation Date:</b> 09-May-24	<b>Related CR:</b> 2024128005	
<u>Change Requested</u>	Link a PT to a HLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Congenital thrombotic thrombocytopenic purpura</i>	Approved as Requested	Proposed PT	
To HLT	<i>Purpura and related conditions</i>		<i>Congenital thrombotic thrombocytopenic purpura</i>	10091107
			To HLT	
			<i>Purpura and related conditions</i>	10037555

MSSO Comment:

# Detail Report

<b>CR Number:</b> 2024130013		<b>Implementation Date:</b> 09-May-24	<b>Related CR:</b> 2024128005	
<u>Change Requested</u>	Link a PT to a HLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Congenital thrombotic thrombocytopenic purpura</i>	Approved as Requested	Proposed PT	
To HLT	<i>Bruising, ecchymosis and purpura</i>		<i>Congenital thrombotic thrombocytopenic purpura</i>	10091107
			To HLT	
			<i>Bruising, ecchymosis and purpura</i>	10006513

MSSO  
Comment:

<b>CR Number:</b> 2024128010		<b>Implementation Date:</b> 13-May-24	<b>Related CR:</b> 2024128010	
<u>Change Requested</u>	Add a New Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	<i>Right conjoint tendon release</i>	Rejected		

MSSO  
Comment: The proposal to add a new term Right conjoint tendon release is not approved. The term tendon release is not specific enough for addition to MedDRA. The word is used for both cutting tissue around the tendon (tenolysis, tendon sheath incision), the tendon itself (tenotomy) or even as tendon release therapy as a form of physiotherapy. Conjoint tendon is a non-specific anatomic location and can refer to the shoulder, abdominal wall (inguinal hernia repair), hamstring etc. In addition, MedDRA does not include laterality of a medical concept, unless it is crucial to the concept itself, such as the distinction between the left and right ventricle. Less specific terms for the concept of tendon or shoulder operation exist and can be used for coding if the concept is unclear from context and cannot be assigned to the more specific LLTs.

<b>CR Number:</b> 2024129001		<b>Implementation Date:</b> 13-May-24	<b>Related CR:</b> 2024129001	
<u>Change Requested</u>	Add a New Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	<i>Rupture of renal pelvis and ureteral junction</i>	Approved Not as Requested	Proposed LLT	
			<i>Rupture of ureteropelvic junction</i>	10091113 Current
			To PT	
			<i>Kidney rupture</i>	10023434

MSSO  
Comment: The proposal to add a new term Rupture of renal pelvis and ureteral junction is approved but not as requested. A rupture of the ureteropelvic junction can occur due to various reasons such as trauma, congenital abnormalities, kidney stones, or other anatomical issues. When the ureteropelvic junction ruptures, it can lead to leakage of urine into the surrounding areas, causing symptoms such as severe pain in the flank or abdomen, hematuria, and possibly signs of shock. Proposed term will be modified and added as LLT Rupture of ureteropelvic junction to PT Kidney rupture aligned with LLT Rupture of renal pelvis. In a related change PT Renal forniceal rupture will be demoted under PT Kidney rupture.

# Detail Report

<b>CR Number:</b> 2024134003		<b>Implementation Date:</b> 13-May-24	<b>Related CR:</b> 2024129001	
<a href="#">Change Requested</a>	Demote a PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
PT to merge	<i>Renal forniceal rupture</i>	Approved as Requested	PT to merge	
To PT	<i>Kidney rupture</i>		<i>Renal forniceal rupture</i>	10089973 Current
			To PT	
			<i>Kidney rupture</i>	10023434

MSSO  
Comment:

<b>CR Number:</b> 2024129002		<b>Implementation Date:</b> 13-May-24	<b>Related CR:</b> 2024129002	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Tooth concussion</i>	Approved as Requested	Proposed LLT	
			<i>Tooth concussion</i>	10091114 Current
			To PT	
			<i>Tooth injury</i>	10044043

MSSO  
Comment:

The proposal to add a new term Tooth concussion is approved as requested. A tooth concussion, also known as dental concussion, is a dental injury that occurs when a tooth receives a blow. Unlike more severe injuries like tooth fracture or avulsion, a tooth concussion doesn't involve visible damage to the tooth structure or displacement from its socket. Tooth concussion will be added as LLT to PT Tooth injury.

<b>CR Number:</b> 2024129003		<b>Implementation Date:</b> 13-May-24	<b>Related CR:</b> 2024129003	
<a href="#">Change Requested</a>	Promote an LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Manufacturing equipment sanitisation issue</i>	Approved as Requested	Proposed LLT	
From PT	<i>Manufacturing equipment cleaning issue</i>		<i>Manufacturing equipment sanitisation issue</i>	10078634
HLT primary	<i>Manufacturing facilities and equipment issues</i>		From PT	
			<i>Manufacturing equipment cleaning issue</i>	10078619
			HLT primary	
			<i>Manufacturing facilities and equipment issues</i>	10077539
			SOC primary	
			<i>Product issues</i>	10077536

MSSO  
Comment:

The proposal to promote the LLT Manufacturing equipment sanitisation issue from PT Manufacturing equipment cleaning issue to primary HLT Manufacturing facilities and equipment issues in SOC Product issues is approved as requested. Sanitization and equipment cleaning both contribute to maintaining a hygienic manufacturing environment. Sanitization specifically targets reduction of the bioburden to ensure product safety. Although they can occur simultaneously, they are sometimes separate steps with different focus. In a related change the American English spelled counterpart LLT Manufacturing equipment sanitization issue will be moved under the newly promoted PT Manufacturing equipment sanitisation issue.



# Detail Report

<b>CR Number:</b> 2024134004		<b>Implementation Date:</b> 13-May-24	<b>Related CR:</b> 2024129003		
<a href="#">Change Requested</a>	Link (move) an LLT to another PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed LLT	Manufacturing equipment sanitization issue	Approved as Requested	Proposed LLT		
From PT	Manufacturing equipment cleaning issue		Manufacturing equipment sanitization issue	10078624	Current
To PT	Manufacturing equipment sanitisation issue		From PT		
			Manufacturing equipment cleaning issue	10078619	
			To PT		
			Manufacturing equipment sanitisation issue	10078634	

MSSO  
Comment:

<b>CR Number:</b> 2024129004		<b>Implementation Date:</b> 13-May-24	<b>Related CR:</b> 2024129004		
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed PT	Manufacturing equipment sterilisation issue	Approved as Requested	Proposed PT		
HLT primary	Manufacturing facilities and equipment issues		Manufacturing equipment sterilisation issue	10091123	
SOC primary	Product issues		HLT primary		
			Manufacturing facilities and equipment issues	10077539	
			SOC primary		
			Product issues	10077536	

MSSO  
Comment: The proposal to add a new PT Manufacturing equipment sterilisation issue to primary HLT Manufacturing facilities and equipment issues in SOC Product issues is approved as requested. Sterilization is distinct from disinfection and sanitization in that those methods reduce rather than eliminate all forms of life and biological agents present. In contrast to sanitization, the purpose of sterilization is to render an object sterile, defined as a 6log (6 orders of magnitude) reduction of the bioburden. In a related change, the American spelled counterpart LLT Manufacturing equipment sterilization issue will be added to PT Manufacturing equipment sterilisation issue.

<b>CR Number:</b> 2024134005		<b>Implementation Date:</b> 13-May-24	<b>Related CR:</b> 2024129004		
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed LLT	Manufacturing equipment sterilization issue	Approved as Requested	Proposed LLT		
To PT	Manufacturing equipment sterilisation issue		Manufacturing equipment sterilization issue	10091130	Current
			To PT		
			Manufacturing equipment sterilisation issue	10091123	

MSSO  
Comment:

# Detail Report

<b>CR Number:</b> 2024129005		<b>Implementation Date:</b> 13-May-24		<b>Related CR:</b> 2024129005	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed LLT	Manufacturing facility high efficiency air filter issue	Approved as Requested	Proposed LLT	Manufacturing facility high efficiency air filter issue	10091129 Current
To PT	Manufacturing facilities issue		To PT	Manufacturing facilities issue	10077794
<b>MSSO Comment:</b> The proposal to add a new LLT Manufacturing facility high efficiency air filter issue to PT Manufacturing facilities issue is approved as requested. In facilities, HEPA filters are part of both the equipment and the facility depending on the clean room grade. A term in parallel to the equipment HEPA filter is needed for the facility.					

<b>CR Number:</b> 2024129006		<b>Implementation Date:</b> 13-May-24		<b>Related CR:</b> 2024129006	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed LLT	Use of inappropriate cleaning agent in manufacturing	Approved as Requested	Proposed LLT	Use of inappropriate cleaning agent in manufacturing	10091125 Current
To PT	Manufacturing equipment cleaning issue		To PT	Manufacturing equipment cleaning issue	10078619
<b>MSSO Comment:</b> The proposal to add a new LLT Use of inappropriate cleaning agent in manufacturing to PT Manufacturing equipment cleaning issue is approved as requested. Use of inappropriate cleaning agent in manufacturing can result in cleaning being ineffective or other issues (re-contaminated equipment).					

<b>CR Number:</b> 2024129007		<b>Implementation Date:</b> 13-May-24		<b>Related CR:</b> 2024129007	
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed PT	Material from non-qualified supplier used	Approved as Requested	Proposed PT	Material from non-qualified supplier used	10091122
HLT primary	Manufacturing materials issues		HLT primary	Manufacturing materials issues	10077542
SOC primary	Product issues		SOC primary	Product issues	10077536
<b>MSSO Comment:</b> The proposal to add a new PT Material from non-qualified supplier used to primary HLT Manufacturing materials issues in SOC Product issues is approved as requested. Use of material coming from a non-qualified supplier is a deviation in the manufacturing process, which can influence the quality of the finished product. Material can refer to active ingredient, inactive or general ingredients, but also closure systems.					

# Detail Report

<b>CR Number:</b> 2024129008		<b>Implementation Date:</b> 13-May-24	<b>Related CR:</b> 2024129008	
<u>Change Requested</u>	Add a New PT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Manufacturing laboratory analytical testing method management issue	Approved as Requested	Proposed PT	
HLT primary	Manufacturing laboratory controls issues		Manufacturing laboratory analytical testing method management issue	10091124
SOC primary	Product issues		HLT primary	
			Manufacturing laboratory controls issues	10077541
			SOC primary	
			Product issues	10077536
<b>MSSO Comment:</b> The proposal to add a new PT Manufacturing laboratory analytical testing method management issue to primary HLT Manufacturing laboratory controls issues in SOC Product issues is approved as requested. Manufacturing laboratory analytical testing method management issues are specific method management issues related to concepts such as missing method life cycle management, documentation of the method not controlled, and uncontrolled modification of integration (e.g., chromatographic parameters). These differentiate from issues with the testing process.				

<b>CR Number:</b> 2024129009		<b>Implementation Date:</b> 13-May-24	<b>Related CR:</b> 2024129009	
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Stability protocol deviation not documented	Approved as Requested	Proposed LLT	
To PT	Manufacturing stability testing issue		Stability protocol deviation not documented	10091128 Current
			To PT	
			Manufacturing stability testing issue	10079047

**MSSO Comment:** The proposal to add a new LLT Stability protocol deviation not documented to PT Manufacturing stability testing issue is approved as requested. Stability protocol deviation not documented refers to a situation where a deviation to the established stability testing protocol occurred.

<b>CR Number:</b> 2024129010		<b>Implementation Date:</b> 13-May-24	<b>Related CR:</b> 2024129010	
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Out of specification test results stability	Approved as Requested	Proposed LLT	
To PT	Out of specification test results		Out of specification test results stability	10091126 Current
			To PT	
			Out of specification test results	10071067

**MSSO Comment:** The proposal to add a new LLT Out of specification test results stability to PT Out of specification test results is approved as requested. Out of specification test results can relate to the stability.

# Detail Report

<b>CR Number:</b> 2024129011		<b>Implementation Date:</b> 13-May-24	<b>Related CR:</b> 2024129011	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Out of trend test result stability</i>	Approved as Requested	Proposed LLT	
To PT	<i>Out of trend test result</i>		<i>Out of trend test result stability</i>	10091127 Current
			To PT	
			<i>Out of trend test result</i>	10087918

**MSSO Comment:** The proposal to add a new LLT Out of trend test result stability to PT Out of trend test result is approved as requested. Out of trend test results can relate to the stability.

<b>CR Number:</b> 2024129015		<b>Implementation Date:</b> 13-May-24	<b>Related CR:</b> 2024129015	
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Ileocaecal valve lipoma</i>	Approved as Requested	Proposed PT	
HLT primary	<i>Lower gastrointestinal neoplasms benign</i>		<i>Ileocaecal valve lipoma</i>	10091131
SOC primary	<i>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</i>		HLT primary	
			<i>Lower gastrointestinal neoplasms benign</i>	10024948
			SOC primary	
			<i>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</i>	10029104
			HLT secondary	
			<i>Benign neoplasms gastrointestinal (excl oral cavity)</i>	10017988
			SOC secondary	
			<i>Gastrointestinal disorders</i>	10017947

**MSSO Comment:** The proposal to add a new PT Ileocaecal valve lipoma to primary HLT Lower gastrointestinal neoplasms benign in SOC Neoplasms benign, malignant and unspecified (incl cysts and polyps) and secondary HLT Benign neoplasms gastrointestinal (excl oral cavity) in SOC Gastrointestinal disorders is approved as requested. This concept was added in change request 2024101005 in the American English spelling. In this change request the same concept in its British English spelling will be added based on MedDRA conventions.

# Detail Report

<b>CR Number:</b> 2024129016		<b>Implementation Date:</b> 13-May-24	<b>Related CR:</b> 2024129016	
<a href="#">Change Requested</a>	Demote a PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
PT to merge	<i>Ileocecal valve lipoma</i>	Approved as Requested	PT to merge	
To PT	<i>Ileocaecal valve lipoma</i>		<i>Ileocecal valve lipoma</i>	10090992 Current
			To PT	
			<i>Ileocaecal valve lipoma</i>	10091131
<b>MSSO Comment:</b> The proposal to demote the PT Ileocecal valve lipoma under PT Ileocaecal valve lipoma is approved as requested. In CR# 2024101005 Ileocecal valve lipoma was added as a PT. Based on MedDRA conventions, the American English spelled term will be an LLT under the new British English spelled term requested in previous change request 2024129015.				

<b>CR Number:</b> 2024129017		<b>Implementation Date:</b> 13-May-24	<b>Related CR:</b> 2024129017	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Dust and sandstorms allergy</i>	Approved Not as Requested	Proposed LLT	
			<i>Sandstorm dust allergy</i>	10091115 Current
			To PT	
			<i>Dust allergy</i>	10077439
<b>MSSO Comment:</b> The proposal to add a new term Dust and sandstorms allergy is approved but not as requested. Dust and sandstorm allergies occur when individuals react to allergens stirred up and carried by storms. Sandstorms can stir up a variety of allergens such as pollen, mold spores, dust mites, and animal dander aggravating symptoms in susceptible individuals. The proposed term will be modified and added as Sandstorm dust allergy to PT Dust allergy.				

<b>CR Number:</b> 2024129019		<b>Implementation Date:</b> 13-May-24	<b>Related CR:</b> 2024129019	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Linogram</i>	Approved as Requested	Proposed PT	
			<i>Linogram</i>	10091116
			HLT primary	
			<i>Vascular imaging procedures NEC</i>	10047078
			SOC primary	
			<i>Investigations</i>	10022891

**MSSO Comment:** The proposal to add a new term Linogram is approved as requested. Dynamic fluoroscopic imaging with contrast injection or linogram, is a commonly used imaging modality to determine tunneled central venous catheter patency when malfunction is suspected. Linogram will be added as a PT to HLT Vascular imaging procedures NEC.

# Detail Report

<b>CR Number:</b> 2024130000		<b>Implementation Date:</b> 13-May-24	<b>Related CR:</b> 2024130000	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Pattern-sensitive epilepsy</i>	Approved Not as Requested	Proposed LLT	
To PT	<i>Photosensitive seizure</i>		<i>Pattern-sensitive seizure</i>	10091117 Current
			To PT	
			<i>Photosensitive seizure</i>	10086294
<b>MSSO Comment:</b> The proposal to add a new LLT Pattern-sensitive epilepsy to PT Photosensitive seizure is approved but not as requested. Pattern-sensitive epilepsy is a form of reflex epilepsy in which seizures are precipitated by visual patterns, typically stripes. Because of the close association between sensitivity to intermittent photic stimulation and sensitivity to visual pattern stimulation, pattern-sensitive epilepsy has been commonly regarded as an extension of photosensitive epilepsy. Any type of seizure could be triggered but tonic-clonic seizures are the most common, thus the proposed term will be modified and added as LLT Pattern-sensitive seizure under PT Photosensitive seizure for better alignment.				

<b>CR Number:</b> 2024130001		<b>Implementation Date:</b> 13-May-24	<b>Related CR:</b> 2024130001	
<a href="#">Change Requested</a>	Rename PT/LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Term to modify	<i>Stoma complication</i>	Rejected		
Replacement term	<i>Stoma related complication</i>			
<b>MSSO Comment:</b> The proposal to rename PT/LLT Stoma complication to Stoma related complication is not approved. The proposed terms are often used interchangeably, but they can refer to slightly different aspects of issues that arise around a stoma. Stoma complication generally refers to any problem directly related to the stoma structure or function itself, such as prolapse, retraction, necrosis, stenosis, or mucocutaneous separation. Stoma site complication refers to issues that occur in the area immediately surrounding the stoma. Stoma related complication is a broader term that encompasses both stoma complications and site complications, as well as any other complications that arise as a result of having a stoma.				

<b>CR Number:</b> 2024130008		<b>Implementation Date:</b> 13-May-24	<b>Related CR:</b> 2024130008	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Pectoral implant</i>	Approved Not as Requested	Proposed PT	
			<i>Pectoral implantation</i>	10091118
			HLT primary	
			<i>Soft tissue therapeutic procedures NEC</i>	10052876
			SOC primary	
			<i>Surgical and medical procedures</i>	10042613
<b>MSSO Comment:</b> The proposal to add a new LLT Pectoral implant is approved but not as requested. Pectoral implants are performed for several reasons, including to treat a congenital or acquired chest wall asymmetry or to enhance the appearance of the chest. The trans-axillary approach is the most common method utilized for the insertion. The proposed term will be modified to clearly indicate a procedure term and not name of product and added as PT Pectoral implantation to HLT Soft tissue therapeutic procedures NEC.				

# Detail Report

<b>CR Number:</b> 2024131000		<b>Implementation Date:</b> 16-May-24	<b>Related CR:</b> 2024131000		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed LLT	<i>Rheumatic arthritis</i>	Rejected			
To PT	<i>Rheumatic fever</i>				

**MSSO Comment:** The proposal to add a new LLT Rheumatic arthritis to PT Rheumatic fever is not approved, based on the possibility of confusion with rheumatoid arthritis.

<b>CR Number:</b> 2024131001		<b>Implementation Date:</b> 16-May-24	<b>Related CR:</b> 2024131001		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed LLT	<i>Congenital absence of internal carotid artery</i>	Approved Not as Requested	Proposed PT		
To PT	<i>Congenital arterial malformation</i>		<i>Carotid hypoplasia</i>		10091136
			HLT primary		
			<i>Vascular anomalies congenital NEC</i>		10047047
			SOC primary		
			<i>Congenital, familial and genetic disorders</i>		10010331
			HLT secondary		
			<i>Congenital and hereditary central nervous system disorders NEC</i>		10010332
			SOC secondary		
			<i>Nervous system disorders</i>		10029205

**MSSO Comment:** The proposal to add a new LLT Congenital absence of internal carotid artery to PT Congenital arterial malformation is approved but not as requested. Internal carotid artery hypoplasia is extremely rare congenital anomaly, which in most of cases is asymptomatic and discovered incidentally. The proposed term will be modified to Carotid hypoplasia, for its wider use in literature and similarity with the existing related PT Vertebral artery hypoplasia, and added as PT with primary link to the HLT Vascular anomalies congenital NEC and secondary links to HLT Congenital and hereditary central nervous system disorders NEC and HLT Vascular malformations and acquired anomalies. In a proactive associated change, a new LLT named Carotid aplasia will be added under the new PT Carotid hypoplasia to represent those cases where the carotid canal presence is completely absent.

# Detail Report

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<b>CR Number:</b> 2024137019		<b>Implementation Date:</b> 16-May-24	<b>Related CR:</b> 2024131001	<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Link a PT to a HLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	
Proposed PT	<i>Carotid hypoplasia</i>	Approved as Requested	Proposed PT	
To HLT	<i>Vascular malformations and acquired anomalies</i>		<i>Carotid hypoplasia</i>	10091136
			To HLT	
			<i>Vascular malformations and acquired anomalies</i>	10047091

MSSO  
Comment:

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<b>CR Number:</b> 2024137020		<b>Implementation Date:</b> 16-May-24	<b>Related CR:</b> 2024131001	<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	
Proposed LLT	<i>Carotid aplasia</i>	Approved as Requested	Proposed LLT	
To PT	<i>Carotid hypoplasia</i>		<i>Carotid aplasia</i>	10091137 Current
			To PT	
			<i>Carotid hypoplasia</i>	10091136

MSSO  
Comment:

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<b>CR Number:</b> 2024131004		<b>Implementation Date:</b> 16-May-24	<b>Related CR:</b> 2024131004	<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	
Proposed LLT	<i>Poroma</i>	Approved as Requested	Proposed LLT	
To PT	<i>Sweat gland tumour</i>		<i>Poroma</i>	10091133 Current
			To PT	
			<i>Sweat gland tumour</i>	10042658

MSSO  
Comment: The proposal to add a new LLT Poroma to PT Sweat gland tumour is approved as requested. Poroma is a benign adnexal neoplasm of the terminal sweat gland duct. Although poromas have traditionally been thought to originate from the eccrine sweat gland, there have been cases of apocrine etiology as well. The unqualified term Poroma will be added to represent the instances when a distinction has not been mentioned.

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# Detail Report

CR Number: 2024131005		Implementation Date: 16-May-24	Related CR: 2024131005		
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed LLT	<i>Klebsiella respiratory tract infection</i>	Rejected			
MSSO Comment:	The proposal to add a new LLT <i>Klebsiella respiratory tract infection</i> is not approved. The proposed term combines a medical concept with additional medical wording related to etiology and/or pathophysiology. Section 3.5 of the MedDRA Term Selection Points to Consider (MTS:PTC) document defines these as "combination terms" and provides coding guidance. When considering the addition of such combination terms, MedDRA generally attempts to limit inclusion to those terms which describe important, distinct and robust medical concepts which are internationally recognized diagnostic entities. As well, please refer to section 3.8 Location-Specific vs. Microorganism-Specific.				

CR Number: 2024131006		Implementation Date: 16-May-24	Related CR: 2024131006		
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed LLT	<i>Bone marrow hemophagocytic macrophages present</i>	Approved as Requested	Proposed LLT <i>Bone marrow hemophagocytic macrophages present</i> To PT <i>Bone marrow haemophagocytic macrophages present</i>	10091135	Current
				10091134	
MSSO Comment:	The proposal to add a new LLT <i>Bone marrow hemophagocytic macrophages present</i> is approved as requested. Available evidence suggests that hemophagocytosis by activated macrophages seen in the bone marrow contributes to the unexplained thrombocytopenia in some patients with sepsis. <i>Bone marrow hemophagocytic macrophages present</i> will be added as LLT to the British English spelled counterpart PT <i>Bone marrow haemophagocytic macrophages present</i> , added in a related change, under HLT <i>Bone marrow and immune tissue histopathology procedures</i> .				

# Detail Report

CR Number: 2024137018		Implementation Date: 16-May-24	Related CR: 2024131006	
<u>Change Requested</u>	Add a New PT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Bone marrow haemophagocytic macrophages present	Approved as Requested	Proposed PT	10091134
HLT primary	Bone marrow and immune tissue histopathology procedures		Bone marrow haemophagocytic macrophages present	
SOC primary	Investigations		HLT primary	10068276
			Bone marrow and immune tissue histopathology procedures	
			SOC primary	10022891
			Investigations	

MSSO  
Comment:

CR Number: 2024131007		Implementation Date: 16-May-24	Related CR: 2024131007	
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Fungal enteritis	Approved Not as Requested	Proposed PT	10091132
			Fungal enteritis	
			HLT primary	10017536
			Fungal infections NEC	
			SOC primary	10021881
			Infections and infestations	
			HLT secondary	10022678
			Intestinal infections	
			SOC secondary	10017947
			Gastrointestinal disorders	

MSSO  
Comment: The proposal to add a new LLT Fungal enteritis is approved but not as requested. Enteritis caused by fungal infection has become more common in recent years. In part this may be because of improved diagnostic methods and increased survival periods of patients whose underlying disease predisposes to secondary infection with opportunistic fungi. Fungal enteritis will be added as new PT under primary HLT Fungal infections NEC and secondary HLT Intestinal infections.

# Detail Report

CR Number: 2024131008		Implementation Date: 16-May-24	Related CR: 2024131008	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Vitreous wick syndrome</i>	Approved Not as Requested	Proposed PT	
To PT	<i>Ocular procedural complication</i>		<i>Vitreous wick syndrome</i>	10091138
			HLT primary	
			<i>Eye and ear procedural complications</i>	10015908
			SOC primary	
			<i>Injury, poisoning and procedural complications</i>	10022117
			HLT secondary	
			<i>Choroid and vitreous structural change, deposit and degeneration</i>	10008776
			SOC secondary	
			<i>Eye disorders</i>	10015919

**MSSO Comment:** The proposal to add a new LLT Vitreous wick syndrome to PT Ocular procedural complication is approved but not as requested. Vitreous wick syndrome occurs after eye surgery or trauma and is characterized by microscopic wound breakdown accompanied by vitreous prolapse that develops into a vitreous 'wick'. Vitreous wick syndrome will be added as a new PT under primary HLT Eye and ear procedural complications and secondary HLT Choroid and vitreous structural change, deposit and degeneration.

CR Number: 2024131010		Implementation Date: 16-May-24	Related CR: 2024131010	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Adrenal lipoma</i>	Approved as Requested	Proposed LLT	
			<i>Adrenal lipoma</i>	10091139 Current
			To PT	
			<i>Benign neoplasm of adrenal gland</i>	10004300

**MSSO Comment:** The proposal to add a new LLT Adrenal lipoma is approved as requested. Adrenal lipomas are rare, small, benign, non-functioning tumors, which must be histopathologically differentiated from other tumors such as myelolipomas or liposarcomas. They are usually identified incidentally during autopsy, imaging, or laparotomy. Adrenal lipoma will be added as LLT to PT Benign neoplasm of adrenal gland.

# Detail Report

CR Number: 2024132000		Implementation Date: 16-May-24	Related CR: 2024132000		
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed LLT	Liver region pain	Rejected			
To PT	abdominal pain upper				

MSSO Comment: The proposal to add a new LLT Liver region pain to PT abdominal pain upper is not approved. Clinically, healthcare providers are more likely to describe pain in the liver region as "right upper quadrant pain" or "right upper abdominal pain." This terminology is more precise and encompasses not only the liver but also other organs and structures in that region, such as the gallbladder, right kidney, parts of the intestines, and the lower part of the right lung.

CR Number: 2024133000		Implementation Date: 16-May-24	Related CR: 2024133000		
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed LLT	Bathmophobia	Approved Not as Requested	Proposed PT Bathmophobia	10091140	
			HLT primary Fear symptoms and phobic disorders (incl social phobia)	10068299	
			SOC primary Psychiatric disorders	10037175	

MSSO Comment: The proposal to add a new LLT Bathmophobia is approved but not as requested. Bathmophobia is the extreme fear of stairs or slopes. It is considered a specific phobia, a condition in which a person has an irrational fear of something that poses little to no danger to their day-to-day life. Bathmophobia will be added as new PT under HLT Fear symptoms and phobic disorders (incl social phobia).

CR Number: 2024134000		Implementation Date: 16-May-24	Related CR: 2024134000		
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed Term	LLT circulatory respiratory failure	Rejected			

MSSO Comment: The proposal to add a new term LLT circulatory respiratory failure is not approved. The proposed term combines two medical concepts of very different pathophysiology. Please refer to Section 3.5 of the MedDRA Term Selection: Points to Consider Document regarding coding approaches/considerations.

# Detail Report

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<b>CR Number:</b> 2024134001	<b>Implementation Date:</b> 16-May-24	<b>Related CR:</b> 2024134001	<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>
Proposed Term	<i>Ischemic renal injury</i>	Rejected	

**MSSO Comment:** The proposal to add a new term Ischemic renal injury is not approved. Ischemic renal injury refers to damage to the kidneys caused by insufficient blood flow. The concept can be represented by existing LLT/PT Ischaemic nephropathy. Depending on the clinical scenario, an even more specific LLT/PT in HLT Renal vascular and ischaemic conditions may be available.

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<b>CR Number:</b> 2024134002	<b>Implementation Date:</b> 16-May-24	<b>Related CR:</b> 2024134002	<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>
Proposed PT	<i>Vulvovaginal mass</i>	Rejected	

**MSSO Comment:** The proposal to add a new PT Vulvovaginal mass is not approved. "Mass" is an imprecise word, and terms containing this word will generally not be added into MedDRA when a more precise "disorder" terms exist.

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<b>CR Number:</b> 2024135000	<b>Implementation Date:</b> 21-May-24	<b>Related CR:</b> 2024135000	<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>
Proposed PT	<i>Atypical parkinsonism</i>	Approved as Requested	
		Proposed PT	
		<i>Atypical parkinsonism</i>	10091145
		HLT primary	
		<i>Parkinson's disease and parkinsonism</i>	10034005
		SOC primary	
		<i>Nervous system disorders</i>	10029205

**MSSO Comment:** The proposal to add a new PT Atypical parkinsonism is approved as requested. Parkinsonism is a clinical syndrome presenting with any combination of bradykinesia, rest tremor, rigidity, and postural instability. The most common form of parkinsonism is Parkinson disease. Atypical parkinsonism, also known as Parkinson-plus syndromes, refers to a group of neurodegenerative disorders (such as Dementia with Lewy bodies, Multiple System Atrophy, Progressive Supranuclear Palsy, Corticobasal Degeneration) that share some symptoms with Parkinson's disease but also have additional distinctive features but generally do not respond well to drug treatment with levodopa. Atypical parkinsonism will be added as a PT to HLT Parkinson's disease and parkinsonism.

# Detail Report

<b>CR Number:</b> 2024135001		<b>Implementation Date:</b> 20-May-24	<b>Related CR:</b> 2024135001		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed LLT	Aciclovir	Rejected			

**MSSO Comment:** The proposal to add a new LLT Aciclovir is not approved. Aciclovir is a drug name and MedDRA does not add drug names except in specific circumstances. In addition, MedDRA cannot accommodate drug test combination terms for every specific drug. HLT Therapeutic drug monitoring analyses includes a variety of terms, such as unqualified test name LLT/PT Antiviral drug level, which might be adequate for your specific coding scenario.

<b>CR Number:</b> 2024135002		<b>Implementation Date:</b> 20-May-24	<b>Related CR:</b> 2024135002		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed LLT	Neoehrlichiosis	Approved as Requested	Proposed PT Neoehrlichiosis		10091146
			HLT primary Rickettsial infectious disorders NEC		10039134
			SOC primary Infections and infestations		10021881

**MSSO Comment:** The proposal to add a new LLT Neoehrlichiosis is approved as requested. Neoehrlichia mikurensis is a gram-negative bacterium carried and spread by Ixodes ricinus ticks often found in Europe and Asia. It causes a disease process called neoehrlichiosis, which can result in vasculitis and thromboembolic events. Neoehrlichiosis will be added as a new PT linked to HLT Rickettsial infectious disorders NEC.

<b>CR Number:</b> 2024135003		<b>Implementation Date:</b> 20-May-24	<b>Related CR:</b> 2024135003		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed LLT	Candidatus neoehrlichia mikurensis infection	Approved Not as Requested	Proposed LLT Neoehrlichia mikurensis infection		10091147 Current
			To PT Neoehrlichiosis		10091146

**MSSO Comment:** The proposal to add a new LLT Candidatus neoehrlichia mikurensis infection is approved but not as requested. Neoehrlichia mikurensis, previously known as Candidatus Neoehrlichia mikurensis, is an intracellular, gram-negative bacteria belonging to the family Anaplasmataceae. Using ticks as vectors, it spreads between animals - mainly rodents, but other mammals as well as humans can get infected. The proposed term will be modified to its current denomination and added as LLT Neoehrlichia mikurensis infection to PT Neoehrlichiosis added in change request 2024135002.

# Detail Report

CR Number: 2024135004		Implementation Date: 21-May-24	Related CR: 2024135004	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Rectoscopy	Approved as Requested	Proposed LLT Rectoscopy	10091150 Current
			To PT Proctoscopy	10036786
MSSO Comment:	The proposal to add a new LLT Rectoscopy is approved as requested. Proctoscopy is the inspection of the rectum with a proctoscope and is also called rectoscopy. Rectoscopy will be added as synonym LLT to PT Proctoscopy.			

CR Number: 2024135005		Implementation Date: 21-May-24	Related CR: 2024135005	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Porto-sinusoidal vascular disorder	Approved as Requested	Proposed LLT Porto-sinusoidal vascular disorder	10091148
			To PT Venoocclusive liver disease	10047216
MSSO Comment:	The proposal to add a new LLT Porto-sinusoidal vascular disorder is approved as requested. Porto-sinusoidal vascular disorder (also called hepatic sinusoidal obstruction syndrome or veno-occlusive disease), is a systemic endothelial disease that typically presents in the days or weeks after hematopoietic cell transplantation with refractory thrombocytopenia, hepatomegaly, ascites, and jaundice, and can rapidly progress to multiorgan dysfunction and death. Porto-sinusoidal vascular disorder will be added as a synonym LLT to PT Venoocclusive liver disease.			

CR Number: 2024135006		Implementation Date: 23-May-24	Related CR: 2024135006	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Developmental and epileptic encephalopathy	Rejected After Suspension		
MSSO Comment:	The proposal to add a new LLT Developmental and epileptic encephalopathy is not approved after suspension. Developmental and epileptic encephalopathy (DEE) is a grouping term describing a group of severe epilepsies that are characterized both by seizures, which are often drug-resistant, as well as encephalopathy, which is a term used to describe significant developmental delay or even loss of developmental skills. The proposed term is not a diagnosis or standalone concept.			

# Detail Report

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<b>CR Number:</b> 2024135007		<b>Implementation Date:</b> 20-May-24	<b>Related CR:</b> 2024135007		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed LLT	<i>Psychiatric health deteriorated</i>	Rejected			

**MSSO Comment:** The proposal to add a new LLT Psychiatric health deteriorated is not approved. MedDRA cannot accommodate a separate term for an aggravated state of every potential disease or condition. The "MedDRA Term selection: Points to consider document" allows the option of splitting and coding to completely represent an adverse event in the absence of a single MedDRA term. Therefore, please consider splitting the verbatim concept and code using existing MedDRA LLT Condition aggravated.

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<b>CR Number:</b> 2024135008		<b>Implementation Date:</b> 21-May-24	<b>Related CR:</b> 2024135008		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed LLT	<i>Altered hearing</i>	Rejected			

**MSSO Comment:** The proposal to add a new LLT Altered hearing is not approved. The proposed term is one of many colloquial expressions that normal language could use to refer to the existing PT Auditory disorder. To avoid the overpopulation of the terminology, MedDRA can not address representation of the endless number of possible such expressions.

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<b>CR Number:</b> 2024135009		<b>Implementation Date:</b> 21-May-24	<b>Related CR:</b> 2024135009		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed LLT	<i>Adermatoglyphia acquired</i>	Approved as Requested	Proposed LLT <i>Adermatoglyphia acquired</i>	10091149	Current
			To PT <i>Fingerprint loss</i>	10069686	

**MSSO Comment:** The proposal to add a new LLT Adermatoglyphia acquired is approved as requested. The loss of epidermal ridges is not an uncommon observation, especially in the elderly population and can be classified by dermatological and non-dermatological causes. Adermatoglyphia acquired will be added as LLT under PT Fingerprint loss.

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# Detail Report

<b>CR Number:</b> 2024135010		<b>Implementation Date:</b> 21-May-24	<b>Related CR:</b> 2024135010		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed LLT	PSDV	Rejected			

**MSSO Comment:** The proposal to add a new LLT PSDV is not approved. The proposed term would have the potential for confusion with other similar acronyms. The spelled out concept was added in change request 2024135005 as LLT Porto-sinusoidal vascular disorder.

<b>CR Number:</b> 2024135011		<b>Implementation Date:</b> 23-May-24	<b>Related CR:</b> 2024135011		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed LLT	DEE	Rejected After Suspension			

**MSSO Comment:** The proposal to add a new LLT DEE is not approved after suspension. Developmental and epileptic encephalopathy (DEE) is a grouping term describing a group of severe epilepsies that are characterized both by seizures, which are often drug-resistant, as well as encephalopathy, which is a term used to describe significant developmental delay or even loss of developmental skills. The proposed term is not a diagnosis or standalone concept.

<b>CR Number:</b> 2024135012		<b>Implementation Date:</b> 21-May-24	<b>Related CR:</b> 2024135012		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed LLT	HMG-CoA antibodies	Rejected			

**MSSO Comment:** The proposal to add a new LLT HMG-CoA antibodies is not approved. The proposed concept exists as LLT/PT HMG CoA reductase antibody test.

# Detail Report

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<b>CR Number:</b> 2024135013	<b>Implementation Date:</b> 21-May-24	<b>Related CR:</b> 2024135013	<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>
Proposed LLT	CMMG	Rejected	

**MSSO Comment:** The proposal to add a new LLT CMMG is not approved. Acyclovir's main metabolite 9-carboxymethoxymethylguanine is a presumptive neurotoxin and should be monitored in patients with impaired renal function or in cases with neurotoxic symptoms. Drug names as well their metabolites, are not added in MedDRA. HLT Therapeutic drug monitoring analyses includes a variety of terms, such as unqualified test name LLT/PT Antiviral drug level, which might be adequate for your specific coding scenario.

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<b>CR Number:</b> 2024135014	<b>Implementation Date:</b> 21-May-24	<b>Related CR:</b> 2024135014	<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>
Proposed LLT	Prophylaxis against human metapneumovirus infection	Rejected	

**MSSO Comment:** The proposal to add a new LLT Prophylaxis against human metapneumovirus infection is not approved. As there is no vaccine for human metapneumovirus licensed for use in humans, and therapies used to treat patients are nonspecific, the proposed concept is not a valid concept at this time. In addition, Section 3.26.4 of the MedDRA Term Selection Points to Consider (MTS:PTC) states, if there is no MedDRA term containing "prevention" or "prophylaxis", choose one of the following options. The preferred option is to select a general prevention/ prophylaxis term and a term for the condition. Alternatively, select a term for the condition alone or a prevention/prophylaxis term alone.

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<b>CR Number:</b> 2024135015	<b>Implementation Date:</b> 20-May-24	<b>Related CR:</b> 2024135015	<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>
Proposed LLT	Non-convulsive status epilepticus	Rejected	

**MSSO Comment:** The proposal to add a new LLT Non-convulsive status epilepticus is not approved. Proposed concept exists as LLT Nonconvulsive status epilepticus under PT Status epilepticus since version 5.1.

# Detail Report

<b>CR Number:</b> 2024135016		<b>Implementation Date:</b> 21-May-24	<b>Related CR:</b> 2024135016	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Fetal Valproate Spectrum Disorder</i>	Approved Not as Requested	Proposed LLT <i>Fetal valproate spectrum disorder</i>	10091151 Current
			To PT <i>Foetal anticonvulsant syndrome</i>	10066485
<b>MSSO Comment:</b> The proposal to add a new LLT Fetal Valproate Spectrum Disorder is approved but not as requested. The term Fetal valproate spectrum disorder includes all the cases from major congenital malformation to neurodevelopmental delays. The term is used in a similar way as fetal alcohol spectrum disorder. The name of the condition has been changed from Fetal valproate syndrome to Fetal valproate spectrum disorder. Proposed term will be modified for MedDRA capitalization conventions and added as LLT Fetal valproate spectrum disorder under PT Foetal anticonvulsant syndrome. In a related change, the British English spelled counterpart LLT Foetal valproate spectrum disorder will also be added under PT Foetal anticonvulsant syndrome.				

<b>CR Number:</b> 2024142021		<b>Implementation Date:</b> 21-May-24	<b>Related CR:</b> 2024135016	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Foetal valproate spectrum disorder</i>	Approved as Requested	Proposed LLT <i>Foetal valproate spectrum disorder</i>	10091152 Current
To PT	<i>Foetal anticonvulsant syndrome</i>		To PT <i>Foetal anticonvulsant syndrome</i>	10066485
<b>MSSO Comment:</b>				

<b>CR Number:</b> 2024135017		<b>Implementation Date:</b> 20-May-24	<b>Related CR:</b> 2024135017	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Dorsal root ganglionopathy</i>	Approved as Requested	Proposed PT <i>Dorsal root ganglionopathy</i>	10091153
			HLT primary <i>Spinal cord and nerve root disorders NEC</i>	10041544
			SOC primary <i>Nervous system disorders</i>	10029205

**MSSO Comment:** The proposal to add a new term Dorsal root ganglionopathy is approved as requested. Ganglionopathies are a subcategory of neuropathies characterized by primary degeneration of the dorsal root ganglia and trigeminal ganglion sensory neurons, resulting in a distinctive clinical presentation. Various conditions can cause dorsal root ganglionopathy, including autoimmune disorders, infections, trauma, or genetic factors. The proposed term will be added as new PT Dorsal root ganglionopathy to HLT Spinal cord and nerve root disorders NEC.

# Detail Report

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<b>CR Number:</b> 2024135018	<b>Implementation Date:</b> 23-May-24	<b>Related CR:</b> 2024135018	<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>
Proposed Term	AAV mediated CSF inflammatory response	Rejected After Suspension	

**MSSO Comment:** The proposal to add a new term AAV mediated CSF inflammatory response is not approved after suspension. AAV mediated CSF inflammatory response is a combination term including a novel treatment option as well as describing the associated pathophysiologic toxicity.

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<b>CR Number:</b> 2024136000	<b>Implementation Date:</b> 21-May-24	<b>Related CR:</b> 2024136000	<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>
Proposed LLT	Retinal vessel attenuation	Approved Not as Requested	Proposed LLT
To PT	Retinal artery stenosis		Retinal vessel attenuation 10091143 Current
			To PT
			Retinal vascular disorder 10038901

**MSSO Comment:** The proposal to add a new LLT Retinal vessel attenuation to PT Retinal artery stenosis is approved but not as requested. Retinal vessel attenuation refers to the narrowing or constriction of blood vessels in the retina. This narrowing can be observed during a retinal examination and may indicate various underlying health conditions, such as hypertension, diabetes, or other vascular disorders. Retinal vessel attenuation will be added as an LLT to PT Retinal vascular disorder aligned with LLT Varying retinal vessel calibre. In a related change, the American English spelled counterpart LLT Varying retinal vessel caliber will also be added under PT Retinal vascular disorder.

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<b>CR Number:</b> 2024142019	<b>Implementation Date:</b> 21-May-24	<b>Related CR:</b> 2024136000	<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>
Proposed LLT	Varying retinal vessel caliber	Approved as Requested	Proposed LLT
To PT	Retinal vascular disorder		Varying retinal vessel caliber 10091144 Current
			To PT
			Retinal vascular disorder 10038901

**MSSO Comment:**

# Detail Report

<b>CR Number:</b> 2024136001		<b>Implementation Date:</b> 21-May-24	<b>Related CR:</b> 2024136001	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Drusenoid pigment epithelium detachment</i>	Approved as Requested	Proposed LLT <i>Drusenoid pigment epithelium detachment</i>	10091142 Current
			To PT <i>Detachment of retinal pigment epithelium</i>	10052501
<b>MSSO Comment:</b> The proposal to add a new LLT Drusenoid pigment epithelium detachment is approved as requested. Drusenoid pigment epithelial detachment is formed by the confluence of large areas of soft drusen and is usually located in the central macula. Drusenoid pigment epithelium detachment was clearly distinguished from the other types by its better prognosis. This avascular pigment epithelium detachment typically develops slowly and causes minimal complaints of blurred vision. The proposed term will be added as LLT Drusenoid pigment epithelium detachment to PT Detachment of retinal pigment epithelium.				

<b>CR Number:</b> 2024136002		<b>Implementation Date:</b> 21-May-24	<b>Related CR:</b> 2024136002	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Throat herpes</i>	Rejected		
<b>MSSO Comment:</b> The proposal to add a new LLT Throat herpes is not approved. Throat herpes is sometimes called oral herpes as it is marked by sores and inflammation at the back of your throat and around your mouth. The formal medical name for the condition is herpes esophagitis because it causes swelling and irritation of the esophagus. Proposed term is ambiguous and may refer to either oral herpes or to the medical condition herpes esophagitis. Based on your clinical scenario, please use the most appropriate existing herpes site specific MedDRA term.				

<b>CR Number:</b> 2024136003		<b>Implementation Date:</b> 20-May-24	<b>Related CR:</b> 2024136003	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Arginine level decreased</i>	Approved as Requested	Proposed PT <i>Arginine level decreased</i>	10091154
			HLT primary <i>Protein analyses NEC</i>	10036998
			SOC primary <i>Investigations</i>	10022891

**MSSO Comment:** The proposal to add a new term Arginine level decreased is approved as requested. The decrease in L-arginine levels in major depression patients is a possible explanation for the decrease in nitric oxide metabolites in major depression patients and therefore may contribute, through endothelial dysfunction, to the increased cardiovascular disease risk associated with major depression. Arginine level decreased will be added as new PT under HLT Protein analyses NEC to represent the decreased counterpart for PT Arginine level increased.

# Detail Report

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<b>CR Number:</b> 2024137000		<b>Implementation Date:</b> 22-May-24	<b>Related CR:</b> 2024137000	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Nodular Acne</i>	Approved Not as Requested	Proposed LLT <i>Nodular acne</i>	10091166 Current
			To PT <i>Acne</i>	10000496
<b>MSSO Comment:</b> The proposal to add a new term Nodular Acne is approved but not as requested. Nodules are something intrinsic to acne vulgaris. Nodular acne is a type of inflammatory acne which causes firm, painful lumps to form under the skin and red bumps to appear on skin surface. The proposed term will be modified in accordance with MedDRA capitalization conventions and will be added as the LLT Nodular acne to the PT Acne.				

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<b>CR Number:</b> 2024137001		<b>Implementation Date:</b> 22-May-24	<b>Related CR:</b> 2024137001	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Pericardiolysis</i>	Approved as Requested	Proposed PT <i>Pericardiolysis</i>	10091159
			HLT primary <i>Cardiac therapeutic procedures NEC</i>	10027660
			SOC primary <i>Surgical and medical procedures</i>	10042613

**MSSO Comment:** The proposal to add a new term Pericardiolysis is approved as requested. Pericardiolysis is the operation of freeing adhesions between the visceral and parietal pericardium or between the pericardium and surrounding tissues or organs. Pericardiolysis will be added as a PT to the HLT Cardiac therapeutic procedures NEC.

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<b>CR Number:</b> 2024137002		<b>Implementation Date:</b> 22-May-24	<b>Related CR:</b> 2024137002	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Uroschesis</i>	Approved as Requested	Proposed LLT <i>Uroschesis</i>	10091165 Current
			To PT <i>Urinary retention</i>	10046555

**MSSO Comment:** The proposal to add a new term Uroschesis is approved as requested. Uroschesis will be added as a synonym LLT of the PT Urinary retention.

# Detail Report

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<b>CR Number:</b> 2024137003		<b>Implementation Date:</b> 22-May-24	<b>Related CR:</b> 2024137003	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	Lacunar tonsillitis	Approved as Requested	Proposed LLT Lacunar tonsillitis	10091161 Current
			To PT Tonsillitis	10044008
<b>MSSO Comment:</b> The proposal to add a new term Lacunar tonsillitis is approved as requested. Lacunar tonsillitis refers to a catarrhal inflammation affecting chiefly the lacunae or crypts of the tonsils. Lacunar tonsillitis will be added as an LLT to the PT tonsillitis.				

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<b>CR Number:</b> 2024137004		<b>Implementation Date:</b> 22-May-24	<b>Related CR:</b> 2024137004	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	Nail bed repair	Approved as Requested	Proposed PT Nail bed repair	10091160
			HLT primary Nail therapeutic procedures	10028701
			SOC primary Surgical and medical procedures	10042613
<b>MSSO Comment:</b> The proposal to add a new term Nail bed repair is approved as requested. Nail bed repair is a short operation which involves numbing the whole finger and removing the nail to provide access to the nail bed followed by repair with dissolvable stitches. In adults this can be done under local anaesthetic but young children will typically require a general anaesthetic. Nail bed repair will be added as a PT to the HLT Nail therapeutic procedures.				

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<b>CR Number:</b> 2024137005		<b>Implementation Date:</b> 22-May-24	<b>Related CR:</b> 2024137005	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	Skin Sparing Mastectomy	Approved Not as Requested	Proposed LLT Skin sparing mastectomy	10091162 Current
			To PT Mastectomy	10026878
<b>MSSO Comment:</b> The proposal to add a new term Skin Sparing Mastectomy is approved but not as requested. In a skin-sparing mastectomy, the breast tissue is removed while most of the healthy breast skin is left. This method is used only if the patient will have immediate breast reconstruction. Proposed term will be modified for MedDRA capitalization conventions and added as LLT Skin sparing mastectomy under PT Mastectomy aligned with LLT Nipple sparing mastectomy.				

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# Detail Report

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<b>CR Number:</b> 2024137006		<b>Implementation Date:</b> 22-May-24	<b>Related CR:</b> 2024137006	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Rhinorrhagia</i>	Approved as Requested	Proposed LLT <i>Rhinorrhagia</i>	10091163 Current
			To PT <i>Epistaxis</i>	10015090
<b>MSSO Comment:</b> The proposal to add a new term Rhinorrhagia is approved as requested. Rhinorrhagia means a rapid hemorrhage from the nose, also called epistaxis. Rhinorrhagia will be added as synonym LLT under PT Epistaxis.				

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<b>CR Number:</b> 2024137007		<b>Implementation Date:</b> 22-May-24	<b>Related CR:</b> 2024137007	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Cephalic vein thrombosis</i>	Approved as Requested	Proposed LLT <i>Cephalic vein thrombosis</i>	10091167 Current
			To PT <i>Superficial vein thrombosis</i>	10086210
<b>MSSO Comment:</b> The proposal to add a new term Cephalic vein thrombosis is approved as requested. Thrombosis of the superficial veins involves the cephalic or basilic veins. Cephalic vein thrombosis is a form of superficial vein thrombosis which is a blood clot in the superficial veins close to the skin's surface. Cephalic vein thrombosis will be added as LLT under PT Superficial vein thrombosis.				

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<b>CR Number:</b> 2024137008		<b>Implementation Date:</b> 22-May-24	<b>Related CR:</b> 2024137008	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Postprandial Distress Syndrome</i>	Approved Not as Requested	Proposed LLT <i>Postprandial distress syndrome</i>	10091164 Current
			To PT <i>Dyspepsia</i>	10013946
<b>MSSO Comment:</b> The proposal to add a new term Postprandial Distress Syndrome is approved but not as requested. Postprandial distress syndrome is a subtype of functional dyspepsia, with meal-related symptoms such as postprandial fullness and early satiation. Proposed term will be modified for MedDRA capitalization conventions and added as LLT Postprandial distress syndrome under PT Dyspepsia.				

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# Detail Report

CR Number: 2024137009		Implementation Date: 22-May-24	Related CR: 2024137009	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	Great saphenous vein varicosities	Approved Not as Requested	Proposed LLT Great saphenous vein varicosity	10091168 Current
			To PT Varicose vein	10046996
MSSO Comment:	The proposal to add a new term Great saphenous vein varicosities is approved but not as requested. The great saphenous vein, like other superficial veins, can become varicose; swollen, twisted and lengthened, and generally considered to be unsightly. Proposed term will be modified into singular form and added as LLT Great saphenous vein varicosity to PT Varicose vein.			

CR Number: 2024137010		Implementation Date: 22-May-24	Related CR: 2024137010	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Rectouterine abscess	Approved Not as Requested	Proposed LLT Rectouterine pouch abscess	10091158 Current
To PT	Douglas' abscess		To PT Douglas' abscess	10049583
MSSO Comment:	The proposal to add a new LLT Rectouterine abscess to PT Douglas' abscess is approved but not as requested. A rectouterine abscess, also known as a Douglas abscess or a pouch of Douglas abscess, is an accumulation of pus in the rectouterine pouch. This pouch is a small cavity located between the rectum and the back wall of the uterus in females. The proposed term will be modified for clarity and added as LLT Rectouterine pouch abscess to PT Douglas' abscess.			

# Detail Report

CR Number: 2024137011		Implementation Date: 22-May-24	Related CR: 2024137011	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Superior Mediastinal Syndrome	Approved Not as Requested	Proposed PT	
To PT	Superior vena cava syndrome		Superior mediastinal syndrome	10091155
			HLT primary	
			Site specific necrosis and vascular insufficiency NEC	10052781
			SOC primary	
			Vascular disorders	10047065
			HLT secondary	
			Oncologic complications and emergencies	10030315
			SOC secondary	
			Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10029104

MSSO Comment: The proposal to add a new LLT Superior Mediastinal Syndrome to PT Superior vena cava syndrome is approved but not as requested. Superior Vena Cava Syndrome (SVCS) refers to signs and symptoms caused by obstruction of the superior vena cava. Superior mediastinal syndrome (SMS) is the term used when SVCS coexists with obstruction of trachea. Although the terms are often used interchangeably in children, because a mediastinal pathology causing SVCS generally results in SMS as well, due to the limited chest volume, these are distinct medical concepts. The proposed term will be modified for MedDRA capitalization rules and added as PT Superior mediastinal syndrome to primary HLT Site specific necrosis and vascular insufficiency NEC, secondary HLT Oncologic complications and emergencies and secondary HLT Tracheal disorders (excl infections and neoplasms).

CR Number: 2024143016		Implementation Date: 22-May-24	Related CR: 2024137011	
<a href="#">Change Requested</a>	Link a PT to a HLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Superior mediastinal syndrome	Approved as Requested	Proposed PT	
To HLT	Tracheal disorders (excl infections and neoplasms)		Superior mediastinal syndrome	10091155
			To HLT	
			Tracheal disorders (excl infections and neoplasms)	10044288

MSSO Comment:

# Detail Report

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<b>CR Number:</b> 2024137012		<b>Implementation Date:</b> 22-May-24	<b>Related CR:</b> 2024137012		
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed LLT	<i>Atopic dermatitis neck</i>	Rejected			

**MSSO Comment:** The proposal to add a new LLT Atopic dermatitis neck is not approved. To avoid the overpopulation of MedDRA, it is not feasible to accommodate terms relating to every possible anatomic location of atopic dermatitis.

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<b>CR Number:</b> 2024137013		<b>Implementation Date:</b> 22-May-24	<b>Related CR:</b> 2024137013		
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed LLT	<i>Mesenteric biopsy</i>	Approved Not as Requested	Proposed PT <i>Mesenteric biopsy</i>	10091156	
			HLT primary <i>Gastrointestinal histopathology procedures</i>	10017962	
			SOC primary <i>Investigations</i>	10022891	

**MSSO Comment:** The proposal to add a new LLT Mesenteric biopsy is approved but not as requested. A mesenteric biopsy is a medical procedure where a small sample of tissue is taken from the mesentery for diagnostic purposes. The mesentery is a fold of tissue that attaches the intestines to the abdominal wall and contains blood vessels, lymph nodes, and nerves. The proposed term will be added as PT Mesenteric biopsy to HLT Gastrointestinal histopathology procedures.

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<b>CR Number:</b> 2024137014		<b>Implementation Date:</b> 22-May-24	<b>Related CR:</b> 2024137014		
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed LLT	<i>Allergy to mildew</i>	Approved as Requested	Proposed LLT <i>Allergy to mildew</i>	10091157 Current	
To PT	<i>Mycotic allergy</i>		To PT <i>Mycotic allergy</i>	10052758	

**MSSO Comment:** The proposal to add a new LLT Allergy to mildew to PT Mycotic allergy is approved as requested. Mildew is a type of mold that typically grows on surfaces in damp or humid environments.

# Detail Report

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<b>CR Number:</b> 2024137015		<b>Implementation Date:</b> 21-May-24	<b>Related CR:</b> 2024137015	
<a href="#">Change Requested</a>	Rename PT/LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Term to modify	<i>Small bowel angioectasias</i>	Approved as Requested	Term to modify	
Replacement term	<i>Small bowel angioectasia</i>		<i>Small bowel angioectasias</i>	10089987
			Replacement term	
			<i>Small bowel angioectasia</i>	10089987 Current
<b>MSSO Comment:</b> The proposal to rename PT/LLT Small bowel angioectasias to Small bowel angioectasia is approved as requested. This term is being renamed to conform to the singular / plural convention for terms at the PT and LLT level where terms are generally added in singular form.				

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<b>CR Number:</b> 2024137016		<b>Implementation Date:</b> 21-May-24	<b>Related CR:</b> 2024137016	
<a href="#">Change Requested</a>	Link (move) an LLT to another PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Foot ray amputation</i>	Approved as Requested	Proposed LLT	
From PT	<i>Metatarsal excision</i>		<i>Foot ray amputation</i>	10090017 Current
To PT	<i>Foot amputation</i>		From PT	
			<i>Metatarsal excision</i>	10027486
			To PT	
			<i>Foot amputation</i>	10016960
<b>MSSO Comment:</b> The proposal to move the LLT Foot ray amputation from PT Metatarsal excision to PT Foot amputation is approved as requested. Although in this intervention the first metatarsal is removed, not only the bone is operated, but all the musculoskeletal structures that surround it are also removed as well making this concept better placed as an amputation. Therefore, LLT Foot ray amputation is better placed under PT Foot amputation.				

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# Detail Report

<b>CR Number:</b> 2024137017		<b>Implementation Date:</b> 28-May-24	<b>Related CR:</b> 2024137017	
<u>Change Requested</u>	Add term to SMQ	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Respiratory tract oedema	Approved as Requested	Proposed PT	
To SMQ	Angioedema (SMQ)		Respiratory tract oedema	10070774
Term scope	Narrow		To SMQ	
			Angioedema (SMQ)	20000024
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	

**MSSO** The proposal to add PT Respiratory tract oedema to Angioedema (SMQ) as a narrow term is approved as requested. The term fulfills the inclusion criteria of Angioedema (SMQ) and will be added to the narrow scope aligned with other anatomical site qualified oedema terms.  
**Comment:**

<b>CR Number:</b> 2024137021		<b>Implementation Date:</b> 21-May-24	<b>Related CR:</b> 2024137021	
<u>Change Requested</u>	Add a New Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	Radiation associated anemia	Rejected		

**MSSO** The proposal to add a new term Radiation associated anemia is not approved. LLT/PT Radiation anaemia already exists in MedDRA.  
**Comment:**

<b>CR Number:</b> 2024137022		<b>Implementation Date:</b> 28-May-24	<b>Related CR:</b> 2024137022	
<u>Change Requested</u>	Update MedDRA term_scope	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Product knowledge deficit	Rejected		
To SMQ	Medication errors (SMQ)			
Term scope	Narrow			

**MSSO** The proposal to change the scope of the PT Product knowledge deficit in Medication errors (SMQ) to Narrow is not approved. Product knowledge deficit may be considered as having a significant potential for identifying medication errors but in itself does not represent a medication error which is the criteria for narrow scope term inclusion. It is aligned with other broad scope terms such as PT Product commingling, PT Product label on wrong product and PT Poor quality device used.  
**Comment:**

# Detail Report

CR Number: 2024137023		Implementation Date: 22-May-24		Related CR: 2024137023	
<u>Change Requested</u>	Add a New PT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>	
Proposed PT	Failure of additional condition for nonprescription use	Approved as Requested	Proposed PT	10091169	
HLT primary	Product quality issues NEC		Failure of additional condition for nonprescription use		
SOC primary	Product issues		HLT primary	10069324	
			Product quality issues NEC		
			SOC primary	10077536	
			Product issues		
MSSO Comment:	The proposal to add a new PT Failure of additional condition for nonprescription use to primary HLT Product quality issues NEC in SOC Product issues is approved as requested. Failure of additional condition for nonprescription use captures the failure of the additional condition for nonprescription use (ACNU) in scenarios where a patient accesses the product without successfully fulfilling the ACNU, fulfills the ACNU completely but could not access the product, or is unable to initialize the process to fulfill the ACNU.				

<b>CR Number:</b> 2024137024		<b>Implementation Date:</b> 22-May-24		<b>Related CR:</b> 2024137024	
<u>Change Requested</u>	Add a New PT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>	
Proposed PT	<i>Issue with additional condition for nonprescription use</i>	Approved as Requested	Proposed PT		
HLT primary	<i>Product quality issues NEC</i>		<i>Issue with additional condition for nonprescription use</i>	10091170	
SOC primary	<i>Product issues</i>		HLT primary		
			<i>Product quality issues NEC</i>	10069324	
			SOC primary		
			<i>Product issues</i>	10077536	
<b>MSSO Comment:</b> The proposal to add a new PT Issue with additional condition for nonprescription use to primary HLT Product quality issues NEC in SOC Product issues is approved as requested. Issue with additional condition for nonprescription use would enable the capturing of scenarios with an unspecified problem with additional condition for nonprescription use (ACNU), difficulty or problem with ACNU, specifically an issue not clearly defined.					

# Detail Report

<b>CR Number:</b> 2024137025		<b>Implementation Date:</b> 29-May-24	<b>Related CR:</b> 2024137025		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed PT	<i>Additional condition nonprescription use product used without completing ACNU</i>	Rejected After Suspension			
HLT primary	<i>Medication errors, product use errors and issues NEC</i>				
SOC primary	<i>Injury, poisoning and procedural complications</i>				
<b>MSSO Comment:</b>	The proposal to add a new PT Additional condition nonprescription use product used without completing ACNU to primary HLT Medication errors, product use errors and issues NEC in SOC Injury, poisoning and procedural complications is not approved after suspension. The proposed term is a very specific scenario of the baseline PT Failure of additional condition for nonprescription use (added in Change Request 2024137023) and may not be relevant or pertinent to the larger user community.				

<b>CR Number:</b> 2024137026		<b>Implementation Date:</b> 29-May-24	<b>Related CR:</b> 2024137026		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed LLT	ANCU failure	Rejected After Suspension			
To PT	Failure of additional condition for nonprescription use				
MSSO Comment:	The proposal to add a new LLT ANCU failure to PT Failure of additional condition for nonprescription use is not approved after suspension. The proposed term is a misspelled acronym of the baseline PT Failure of additional condition for nonprescription use (added in Change Request 2024137023) and may not be relevant or pertinent to the larger user community. Additionally, "ACNU" could be understood to represent a different concept than the one it is intended for, such as the abbreviation of 1-(4-amino-2-methyl-5-pyrimidinyl) methyl- 3-(2-chloroethyl)-3-nitrosourea hydrochloride, the anti-cancer medication Nimustine Hydrochloride.				

<b>CR Number:</b> 2024137027		<b>Implementation Date:</b> 29-May-24	<b>Related CR:</b> 2024137027		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed LLT	<i>Consumer fulfilled the additional condition for nonprescription use but could not access product</i>	Rejected After Suspension			
To PT	<i>Failure of additional condition for nonprescription use</i>				
<b>MSSO Comment:</b>	The proposal to add a new LLT Consumer fulfilled the additional condition for nonprescription use but could not access product to PT Failure of additional condition for nonprescription use is not approved after suspension. The proposed term is a very specific scenario of the baseline PT Failure of additional condition for nonprescription use (added in Change Request 2024137023) and may not be relevant or pertinent to the larger user community.				

# Detail Report

<b>CR Number:</b> 2024137028		<b>Implementation Date:</b> 29-May-24	<b>Related CR:</b> 2024137028		
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed LLT	Consumer fulfilled the ACNU but could not access product	Rejected After Suspension			
To PT	Failure of additional condition for nonprescription use				
<b>MSSO Comment:</b>	The proposal to add a new LLT Consumer fulfilled the ACNU but could not access product to PT Failure of additional condition for nonprescription use is not approved after suspension. The proposed term is a very specific scenario of the baseline PT Failure of additional condition for nonprescription use (added in Change Request 2024137023) and may not be relevant or pertinent to the larger user community. Additionally, "ACNU" could be understood to represent a different concept than the one it is intended for, such as the abbreviation of 1-(4-amino-2-methyl-5-pyrimidinyl) methyl- 3-(2-chloroethyl)-3-nitrosourea hydrochloride, the anti-cancer medication Nimustine Hydrochloride.				

<b>CR Number:</b> 2024137029		<b>Implementation Date:</b> 29-May-24	<b>Related CR:</b> 2024137029		
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed LLT	Unable to initialize the process to fulfill the additional condition for nonprescription use	Rejected After Suspension			
To PT	Failure of additional condition for nonprescription use				
<b>MSSO Comment:</b> The proposal to add a new LLT Unable to initialize the process to fulfill the additional condition for nonprescription use to PT Failure of additional condition for nonprescription use is not approved after suspension. The proposed term is a very specific scenario of the baseline PT Failure of additional condition for nonprescription use (added in Change Request 2024137023) and may not be relevant or pertinent to the larger user community.					

<b>CR Number:</b> 2024137030		<b>Implementation Date:</b> 29-May-24	<b>Related CR:</b> 2024137030		
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed LLT	<i>Additional condition for nonprescription use design issue</i>	Rejected After Suspension			
To PT	<i>Product design issue</i>				
<b>MSSO Comment:</b>	The proposal to add a new LLT Additional condition for nonprescription use design issue to PT Product design issue is not approved after suspension. The proposed term is a very specific scenario of the baseline PT Product design issue and may not be relevant or pertinent to the larger user community. The proposed concept maybe represented by existing LLT/PT Product design issue.				



# Detail Report

<b>CR Number:</b> 2024137031		<b>Implementation Date:</b> 22-May-24	<b>Related CR:</b> 2024137031	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Product self-selection error</i>	Approved as Requested	Proposed LLT	
To PT	<i>Product selection error</i>		<i>Product self-selection error</i>	10091171 Current
			To PT	
			<i>Product selection error</i>	10076542

**MSSO** The proposal to add a new LLT Product self-selection error to PT Product selection error is approved as requested. This term would be used when consumers accidentally  
**Comment:** select a product they think they need but in reality do not. The term would capture various self-selection error scenarios by consumers.

<b>CR Number:</b> 2024137032		<b>Implementation Date:</b> 22-May-24	<b>Related CR:</b> 2024137032	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Ring shaped lateral ventricular nodules</i>	Approved Not as Requested	Proposed PT	
			<i>Ring shaped lateral ventricular nodule</i>	10091172
			HLT primary	
			<i>Nervous system neoplasms unspecified malignancy NEC</i>	10029213
			SOC primary	
			<i>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</i>	10029104
			HLT secondary	
			<i>Nervous system neoplasms unspecified malignancy NEC</i>	10029213
			SOC secondary	
			<i>Nervous system disorders</i>	10029205

**MSSO** The proposal to add a new term Ring shaped lateral ventricular nodules is approved but not as requested. Ring-shaped lateral ventricular nodules (RSLVN) are small  
**Comment:** nodular ring-shaped lesions attached generally to the ependyma of the roof and body of the lateral ventricles. The nature of the RSLVNs is controversial and includes neuroglial/glioependymal cyst, inflammatory or reactive formation of ependyma, astrocytic gliosis reaction near subependymal veins, redetachment of the fused portion of coarctation of the frontal horn or a variant of subependymoma. Proposed term will be modified to the singular form and added as PT Ring shaped lateral ventricular nodule to bi-axial HLT Nervous system neoplasms unspecified malignancy NEC (primary SOC Neoplasms benign, malignant and unspecified (incl cysts and polyps) and to secondary SOC Nervous system disorders).

# Detail Report

CR Number: 2024138001		Implementation Date: 23-May-24	Related CR: 2024138001	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Sinistral portal hypertension</i>	Approved as Requested	Proposed LLT <i>Sinistral portal hypertension</i>	10091174 Current
			To PT <i>Left-sided portal hypertension</i>	10091173
MSSO Comment: The proposal to add a new term Sinistral portal hypertension is approved as requested. Left-sided portal hypertension, also known as segmental, regional, localized, compartmental, lineal, splenoportal, or sinistral hypertension is a rare, but life-threatening cause of upper gastrointestinal bleeding. It usually occurs as a result of isolated obstruction of the splenic vein. Sinistral portal hypertension will be added as an LLT to PT Left-sided portal hypertension, which will be added, in a related change, to primary HLT Gastrointestinal vascular occlusion and infarction and to secondary HLT Portal hypertension.				

CR Number: 2024144011		Implementation Date: 23-May-24	Related CR: 2024138001	
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Left-sided portal hypertension</i>	Approved as Requested	Proposed PT <i>Left-sided portal hypertension</i>	10091173
HLT primary	<i>Gastrointestinal vascular occlusion and infarction</i>		HLT primary <i>Gastrointestinal vascular occlusion and infarction</i>	10017997
SOC primary	<i>Gastrointestinal disorders</i>		SOC primary <i>Gastrointestinal disorders</i>	10017947
			HLT secondary <i>Portal hypertension</i>	10036201
			SOC secondary <i>Vascular disorders</i>	10047065

MSSO  
Comment:

# Detail Report

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<b>CR Number:</b> 2024138002		<b>Implementation Date:</b> 23-May-24	<b>Related CR:</b> 2024138002		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed LLT	<i>Drug dermatitis</i>	Rejected			
To PT	<i>drug eruption</i>				

**MSSO Comment:** The proposal to add a new LLT Drug dermatitis to PT drug eruption is not approved. The proposed concept can be represented by existing LLT Dermatitis medicamentosa.

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<b>CR Number:</b> 2024138003		<b>Implementation Date:</b> 23-May-24	<b>Related CR:</b> 2024138003		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed PT	<i>Persistent paraesthesia</i>	Rejected			
HLT primary	<i>Paraesthesias and dysaesthesias</i>				
SOC primary	<i>Nervous system disorders</i>				

**MSSO Comment:** The proposal to add a new PT Persistent paraesthesia to primary HLT Paraesthesias and dysaesthesias in SOC Nervous system disorders is not approved. Persistent/ongoing may be a database variable but such qualifiers are not added to MedDRA. MedDRA cannot accommodate a separate term for a persistent state of every potential disease or condition. Moreover, there does not seem to be an internationally clear definition of what is considered a persistent paresthesia.

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<b>CR Number:</b> 2024138004		<b>Implementation Date:</b> 23-May-24	<b>Related CR:</b> 2024138004		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed Term	<i>Stoma site dryness</i>	Rejected			

**MSSO Comment:** The proposal to add a new term Stoma site dryness is not approved. Stoma sites can be subject to multiple specific complications for which MedDRA cannot add a specific site stoma term. The proposed concept can be represented through combined coding with the PT Stoma site complication added in change request 2024108015, and an appropriate LLT to represent the nature of the complication. See Section 3.5.4 of the MedDRA Term Selection Points to Consider (MTS: PTC) document - When to "split" into more than one MedDRA term.

# Detail Report

CR Number: 2024138005		Implementation Date: 23-May-24	Related CR: 2024138005		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed Term	Stoma site erosion	Rejected			
MSSO Comment: The proposal to add a new term Stoma site erosion is not approved. Stoma sites can be subject to multiple specific complications for which MedDRA cannot add a specific site stoma term. The proposed concept can be represented through combined coding with the PT Stoma site complication added in change request 2024108015, and an appropriate LLT to represent the nature of the complication. See Section 3.5.4 of the MedDRA Term Selection Points to Consider (MTS: PTC) document - When to "split" into more than one MedDRA term.					

CR Number: 2024138006		Implementation Date: 23-May-24	Related CR: 2024138006		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed Term	Stoma site burning	Rejected			
MSSO Comment: The proposal to add a new term Stoma site burning is not approved. Stoma sites can be subject to multiple specific complications for which MedDRA cannot add a specific site stoma term. The proposed concept can be represented through combined coding with the PT Stoma site complication added in change request 2024108015, and an appropriate LLT to represent the nature of the complication. See Section 3.5.4 of the MedDRA Term Selection Points to Consider (MTS: PTC) document - When to "split" into more than one MedDRA term.					

CR Number: 2024138007		Implementation Date: 23-May-24	Related CR: 2024138007		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed LLT	Maternal exposure via partner	Rejected			
MSSO Comment: The proposal to add a new LLT Maternal exposure via partner is not approved. Please consider using existing maternal exposure terms or please re-submit clarifying the context of your specific scenario.					

# Detail Report

CR Number: 2024138008		Implementation Date: 23-May-24	Related CR: 2024138008		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed LLT	Maternal exposure via partner before pregnancy	Rejected			

MSSO Comment: The proposal to add a new LLT Maternal exposure via partner before pregnancy is not approved. Please consider using existing maternal exposure terms or please re-submit clarifying the context of your specific scenario.

CR Number: 2024138009		Implementation Date: 23-May-24	Related CR: 2024138009		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed LLT	Rhino-laryngopharyngitis	Rejected			

MSSO Comment: The proposal to add a new LLT Rhino-laryngopharyngitis is not approved. Please refer to Section 3.5 of the MedDRA Term Selection Points to Consider (MTS:PTC) document, which defines these as "combination terms" and provides coding guidance. When considering the addition of such combination terms, MedDRA generally attempts to limit inclusion to those terms which describe important, distinct and robust medical concepts which are internationally recognized diagnostic entities. It is not possible to have all the various anatomic combination terms for "laryngitis".

CR Number: 2024138010		Implementation Date: 23-May-24	Related CR: 2024138010		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed LLT	Infected bronchiectasis	Rejected			

MSSO Comment: The proposal to add a new LLT Infected bronchiectasis is not approved. Bronchiectasis exacerbations are significant events in the natural course of the disease and determine long-term clinical outcomes. The concept is represented by existing PT Infective exacerbation of bronchiectasis.

# Detail Report

<b>CR Number:</b> 2024138011		<b>Implementation Date:</b> 23-May-24		<b>Related CR:</b> 2024138011	
<a href="#">Change Requested</a>	Promote an LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed LLT	<i>Nausea post radiotherapy</i>	Rejected			
From PT	<i>Procedural nausea</i>				
HLT primary	<i>Radiation injuries</i>				
<b>MSSO Comment:</b>	The proposal to promote the LLT Nausea post radiotherapy from PT Procedural nausea to primary HLT Radiation injuries in SOC Injury, poisoning and procedural complications is not approved. HLT Radiation injuries is about inflammation of organ or tissues, not about the resulting symptoms. Nausea post radiotherapy is a symptom and not a true "radiation injury" per se. Radiation injury is damage to tissues caused by exposure to ionizing radiation. Therefore, the current placement is correct.				

<b>CR Number:</b> 2024138012		<b>Implementation Date:</b> 23-May-24		<b>Related CR:</b> 2024138012	
<a href="#">Change Requested</a>	Promote an LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed LLT	<i>Vomiting post radiotherapy</i>	Rejected			
From PT	<i>Procedural vomiting</i>				
HLT primary	<i>Radiation injuries</i>				
<b>MSSO Comment:</b>	The proposal to promote the LLT Vomiting post radiotherapy from PT Procedural vomiting to primary HLT Radiation injuries in SOC Injury, poisoning and procedural complications is not approved. HLT Radiation injuries is about inflammation of organ or tissues, not about the resulting symptoms. Vomiting post radiotherapy is a symptom and not a true "radiation injury" per se. Radiation injury is damage to tissues caused by exposure to ionizing radiation. Therefore, the current placement is correct.				

<b>CR Number:</b> 2024139000		<b>Implementation Date:</b> 05-Jun-24		<b>Related CR:</b> 2024139000	
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed PT	<i>Ablutophobia</i>	Rejected After Suspension			
<b>MSSO Comment:</b>	The proposal to add a new PT Ablutophobia is not approved after suspension. This term and the terms in this batch are very rare and obscure "phobias" which are not likely encountered in clinical or post market scenarios where they need to be captured. The validity for the need of these terms has not been specified and the justification is insufficient.				

# Detail Report

<b>CR Number:</b> 2024139001		<b>Implementation Date:</b> 05-Jun-24	<b>Related CR:</b> 2024139001		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed PT	<i>Acarophobia</i>	Rejected After Suspension			

**MSSO Comment:** The proposal to add a new PT Acarophobia is not approved after suspension. This term and the terms in this batch are very rare and obscure "phobias" which are not likely encountered in clinical or post market scenarios where they need to be captured. The validity for the need of these terms has not been specified and the justification is insufficient.

<b>CR Number:</b> 2024139002		<b>Implementation Date:</b> 05-Jun-24	<b>Related CR:</b> 2024139002		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed PT	<i>Acerophobia</i>	Rejected After Suspension			

**MSSO Comment:** The proposal to add a new PT Acerophobia is not approved after suspension. This term and the terms in this batch are very rare and obscure "phobias" which are not likely encountered in clinical or post market scenarios where they need to be captured. The validity for the need of these terms has not been specified and the justification is insufficient.

<b>CR Number:</b> 2024139003		<b>Implementation Date:</b> 05-Jun-24	<b>Related CR:</b> 2024139003		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed PT	<i>Achluophobia</i>	Rejected After Suspension			

**MSSO Comment:** The proposal to add a new PT Achluophobia is not approved after suspension. This term and the terms in this batch are very rare and obscure "phobias" which are not likely encountered in clinical or post market scenarios where they need to be captured. The validity for the need of these terms has not been specified and the justification is insufficient.

# Detail Report

<b>CR Number:</b> 2024139004		<b>Implementation Date:</b> 05-Jun-24	<b>Related CR:</b> 2024139004		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed PT	Acousticophobia	Rejected After Suspension			

**MSSO Comment:** The proposal to add a new PT Acousticophobia is not approved after suspension. This term and the terms in this batch are very rare and obscure "phobias" which are not likely encountered in clinical or post market scenarios where they need to be captured. The validity for the need of these terms has not been specified and the justification is insufficient.

<b>CR Number:</b> 2024139005		<b>Implementation Date:</b> 05-Jun-24	<b>Related CR:</b> 2024139005		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed PT	Agrizoophobia	Rejected After Suspension			

**MSSO Comment:** The proposal to add a new PT Agrizoophobia is not approved after suspension. This term and the terms in this batch are very rare and obscure "phobias" which are not likely encountered in clinical or post market scenarios where they need to be captured. The validity for the need of these terms has not been specified and the justification is insufficient.

<b>CR Number:</b> 2024139006		<b>Implementation Date:</b> 05-Jun-24	<b>Related CR:</b> 2024139006		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed PT	Agyrophobia	Rejected After Suspension			

**MSSO Comment:** The proposal to add a new PT Agyrophobia is not approved after suspension. This term and the terms in this batch are very rare and obscure "phobias" which are not likely encountered in clinical or post market scenarios where they need to be captured. The validity for the need of these terms has not been specified and the justification is insufficient.



# Detail Report

<b>CR Number: 2024139007</b>		<b>Implementation Date:</b> 05-Jun-24	<b>Related CR:</b> 2024139007		
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed PT	<i>Ailurophobia</i>	Rejected After Suspension			

**MSSO Comment:** The proposal to add a new PT Ailurophobia is not approved after suspension. This term and the terms in this batch are very rare and obscure "phobias" which are not likely encountered in clinical or post market scenarios where they need to be captured. The validity for the need of these terms has not been specified and the justification is insufficient.

<b>CR Number:</b> 2024139008		<b>Implementation Date:</b> 05-Jun-24	<b>Related CR:</b> 2024139008		
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed PT	<i>Albuminurophobia</i>	Rejected After Suspension			

**MSSO Comment:** The proposal to add a new PT Albuminurophobia is not approved after suspension. This term and the terms in this batch are very rare and obscure "phobias" which are not likely encountered in clinical or post market scenarios where they need to be captured. The validity for the need of these terms has not been specified and the justification is insufficient.

<b>CR Number:</b> 2024139009		<b>Implementation Date:</b> 05-Jun-24	<b>Related CR:</b> 2024139009		
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed PT	<i>Alektorophobia</i>	Rejected After Suspension			

**MSSO Comment:** The proposal to add a new PT Alektorophobia is not approved after suspension. This term and the terms in this batch are very rare and obscure "phobias" which are not likely encountered in clinical or post market scenarios where they need to be captured. The validity for the need of these terms has not been specified and the justification is insufficient.

# Detail Report

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<b>CR Number:</b> 2024139010	<b>Implementation Date:</b> 05-Jun-24	<b>Related CR:</b> 2024139010	<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>
Proposed PT	Alliumphobia	Rejected After Suspension	

**MSSO Comment:** The proposal to add a new PT Alliumphobia is not approved after suspension. This term and the terms in this batch are very rare and obscure "phobias" which are not likely encountered in clinical or post market scenarios where they need to be captured. The validity for the need of these terms has not been specified and the justification is insufficient.

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<b>CR Number:</b> 2024139011	<b>Implementation Date:</b> 05-Jun-24	<b>Related CR:</b> 2024139011	<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>
Proposed PT	Allodoxaphobia	Rejected After Suspension	

**MSSO Comment:** The proposal to add a new PT Allodoxaphobia is not approved after suspension. This term and the terms in this batch are very rare and obscure "phobias" which are not likely encountered in clinical or post market scenarios where they need to be captured. The validity for the need of these terms has not been specified and the justification is insufficient.

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<b>CR Number:</b> 2024139012	<b>Implementation Date:</b> 05-Jun-24	<b>Related CR:</b> 2024139012	<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>
Proposed PT	Amathophobia	Rejected After Suspension	

**MSSO Comment:** The proposal to add a new PT Amathophobia is not approved after suspension. This term and the terms in this batch are very rare and obscure "phobias" which are not likely encountered in clinical or post market scenarios where they need to be captured. The validity for the need of these terms has not been specified and the justification is insufficient.

# Detail Report

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<b>CR Number:</b> 2024139013		<b>Implementation Date:</b> 05-Jun-24	<b>Related CR:</b> 2024139013		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed PT	<i>Amaxophobia</i>	Rejected After Suspension			

**MSSO Comment:** The proposal to add a new PT Amaxophobia is not approved after suspension. This term and the terms in this batch are very rare and obscure "phobias" which are not likely encountered in clinical or post market scenarios where they need to be captured. The validity for the need of these terms has not been specified and the justification is insufficient.

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<b>CR Number:</b> 2024139014		<b>Implementation Date:</b> 05-Jun-24	<b>Related CR:</b> 2024139014		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed PT	<i>Ambulophobia</i>	Rejected After Suspension			

**MSSO Comment:** The proposal to add a new PT Ambulophobia is not approved after suspension. This term and the terms in this batch are very rare and obscure "phobias" which are not likely encountered in clinical or post market scenarios where they need to be captured. The validity for the need of these terms has not been specified and the justification is insufficient.

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<b>CR Number:</b> 2024139015		<b>Implementation Date:</b> 05-Jun-24	<b>Related CR:</b> 2024139015		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed PT	<i>Amychophobia</i>	Rejected After Suspension			

**MSSO Comment:** The proposal to add a new PT Amychophobia is not approved after suspension. This term and the terms in this batch are very rare and obscure "phobias" which are not likely encountered in clinical or post market scenarios where they need to be captured. The validity for the need of these terms has not been specified and the justification is insufficient.

# Detail Report

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<b>CR Number:</b> 2024139016		<b>Implementation Date:</b> 05-Jun-24	<b>Related CR:</b> 2024139016		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed PT	Anablephobia	Rejected After Suspension			

**MSSO Comment:** The proposal to add a new PT Anablephobia is not approved after suspension. This term and the terms in this batch are very rare and obscure "phobias" which are not likely encountered in clinical or post market scenarios where they need to be captured. The validity for the need of these terms has not been specified and the justification is insufficient.

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<b>CR Number:</b> 2024139017		<b>Implementation Date:</b> 05-Jun-24	<b>Related CR:</b> 2024139017		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed PT	Androphobia	Rejected After Suspension			

**MSSO Comment:** The proposal to add a new PT Androphobia is not approved after suspension. This term and the terms in this batch are very rare and obscure "phobias" which are not likely encountered in clinical or post market scenarios where they need to be captured. The validity for the need of these terms has not been specified and the justification is insufficient.

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<b>CR Number:</b> 2024139018		<b>Implementation Date:</b> 05-Jun-24	<b>Related CR:</b> 2024139018		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed PT	Anemophobia	Rejected After Suspension			

**MSSO Comment:** The proposal to add a new PT Anemophobia is not approved after suspension. This term and the terms in this batch are very rare and obscure "phobias" which are not likely encountered in clinical or post market scenarios where they need to be captured. The validity for the need of these terms has not been specified and the justification is insufficient.

# Detail Report

<b>CR Number: 2024139019</b>		<b>Implementation Date:</b> 05-Jun-24	<b>Related CR:</b> 2024139019		
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed PT	Anglophobia	Rejected After Suspension			
MSSO Comment:	The proposal to add a new PT Anglophobia is not approved after suspension. This term and the terms in this batch are very rare and obscure "phobias" which are not likely encountered in clinical or post market scenarios where they need to be captured. The validity for the need of these terms has not been specified and the justification is insufficient.				

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<b>CR Number: 2024139020</b>		<b>Implementation Date:</b> 05-Jun-24	<b>Related CR:</b> 2024139020		
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed PT	Anginophobia	Rejected After Suspension			
MSSO Comment:	The proposal to add a new PT Anginophobia is not approved after suspension. This term and the terms in this batch are very rare and obscure "phobias" which are not likely encountered in clinical or post market scenarios where they need to be captured. The validity for the need of these terms has not been specified and the justification is insufficient.				

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<b>CR Number: 2024139021</b>		<b>Implementation Date:</b> 05-Jun-24	<b>Related CR:</b> 2024139021		
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed PT	Anthrophobia	Rejected After Suspension			
MSSO Comment:	The proposal to add a new PT Anthrophobia is not approved after suspension. This term and the terms in this batch are very rare and obscure "phobias" which are not likely encountered in clinical or post market scenarios where they need to be captured. The validity for the need of these terms has not been specified and the justification is insufficient.				

# Detail Report

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<b>CR Number:</b> 2024139022	<b>Implementation Date:</b> 05-Jun-24	<b>Related CR:</b> 2024139022	<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>
Proposed PT	<i>Antlophobia</i>	Rejected After Suspension	

**MSSO Comment:** The proposal to add a new PT Antlophobia is not approved after suspension. This term and the terms in this batch are very rare and obscure "phobias" which are not likely encountered in clinical or post market scenarios where they need to be captured. The validity for the need of these terms has not been specified and the justification is insufficient.

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<b>CR Number:</b> 2024139023	<b>Implementation Date:</b> 05-Jun-24	<b>Related CR:</b> 2024139023	<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>
Proposed PT	<i>Anuptaphobia</i>	Rejected After Suspension	

**MSSO Comment:** The proposal to add a new PT Anuptaphobia is not approved after suspension. This term and the terms in this batch are very rare and obscure "phobias" which are not likely encountered in clinical or post market scenarios where they need to be captured. The validity for the need of these terms has not been specified and the justification is insufficient.

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<b>CR Number:</b> 2024139024	<b>Implementation Date:</b> 05-Jun-24	<b>Related CR:</b> 2024139024	<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>
Proposed PT	<i>Apeirophobia</i>	Rejected After Suspension	

**MSSO Comment:** The proposal to add a new PT Apeirophobia is not approved after suspension. This term and the terms in this batch are very rare and obscure "phobias" which are not likely encountered in clinical or post market scenarios where they need to be captured. The validity for the need of these terms has not been specified and the justification is insufficient.

# Detail Report

<b>CR Number:</b> 2024139025		<b>Implementation Date:</b> 05-Jun-24	<b>Related CR:</b> 2024139025		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed PT	<i>Aphenphosmphobia</i>	Rejected After Suspension			

**MSSO Comment:** The proposal to add a new PT Aphenphosmphobia is not approved after suspension. This term and the terms in this batch are very rare and obscure "phobias" which are not likely encountered in clinical or post market scenarios where they need to be captured. The validity for the need of these terms has not been specified and the justification is insufficient.

<b>CR Number:</b> 2024139026		<b>Implementation Date:</b> 05-Jun-24	<b>Related CR:</b> 2024139026		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed PT	<i>Apiphobia</i>	Rejected After Suspension			

**MSSO Comment:** The proposal to add a new PT Apiphobia is not approved after suspension. This term and the terms in this batch are very rare and obscure "phobias" which are not likely encountered in clinical or post market scenarios where they need to be captured. The validity for the need of these terms has not been specified and the justification is insufficient.

<b>CR Number:</b> 2024139027		<b>Implementation Date:</b> 05-Jun-24	<b>Related CR:</b> 2024139027		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed PT	<i>Arachibutyrophobia</i>	Rejected After Suspension			

**MSSO Comment:** The proposal to add a new PT Arachibutyrophobia is not approved after suspension. This term and the terms in this batch are very rare and obscure "phobias" which are not likely encountered in clinical or post market scenarios where they need to be captured. The validity for the need of these terms has not been specified and the justification is insufficient.

# Detail Report

<b>CR Number:</b> 2024139028		<b>Implementation Date:</b> 05-Jun-24	<b>Related CR:</b> 2024139028		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed PT	<i>Aquaphobia</i>	Rejected After Suspension			

**MSSO Comment:** The proposal to add a new PT Aquaphobia is not approved after suspension. This term and the terms in this batch are very rare and obscure "phobias" which are not likely encountered in clinical or post market scenarios where they need to be captured. The validity for the need of these terms has not been specified and the justification is insufficient.

<b>CR Number:</b> 2024139029		<b>Implementation Date:</b> 05-Jun-24	<b>Related CR:</b> 2024139029		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed PT	<i>Arithmophobia</i>	Rejected After Suspension			

**MSSO Comment:** The proposal to add a new PT Arithmophobia is not approved after suspension. This term and the terms in this batch are very rare and obscure "phobias" which are not likely encountered in clinical or post market scenarios where they need to be captured. The validity for the need of these terms has not been specified and the justification is insufficient.

<b>CR Number:</b> 2024139030		<b>Implementation Date:</b> 05-Jun-24	<b>Related CR:</b> 2024139030		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed PT	<i>Asthenophobia</i>	Rejected After Suspension			

**MSSO Comment:** The proposal to add a new PT Asthenophobia is not approved after suspension. This term and the terms in this batch are very rare and obscure "phobias" which are not likely encountered in clinical or post market scenarios where they need to be captured. The validity for the need of these terms has not been specified and the justification is insufficient.



# Detail Report

<b>CR Number:</b> 2024139031		<b>Implementation Date:</b> 05-Jun-24	<b>Related CR:</b> 2024139031		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed PT	Ataxiophobia	Rejected After Suspension			

**MSSO Comment:** The proposal to add a new PT Ataxiophobia is not approved after suspension. This term and the terms in this batch are very rare and obscure "phobias" which are not likely encountered in clinical or post market scenarios where they need to be captured. The validity for the need of these terms has not been specified and the justification is insufficient.

<b>CR Number:</b> 2024139032		<b>Implementation Date:</b> 05-Jun-24	<b>Related CR:</b> 2024139032		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed PT	Ataxophobia	Rejected After Suspension			

**MSSO Comment:** The proposal to add a new PT Ataxophobia is not approved after suspension. This term and the terms in this batch are very rare and obscure "phobias" which are not likely encountered in clinical or post market scenarios where they need to be captured. The validity for the need of these terms has not been specified and the justification is insufficient.

<b>CR Number:</b> 2024139033		<b>Implementation Date:</b> 05-Jun-24	<b>Related CR:</b> 2024139033		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed PT	Atelophobia	Rejected After Suspension			

**MSSO Comment:** The proposal to add a new PT Atelophobia is not approved after suspension. This term and the terms in this batch are very rare and obscure "phobias" which are not likely encountered in clinical or post market scenarios where they need to be captured. The validity for the need of these terms has not been specified and the justification is insufficient.

# Detail Report

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<b>CR Number:</b> 2024139034	<b>Implementation Date:</b> 05-Jun-24	<b>Related CR:</b> 2024139034	<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>
Proposed PT	Athazagoraphobia	Rejected After Suspension	

**MSSO Comment:** The proposal to add a new PT Athazagoraphobia is not approved after suspension. This term and the terms in this batch are very rare and obscure "phobias" which are not likely encountered in clinical or post market scenarios where they need to be captured. The validity for the need of these terms has not been specified and the justification is insufficient.

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<b>CR Number:</b> 2024139035	<b>Implementation Date:</b> 05-Jun-24	<b>Related CR:</b> 2024139035	<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>
Proposed PT	Atychiphobia	Rejected After Suspension	

**MSSO Comment:** The proposal to add a new PT Atychiphobia is not approved after suspension. This term and the terms in this batch are very rare and obscure "phobias" which are not likely encountered in clinical or post market scenarios where they need to be captured. The validity for the need of these terms has not been specified and the justification is insufficient.

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<b>CR Number:</b> 2024139036	<b>Implementation Date:</b> 05-Jun-24	<b>Related CR:</b> 2024139036	<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>
Proposed PT	Aulophobia	Rejected After Suspension	

**MSSO Comment:** The proposal to add a new PT Aulophobia is not approved after suspension. This term and the terms in this batch are very rare and obscure "phobias" which are not likely encountered in clinical or post market scenarios where they need to be captured. The validity for the need of these terms has not been specified and the justification is insufficient.

# Detail Report

CR Number: 2024139037		Implementation Date: 05-Jun-24	Related CR: 2024139037		MedDRA Code #
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed PT	Auroraphobia	Rejected After Suspension			

MSSO Comment: The proposal to add a new PT Auroraphobia is not approved after suspension. This term and the terms in this batch are very rare and obscure "phobias" which are not likely encountered in clinical or post market scenarios where they need to be captured. The validity for the need of these terms has not been specified and the justification is insufficient.

CR Number: 2024139038		Implementation Date: 05-Jun-24	Related CR: 2024139038		MedDRA Code #
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed PT	Automatonophobia	Rejected After Suspension			

MSSO Comment: The proposal to add a new PT Automatonophobia is not approved after suspension. This term and the terms in this batch are very rare and obscure "phobias" which are not likely encountered in clinical or post market scenarios where they need to be captured. The validity for the need of these terms has not been specified and the justification is insufficient.

CR Number: 2024139039		Implementation Date: 05-Jun-24	Related CR: 2024139039		MedDRA Code #
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed PT	Automysophobia	Rejected After Suspension			

MSSO Comment: The proposal to add a new PT Automysophobia is not approved after suspension. This term and the terms in this batch are very rare and obscure "phobias" which are not likely encountered in clinical or post market scenarios where they need to be captured. The validity for the need of these terms has not been specified and the justification is insufficient.

# Detail Report

CR Number: 2024139040		Implementation Date: 05-Jun-24	Related CR: 2024139040		
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed PT	Aviophobia	Rejected After Suspension			

MSSO Comment: The proposal to add a new PT Aviophobia is not approved after suspension. This term and the terms in this batch are very rare and obscure "phobias" which are not likely encountered in clinical or post market scenarios where they need to be captured. The validity for the need of these terms has not been specified and the justification is insufficient.

CR Number: 2024139041		Implementation Date: 05-Jun-24	Related CR: 2024139041		
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed PT	<i>Aurophobia</i>	Rejected After Suspension			

MSSO Comment: The proposal to add a new PT Aurophobia is not approved after suspension. This term and the terms in this batch are very rare and obscure "phobias" which are not likely encountered in clinical or post market scenarios where they need to be captured. The validity for the need of these terms has not been specified and the justification is insufficient.

# Detail Report

CR Number: 2024141000		Implementation Date: 28-May-24	Related CR: 2024141000	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Metabolic dysfunction-associated liver disease	Approved as Requested	Proposed PT	
To SMQ	Hepatic failure, fibrosis and cirrhosis and other liver damage-related conditions (SMQ)		Metabolic dysfunction-associated liver disease	10090857
Term scope	Narrow		To SMQ	
			Hepatic failure, fibrosis and cirrhosis and other liver damage-related conditions (SMQ)	20000013
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	
MSSO Comment:	The proposal to add PT Metabolic dysfunction-associated liver disease to Hepatic failure, fibrosis and cirrhosis and other liver damage-related conditions (SMQ) as a narrow term is approved as requested. Steatotic liver disease develops for many reasons, involves many different biochemical mechanisms, and causes different types of liver damage. Pathophysiology involves fat accumulation (steatosis), inflammation, and, variably, fibrosis.			

CR Number: 2024141001		Implementation Date: 24-May-24	Related CR: 2024141001	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Foetal topiramate syndrome	Rejected		
To PT	Foetal anticonvulsant syndrome			
MSSO Comment:	The proposal to add a new LLT Foetal topiramate syndrome to PT Foetal anticonvulsant syndrome is not approved. It is agreed that topiramate carries great risks to the fetus if exposed during pregnancy, however, there are as of yet no official medical references for the concept 'Fetal topiramate syndrome'. The proposed term is not yet a coined expression specifically with this drug.			

# Detail Report

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<b>CR Number:</b> 2024141002		<b>Implementation Date:</b> 24-May-24	<b>Related CR:</b> 2024141002	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Idiopathic external hydrocephalus</i>	Approved as Requested	Proposed LLT <i>Idiopathic external hydrocephalus</i>	10091177 Current
			To PT <i>External hydrocephalus</i>	10076670

**MSSO Comment:** The proposal to add a new term Idiopathic external hydrocephalus is approved as requested. External hydrocephalus is a condition in which infants with rapidly enlarging heads are found to have a CT scan that shows widening of the subarachnoid space with mild or no ventricular dilation. The word "benign/idiopathic" is often used together with "external hydrocephalus," reflecting the common view that this is a self-limiting condition occurring during infancy, resolving spontaneously during childhood. Hence, most patients are probably not treated. Idiopathic external hydrocephalus will be added as sub-concept LLT to PT External hydrocephalus.

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<b>CR Number:</b> 2024141003		<b>Implementation Date:</b> 24-May-24	<b>Related CR:</b> 2024141003	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Pre-eclampsia, postpartum</i>	Rejected		

**MSSO Comment:** The proposal to add a new term Pre-eclampsia, postpartum is not approved. The proposed concept already exists in the natural word order as LLT Postpartum pre-eclampsia.

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<b>CR Number:</b> 2024141004		<b>Implementation Date:</b> 24-May-24	<b>Related CR:</b> 2024141004	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Neonatal bacterial conjunctivitis</i>	Approved as Requested	Proposed LLT <i>Neonatal bacterial conjunctivitis</i>	10091175 Current
			To PT <i>Ophthalmia neonatorum</i>	10030861

**MSSO Comment:** The proposal to add a new term Neonatal bacterial conjunctivitis is approved as requested. Neonatal conjunctivitis, also known as ophthalmia neonatorum, presents during the first month of life. It may be aseptic or septic and, if left untreated, may be blinding. Bacterial and viral infections are major causes of septic neonatal conjunctivitis, with Chlamydia being the most common infectious agent and Neisseria being the most visually threatening. Neonatal bacterial conjunctivitis will be added as an LLT to PT Ophthalmia neonatorum.

# Detail Report

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<b>CR Number:</b> 2024141005		<b>Implementation Date:</b> 24-May-24	<b>Related CR:</b> 2024141005	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	Gestational diabetes type A1	Approved as Requested	Proposed LLT Gestational diabetes type A1	10091178 Current
			To PT Gestational diabetes	10018209
<b>MSSO Comment:</b> The proposal to add a new term Gestational diabetes type A1 is approved as requested. Gestational diabetes is a condition in which the blood sugar levels become high during pregnancy. There are two types of gestational diabetes. Type A1 is used to describe gestational diabetes that can be managed through diet alone. Gestational diabetes type A1 will be added as a sub-concept LLT under PT Gestational diabetes.				

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<b>CR Number:</b> 2024141006		<b>Implementation Date:</b> 24-May-24	<b>Related CR:</b> 2024141006	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	Gestational diabetes A2	Approved Not as Requested	Proposed LLT Gestational diabetes type A2	10091176 Current
			To PT Gestational diabetes	10018209
<b>MSSO Comment:</b> The proposal to add a new term Gestational diabetes A2 is approved but not as requested. Gestational diabetes is a condition in which the blood sugar levels become high during pregnancy. There are two types of gestational diabetes. Type A2 is used to describe gestational diabetes where insulin or oral medications are needed to manage the condition. The proposed term will be modified as Gestational diabetes type A2 to clarify the term and added as sub-concept LLT under PT Gestational diabetes.				

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<b>CR Number:</b> 2024141007		<b>Implementation Date:</b> 24-May-24	<b>Related CR:</b> 2024141007	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	Neonatal bacterial sepsis	Rejected		
<b>MSSO Comment:</b> The proposal to add a new term Neonatal bacterial sepsis is not approved. Neonatal sepsis is defined as a generalised bacterial infection accompanied by a positive blood culture within the first month of life. The MSSO generally refrains from adding concepts which can be represented by existing terms. Please review the LLT/PT Neonatal sepsis and LLT/PT Bacterial sepsis for your coding needs.				

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# Detail Report

CR Number: 2024141008		Implementation Date: 24-May-24	Related CR: 2024141008		
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed Term	Axis IV disorder	Rejected			

MSSO Comment: The proposal to add a new term Axis IV disorder is not approved. In the United States, healthcare professionals consult the Diagnostic and Statistical Manual of Mental Disorders (DSM) when diagnosing mental health conditions. The DSM is published by the American Psychiatric Association (APA). The APA instituted the multi-axial system in the third edition of the DSM (DSM-III). The Axes were introduced as a way for clinicians to record additional diagnostic information. It was determined that there was no scientific basis for dividing the disorders in this manner, so the APA stopped using the multi-axial system starting with the DSM-5 in 2013. The requested term Axis IV disorder represents an expression which may not have an universally accepted international interpretation. Within MedDRA, SOC Social circumstances includes specific social and environmental problems which can be used according to the specific scenario.

CR Number: 2024141009		Implementation Date: 24-May-24	Related CR: 2024141009		
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed Term	HIV complicating pregnancy	Rejected			

MSSO Comment: The proposal to add a new term HIV complicating pregnancy is not approved. Pregnancy can be subject to multiple complications for which MedDRA cannot add a specific pregnancy complication and a disease combination term. The proposed concept can be represented through split coding. Section 3.5 of the MedDRA Term Selection Points to Consider (MTS: PTC) document defines these as "combination terms". Please consider LLT/PT Maternal disease complicating pregnancy and other relevant terms based on your specific clinical scenario.



# Detail Report

CR Number: 2024141011		Implementation Date: 28-May-24	Related CR: 2024141011	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Atypical Stevens-Johnson syndrome</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Oropharyngeal conditions (excl neoplasms, infections and allergies) (SMQ)</i>		<i>Atypical Stevens-Johnson syndrome</i>	10091034
Term scope	<i>Narrow</i>		To SMQ	
			<i>Oropharyngeal conditions (excl neoplasms, infections and allergies) (SMQ)</i>	20000114
			Term scope	
			<i>Narrow</i>	
			Term_category	
			A	
			Term_weight	
			0	

**MSSO Comment:** The proposal to add PT Atypical Stevens-Johnson syndrome to Oropharyngeal conditions (excl neoplasms, infections and allergies) (SMQ) as a Narrow term is approved as requested. PT Atypical Stevens-Johnson syndrome was added in Version 27.1 and is a rare variation of Stevens-Johnsons syndrome with a complete absence of or only a few cutaneous manifestations. It is usually seen in children infected by Mycoplasma pneumoniae, but it is also found with other infective pathogens as well as certain drugs. Addition of PT Atypical Stevens-Johnson syndrome is in line with the already included PTs Stevens-Johnson syndrome, Toxic epidermal necrolysis and SJS-TEN overlap. All PTs in this SMQ are narrow in scope.

CR Number: 2024141012		Implementation Date: 28-May-24	Related CR: 2024141012	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Hypothyroid cardiomyopathy</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Hypothyroidism (SMQ)</i>		<i>Hypothyroid cardiomyopathy</i>	10090970
Term scope	<i>Narrow</i>		To SMQ	
			<i>Hypothyroidism (SMQ)</i>	20000160
			Term scope	
			<i>Narrow</i>	
			Term_category	
			A	
			Term_weight	
			0	

**MSSO Comment:** The proposal to add PT Hypothyroid cardiomyopathy to Hypothyroidism (SMQ) as a Narrow term is approved as requested. PT Hypothyroid cardiomyopathy was added in version 27.1 and represents an uncommon manifestation of hypothyroidism that can take the form of dilated cardiomyopathy or, less frequently, asymmetric septal hypertrophy. The condition is reversible with restoration of euthyroid state. PT Hypothyroid cardiomyopathy will be added with narrow scope, in line with the already included PT Hypothyroid myopathy.

# Detail Report

CR Number: 2024141013		Implementation Date: 28-May-24	Related CR: 2024141013	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Pseudomonas stomatitis</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Oropharyngeal infections (SMQ)</i>		<i>Pseudomonas stomatitis</i>	10090868
Term scope	<i>Narrow</i>		To SMQ	
			<i>Oropharyngeal infections (SMQ)</i>	20000111
			Term scope	
			<i>Narrow</i>	
			Term_category	
			A	
			Term_weight	
			0	

MSSO      The proposal to add PT Pseudomonas stomatitis to Oropharyngeal infections (SMQ) as a Narrow term is approved as requested. PT Pseudomonas stomatitis was added  
Comment: in version 27.1 and fits the inclusion criterion "Oropharyngeal infections". All PTs of this SMQ are narrow in scope.

CR Number: 2024141014		Implementation Date: 28-May-24	Related CR: 2024141014	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Salivary gland myoepithelioma</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Oropharyngeal neoplasms (SMQ)</i>		<i>Salivary gland myoepithelioma</i>	10090974
Term scope	<i>Narrow</i>		To SMQ	
			<i>Oropharyngeal neoplasms (SMQ)</i>	20000110
			Term scope	
			<i>Narrow</i>	
			Term_category	
			A	
			Term_weight	
			0	

MSSO      The proposal to add PT Salivary gland myoepithelioma to Oropharyngeal neoplasms (SMQ) as a Narrow term is approved as requested. PT Salivary gland  
Comment: myoepithelioma was added in version 27.1 and is a benign tumor of the oral cavity, arising predominantly from major and minor salivary glands, accounting for 1–1.5% of all glandular tumors. It is mainly composed of myoepithelial cells located between the basal surface of acinar units, basement membrane, and surrounding intercalated duct. Addition of PT Salivary gland myoepithelioma is in line with the inclusion criterion "Oropharyngeal neoplasms, cysts, and pre-neoplastic lesions". All PTs of this SMQ are narrow in scope.

# Detail Report

CR Number: 2024141015		Implementation Date: 28-May-24	Related CR: 2024141015	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Salivary stasis	Approved as Requested	Proposed PT	
To SMQ	Oropharyngeal conditions (excl neoplasms, infections and allergies) (SMQ)		Salivary stasis	10090924
Term scope	Narrow		To SMQ	
			Oropharyngeal conditions (excl neoplasms, infections and allergies) (SMQ)	20000114
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	

**MSSO Comment:** The proposal to add PT Salivary stasis to Oropharyngeal conditions (excl neoplasms, infections and allergies) (SMQ) as a Narrow term is approved as requested. PT Salivary stasis was added in version 27.1 and is one of the main precipitating factors of acute suppurative sialadenitis. Salivary stasis can be caused by medications or sialolithiasis. It is associated with dehydration and common medications, including tricyclic antidepressants, antipsychotics, benzodiazepines, anticholinergics,  $\beta$ -blockers, and antihistamines. Addition of this PT is in line with already included PT Saliva altered, PT Saliva discolouration, PT Salivary hyposecretion etc. All PTs of this SMQ are narrow in scope.

CR Number: 2024141016		Implementation Date: 28-May-24	Related CR: 2024141016	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Pericardiodesis	Approved as Requested	Proposed PT	
To SMQ	Noninfectious myocarditis/pericarditis (SMQ)		Pericardiodesis	10091072
Term scope	Broad		To SMQ	
			Noninfectious myocarditis/pericarditis (SMQ)	20000239
			Term scope	
			Broad	
			Term_category	
			A	
			Term_weight	
			0	

**MSSO Comment:** The proposal to add PT Pericardiodesis to Noninfectious myocarditis/pericarditis (SMQ) as a Broad term is approved as requested. Non-infectious conditions (such as certain malignancies) can predispose a patient to recurrent pericardial effusions. Pericardiodesis is a procedure performed to obliterate the pericardial space by means of induced pericardial sclerosis in order to prevent recurrent effusions. This term describes a therapeutic procedure that can be used to treat non-infectious pericarditis and will be added to the broad search terms of this SMQ.

# Detail Report

<b>CR Number:</b> 2024141017		<b>Implementation Date:</b> 28-May-24	<b>Related CR:</b> 2024141017		
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed PT	<i>Spontaneous subdural haematoma</i>	Approved as Requested	Proposed PT		
To SMQ	<i>Haemorrhagic central nervous system vascular conditions (SMQ)</i>		<i>Spontaneous subdural haematoma</i>	10090938	
Term scope	<i>Narrow</i>		To SMQ		
			<i>Haemorrhagic central nervous system vascular conditions (SMQ)</i>	20000064	
			Term scope		
			<i>Narrow</i>		
			Term_category		
			A		
			Term_weight		
			0		

**MSSO Comment:** The proposal to add PT Spontaneous subdural haematoma to Haemorrhagic central nervous system vascular conditions (SMQ) as a Narrow term is approved as requested. Although head trauma is the most common cause of subdural haematoma, subdural haematoma may be spontaneous or triggered by an inciting event. Risk factors for the development of spontaneous subdural haematoma include hypertension, vascular abnormalities and deficit of coagulation. This term will be added to this SMQ which is entirely comprised of narrow search terms.

<b>CR Number:</b> 2024141018		<b>Implementation Date:</b> 28-May-24	<b>Related CR:</b> 2024141018		
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed PT	<i>Thalamic microhaemorrhage</i>	Approved as Requested	Proposed PT		
To SMQ	<i>Haemorrhagic central nervous system vascular conditions (SMQ)</i>		<i>Thalamic microhaemorrhage</i>	10090985	
Term scope	<i>Narrow</i>		To SMQ		
			<i>Haemorrhagic central nervous system vascular conditions (SMQ)</i>	20000064	
			Term scope		
			<i>Narrow</i>		
			Term_category		
			A		
			Term_weight		
			0		

**MSSO Comment:** The proposal to add PT Thalamic microhaemorrhage to Haemorrhagic central nervous system vascular conditions (SMQ) as a Narrow term is approved as requested. Thalamic microhaemorrhages can be seen in small vessel disease, after trauma, secondary to initial infarction, or in the setting of adjacent brain tumors. This term, which describes a specific type of central nervous system haemorrhage that is not exclusively trauma-related, will be added to this SMQ which is entirely comprised of narrow search terms.

# Detail Report

CR Number: 2024141019		Implementation Date: 28-May-24	Related CR: 2024141019	
<u>Change Requested</u>	Add term to SMQ	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Traumatic pain	Approved as Requested	Proposed PT	
To SMQ	Accidents and injuries (SMQ)		Traumatic pain	10090951
Term scope	Broad		To SMQ	
			Accidents and injuries (SMQ)	20000135
			Term scope	
			Broad	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Traumatic pain to Accidents and injuries (SMQ) as a Broad term is approved as requested. This term, which describes a specific consequence of trauma (i.e., the development of the perception of pain), will be added to this SMQ. Although the nature of the pain is non-specific, a similar concept (i.e., PT Post-traumatic pain) is already included in the broad search terms of this SMQ.

CR Number: 2024141020		Implementation Date: 28-May-24	Related CR: 2024141020	
<u>Change Requested</u>	Add term to SMQ	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Traumatic subarachnoid haemorrhage	Approved as Requested	Proposed PT	
To SMQ	Accidents and injuries (SMQ)		Traumatic subarachnoid haemorrhage	10090895
Term scope	Narrow		To SMQ	
			Accidents and injuries (SMQ)	20000135
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Traumatic subarachnoid haemorrhage to Accidents and injuries (SMQ) as a Narrow term is approved as requested. Subarachnoid haemorrhage, when caused by trauma, meets the criteria for inclusion in this SMQ. More specifically, because it describes a particular type of trauma-induced haemorrhage, it will be added to the narrow search terms of this SMQ.

# Detail Report

CR Number: 2024141021		Implementation Date: 28-May-24	Related CR: 2024141021	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Atypical Stevens-Johnson syndrome</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Hypersensitivity (SMQ)</i>		<i>Atypical Stevens-Johnson syndrome</i>	10091034
Term scope	<i>Narrow</i>		To SMQ	
			<i>Hypersensitivity (SMQ)</i>	20000214
			Term scope	
			<i>Narrow</i>	
			Term_category	
			A	
			Term_weight	
			0	

**MSSO**  
**Comment:** The proposal to add PT Atypical Stevens-Johnson syndrome to Hypersensitivity (SMQ) as a Narrow term is approved as requested. Atypical Stevens-Johnson syndrome is a rare variation of Steven-Johnson syndrome with a complete absence of or only a few cutaneous manifestations. Although it is usually seen in children infected by M. pneumoniae, it can also occur after drug exposure. Atypical Stevens-Johnson syndrome will be added as a narrow scope search term to the Hypersensitivity (SMQ) in line with other Steven-Johnson syndrome related terms.

CR Number: 2024141022		Implementation Date: 28-May-24	Related CR: 2024141022	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Corneal pseudoguttata</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Corneal disorders (SMQ)</i>		<i>Corneal pseudoguttata</i>	10090966
Term scope	<i>Narrow</i>		To SMQ	
			<i>Corneal disorders (SMQ)</i>	20000156
			Term scope	
			<i>Narrow</i>	
			Term_category	
			A	
			Term_weight	
			0	

**MSSO**  
**Comment:** The proposal to add PT Corneal pseudoguttata to Corneal disorders (SMQ) as a Narrow term is approved as requested. Corneal pseudoguttata, also known as pseudoguttatae or secondary guttata, is a transient, reversible endothelial edema commonly associated with anterior segment pathology. Corneal pseudoguttata presents as dark lesions on slit-lamp exam with specular illumination, similar to primary corneal guttata. The term meets the inclusion criteria of the SMQ and will be added to the narrow scope.

# Detail Report

CR Number: 2024141023		Implementation Date: 28-May-24	Related CR: 2024141023	
<u>Change Requested</u>	Add term to SMQ	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Retinal pigment epithelium change	Approved as Requested	Proposed PT	
To SMQ	Retinal disorders (SMQ)		Retinal pigment epithelium change	10090967
Term scope	Narrow		To SMQ	
			Retinal disorders (SMQ)	20000158
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Retinal pigment epithelium change to Retinal disorders (SMQ) as a Narrow term is approved as requested. The retinal pigment epithelium is a single layer of cells tightly joined so that they form a barrier between the retina and the underlying choroid. As the retinal pigment epithelium ages or is affected by disease, a number of structural changes may occur. Retinal pigment epithelium change meets the inclusion criteria of the SMQ and will be added to the narrow scope.

CR Number: 2024141024		Implementation Date: 28-May-24	Related CR: 2024141024	
<u>Change Requested</u>	Add term to SMQ	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Glaucoma drainage device exposure	Approved as Requested	Proposed PT	
To SMQ	Glaucoma (SMQ)		Glaucoma drainage device exposure	10090878
Term scope	Broad		To SMQ	
			Glaucoma (SMQ)	20000146
			Term scope	
			Broad	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Glaucoma drainage device exposure to Glaucoma (SMQ) as a Broad term is approved as requested. The term Glaucoma drainage device exposure refers to a complication related to a glaucoma drainage device in which a part of the device dislocates and causes complications. The term matches the inclusion criteria of the SMQ as it refers to a glaucoma therapy and it will be placed in the broad scope as it is indicating a complication of the therapy and not the therapy itself.

# Detail Report

CR Number: 2024141025		Implementation Date: 28-May-24	Related CR: 2024141025	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Myelodysplastic syndrome/myeloproliferative neoplasm overlap syndrome	Approved as Requested	Proposed PT	
To SMQ	Haematopoietic cytopenias affecting more than one type of blood cell (SMQ)		Myelodysplastic syndrome/myeloproliferative neoplasm overlap syndrome	10090858
Term scope	Broad		To SMQ	
			Haematopoietic cytopenias affecting more than one type of blood cell (SMQ)	20000028
			Term scope	
			Broad	
			Term_category	
			A	
			Term_weight	
			0	
MSSO Comment:	The proposal to add PT Myelodysplastic syndrome/myeloproliferative neoplasm overlap syndrome to Haematopoietic cytopenias affecting more than one type of blood cell (SMQ) as a Broad term is approved as requested. PT Myelodysplastic syndrome/myeloproliferative neoplasm overlap syndrome was added in version 27.1 and comprises a heterogeneous group of neoplasms in which the myeloproliferative component coexists together with the ineffective hematopoiesis, leading to cytopenia. PT Myelodysplastic syndrome/myeloproliferative neoplasm overlap syndrome will be added with broad scope, in line with already included PTs representing myelodysplastic syndromes.			

CR Number: 2024141026		Implementation Date: 28-May-24	Related CR: 2024141026	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Lacrimal gland biopsy	Approved as Requested	Proposed PT	
To SMQ	Lacrimal disorders (SMQ)		Lacrimal gland biopsy	10090897
Term scope	Narrow		To SMQ	
			Lacrimal disorders (SMQ)	20000176
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	
MSSO Comment:	The proposal to add PT Lacrimal gland biopsy to Lacrimal disorders (SMQ) as a Narrow term is approved as requested. This term fits the inclusion criteria for this SMQ which includes terms for lacrimal apparatus procedures. Similar terms such as PT Lacrimal duct procedure and PT Lacrimal duct operation are already included.			



# Detail Report

CR Number: 2024141027		Implementation Date: 28-May-24	Related CR: 2024141027	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	ARID1A gene mutation	Approved as Requested	Proposed PT	
To SMQ	Congenital, familial and genetic disorders (SMQ)		ARID1A gene mutation	10091033
Term scope	Narrow		To SMQ	
			Congenital, familial and genetic disorders (SMQ)	20000077
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	
MSSO Comment:	The proposal to add PT ARID1A gene mutation to Congenital, familial and genetic disorders (SMQ) as a Narrow term is approved as requested. This term fits the inclusion criteria for this SMQ which includes all PTs in SOC Congenital, familial and genetic disorders. All terms in this SMQ are narrow in scope.			

CR Number: 2024141028		Implementation Date: 28-May-24	Related CR: 2024141028	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Accessory ostium of maxillary sinus	Approved as Requested	Proposed PT	
To SMQ	Congenital, familial and genetic disorders (SMQ)		Accessory ostium of maxillary sinus	10090901
Term scope	Narrow		To SMQ	
			Congenital, familial and genetic disorders (SMQ)	20000077
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	
MSSO Comment:	The proposal to add PT Accessory ostium of maxillary sinus to Congenital, familial and genetic disorders (SMQ) as a Narrow term is approved as requested. This term fits the inclusion criteria for this SMQ which includes all PTs in SOC Congenital, familial and genetic disorders. All terms in this SMQ are narrow in scope.			

# Detail Report

CR Number: 2024141029		Implementation Date: 28-May-24	Related CR: 2024141029		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed PT	Body stalk anomaly	Approved as Requested	Proposed PT		
To SMQ	Congenital, familial and genetic disorders (SMQ)		Body stalk anomaly		10090905
Term scope	Narrow		To SMQ		
			Congenital, familial and genetic disorders (SMQ)		20000077
			Term scope		
			Narrow		
			Term_category		
			A		
			Term_weight		
			0		

MSSO Comment: The proposal to add PT Body stalk anomaly to Congenital, familial and genetic disorders (SMQ) as a Narrow term is approved as requested. This term fits the inclusion criteria for this SMQ which includes all PTs in SOC Congenital, familial and genetic disorders. All terms in this SMQ are narrow in scope.

CR Number: 2024141030		Implementation Date: 28-May-24	Related CR: 2024141030		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed PT	Hereditary breast and ovarian cancer syndrome	Approved as Requested	Proposed PT		
To SMQ	Congenital, familial and genetic disorders (SMQ)		Hereditary breast and ovarian cancer syndrome		10090911
Term scope	Narrow		To SMQ		
			Congenital, familial and genetic disorders (SMQ)		20000077
			Term scope		
			Narrow		
			Term_category		
			A		
			Term_weight		
			0		

MSSO Comment: The proposal to add PT Hereditary breast and ovarian cancer syndrome to Congenital, familial and genetic disorders (SMQ) as a Narrow term is approved as requested. This term fits the inclusion criteria for this SMQ which includes all PTs in SOC Congenital, familial and genetic disorders. All terms in this SMQ are narrow in scope.

# Detail Report

CR Number: 2024141031		Implementation Date: 28-May-24	Related CR: 2024141031	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Uterine cervix agenesis	Approved as Requested	Proposed PT	
To SMQ	Congenital, familial and genetic disorders (SMQ)		Uterine cervix agenesis	10091075
Term scope	Narrow		To SMQ	
			Congenital, familial and genetic disorders (SMQ)	20000077
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Uterine cervix agenesis to Congenital, familial and genetic disorders (SMQ) as a Narrow term is approved as requested. This term fits the inclusion criteria for this SMQ which includes all PTs in SOC Congenital, familial and genetic disorders. All terms in this SMQ are narrow in scope.

CR Number: 2024141032		Implementation Date: 28-May-24	Related CR: 2024141032	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Spontaneous subdural haematoma	Approved as Requested	Proposed PT	
To SMQ	Haemorrhage terms (excl laboratory terms) (SMQ)		Spontaneous subdural haematoma	10090938
Term scope	Narrow		To SMQ	
			Haemorrhage terms (excl laboratory terms) (SMQ)	20000039
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Spontaneous subdural haematoma to Haemorrhage terms (excl laboratory terms) (SMQ) as a Narrow term is approved as requested. This term fits the inclusion criteria for this SMQ. Similar terms such as PT Subarachnoid haematoma and PT Subdural haematoma are already included as narrow scope terms.

# Detail Report

CR Number: 2024141033		Implementation Date: 28-May-24	Related CR: 2024141033	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Thalamic microhaemorrhage	Approved as Requested	Proposed PT	
To SMQ	Haemorrhage terms (excl laboratory terms) (SMQ)		Thalamic microhaemorrhage	10090985
Term scope	Narrow		To SMQ	
			Haemorrhage terms (excl laboratory terms) (SMQ)	20000039
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	
MSSO Comment: The proposal to add PT Thalamic microhaemorrhage to Haemorrhage terms (excl laboratory terms) (SMQ) as a Narrow term is approved as requested. This term fits the inclusion criteria for this SMQ. Similar terms such as PT Brain stem microhaemorrhage and PT Cerebellar microhaemorrhage are already included as narrow scope terms.				

CR Number: 2024141034		Implementation Date: 28-May-24	Related CR: 2024141034	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Traumatic subarachnoid haemorrhage	Approved as Requested	Proposed PT	
To SMQ	Haemorrhage terms (excl laboratory terms) (SMQ)		Traumatic subarachnoid haemorrhage	10090895
Term scope	Narrow		To SMQ	
			Haemorrhage terms (excl laboratory terms) (SMQ)	20000039
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	
MSSO Comment: The proposal to add PT Traumatic subarachnoid haemorrhage to Haemorrhage terms (excl laboratory terms) (SMQ) as a Narrow term is approved as requested. This term fits the inclusion criteria for this SMQ. Similar terms such as PT Subarachnoid haemorrhage and PT Traumatic intracranial haemorrhage are already included as narrow scope terms.				

# Detail Report

CR Number: 2024141035		Implementation Date: 28-May-24	Related CR: 2024141035	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Intracameral implant</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Glaucoma (SMQ)</i>		<i>Intracameral implant</i>	10090902
Term scope	<i>Broad</i>		To SMQ	
			<i>Glaucoma (SMQ)</i>	20000146
			Term scope	
			<i>Broad</i>	
			Term_category	
			A	
			Term_weight	
			0	

**MSSO Comment:** The proposal to add PT Intracameral implant to Glaucoma (SMQ) as a Broad term is approved as requested. Intracameral implants are devices or substances that are placed directly into the anterior chamber of the eye. These implants are used for various purposes in ophthalmology, such as delivering medications for the treatment of conditions like glaucoma or infections. Although intracameral implants can be used for different conditions, these are often used in glaucoma treatment and thus meet the inclusion criteria of the SMQ. The term will be added to the broad scope in line with other eye procedures which are not exclusively linked to glaucoma.

CR Number: 2024141036		Implementation Date: 28-May-24	Related CR: 2024141036	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Saccadic eye movement disorder</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Ocular motility disorders (SMQ)</i>		<i>Saccadic eye movement disorder</i>	10091076
Term scope	<i>Narrow</i>		To SMQ	
			<i>Ocular motility disorders (SMQ)</i>	20000184
			Term scope	
			<i>Narrow</i>	
			Term_category	
			A	
			Term_weight	
			0	

**MSSO Comment:** The proposal to add PT Saccadic eye movement disorder to Ocular motility disorders (SMQ) as a Narrow term is approved as requested. Saccadic eye movement disorder is the qualified version of the term 'Saccadic eye movement' which could be interpreted as normal saccadic eye movement. The term Saccadic eye movement previously part of the narrow scope of this SMQ was made non-current. In its place Saccadic eye movement disorder will be added to the narrow scope of Ocular motility disorders (SMQ).

# Detail Report

CR Number: 2024141037		Implementation Date: 28-May-24	Related CR: 2024141037	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Ewing's sarcoma of adrenal gland	Approved as Requested	Proposed PT	
To SMQ	Non-haematological malignant tumours (SMQ)		Ewing's sarcoma of adrenal gland	10090855
Term scope	Narrow		To SMQ	
			Non-haematological malignant tumours (SMQ)	20000228
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	
MSSO Comment:	The proposal to add PT Ewing's sarcoma of adrenal gland to Non-haematological malignant tumours (SMQ) as a Narrow term is approved as requested. Ewing's sarcoma or primitive neuro-ectodermal tumor typically occurs in long or flat bones, the chest wall, extra-skeletal soft tissue, and rarely in solid organs. Incidence of adrenal Ewing's sarcoma is very rare. Ewing's sarcoma of adrenal gland matches the inclusion criteria of Non-haematological malignant tumours (SMQ), which has only narrow search terms.			

CR Number: 2024141038		Implementation Date: 28-May-24	Related CR: 2024141038	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Melanocytic tumour of uncertain malignant potential	Approved as Requested	Proposed PT	
To SMQ	Non-haematological tumours of unspecified malignancy (SMQ)		Melanocytic tumour of uncertain malignant potential	10091063
Term scope	Narrow		To SMQ	
			Non-haematological tumours of unspecified malignancy (SMQ)	20000230
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	
MSSO Comment:	The proposal to add PT Melanocytic tumour of uncertain malignant potential to Non-haematological tumours of unspecified malignancy (SMQ) as a Narrow term is approved as requested. Although most melanocytic lesions can be diagnosed by histopathologists as benign or malignant with high confidence, a subset of morphologically ambiguous lesions does exist and still represents a significant problem for pathologists. Melanocytic tumour of uncertain malignant potential will be added to Non-haematological tumours of unspecified malignancy (SMQ), which has only narrow search terms.			

# Detail Report

CR Number: 2024141039		Implementation Date: 28-May-24	Related CR: 2024141039	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Melanocytic tumour of uncertain malignant potential	Approved as Requested	Proposed PT	
To SMQ	Skin tumours of unspecified malignancy (SMQ)		Melanocytic tumour of uncertain malignant potential	10091063
Term scope	Narrow		To SMQ	
			Skin tumours of unspecified malignancy (SMQ)	20000205
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	
<div>MSSO</div> <div>Comment:</div> <div>The proposal to add PT Melanocytic tumour of uncertain malignant potential to Skin tumours of unspecified malignancy (SMQ) as a Narrow term is approved as requested. Although most melanocytic lesions can be diagnosed by histopathologists as benign or malignant with high confidence, a subset of morphologically ambiguous lesions does exist and still represents a significant problem for pathologists. Melanocytic tumour of uncertain malignant potential will be added to the narrow scope of Skin tumours of unspecified malignancy (SMQ).</div>				

CR Number: 2024141040		Implementation Date: 28-May-24	Related CR: 2024141040	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Myelodysplastic syndrome/myeloproliferative neoplasm overlap syndrome	Approved as Requested	Proposed PT	
To SMQ	Myelodysplastic syndrome (SMQ)		Myelodysplastic syndrome/myeloproliferative neoplasm overlap syndrome	10090858
Term scope	Narrow		To SMQ	
			Myelodysplastic syndrome (SMQ)	20000217
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	
<div>MSSO</div> <div>Comment:</div> <div>The proposal to add PT Myelodysplastic syndrome/myeloproliferative neoplasm overlap syndrome to Myelodysplastic syndrome (SMQ) as a Narrow term is approved as requested. Myelodysplastic syndrome/myeloproliferative neoplasm (MDS/MPN) overlap syndrome represents a chronic clonal myeloid malignancy in which there are features of both MDS and MPN at the time of presentation. Myelodysplastic syndrome/myeloproliferative neoplasm overlap syndrome matches the inclusion criteria and will be added to the narrow scope of Myelodysplastic syndrome (SMQ).</div>				

# Detail Report

CR Number: 2024141041		Implementation Date: 28-May-24	Related CR: 2024141041		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed PT	Non-clear cell renal cell carcinoma	Approved as Requested	Proposed PT		
To SMQ	Non-haematological malignant tumours (SMQ)		Non-clear cell renal cell carcinoma		10090987
Term scope	Narrow		To SMQ		
			Non-haematological malignant tumours (SMQ)		20000228
			Term scope		
			Narrow		
			Term_category		
			A		
			Term_weight		
			0		

**MSSO Comment:** The proposal to add PT Non-clear cell renal cell carcinoma to Non-haematological malignant tumours (SMQ) as a Narrow term is approved as requested. Non-clear cell renal cell carcinoma (ncRCC) is a heterogeneous group of diseases including a number of histological subtypes that are disparate in presentation, clinical course, and genetic basis. Survival of all subtypes of ncRCC in the metastatic setting is uniformly worse than the clear-cell counterpart. Non-clear cell renal cell carcinoma matches the inclusion criteria and will be added to Non-haematological malignant tumours (SMQ), which has only narrow search terms.

CR Number: 2024141042		Implementation Date: 28-May-24	Related CR: 2024141042		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed PT	Breast ablation	Approved as Requested	Proposed PT		
To SMQ	Breast malignant tumours (SMQ)		Breast ablation		10090883
Term scope	Narrow		To SMQ		
			Breast malignant tumours (SMQ)		20000198
			Term scope		
			Narrow		
			Term_category		
			A		
			Term_weight		
			0		

**MSSO Comment:** The proposal to add PT Breast ablation to Breast malignant tumours (SMQ) as a Narrow term is approved as requested. Ablative techniques used in breast cancer are cryoablation, radiofrequency ablation, microwave ablation, high-intensity focused ultrasound, and laser ablation. Breast ablation will be added in line with other therapeutic procedures to the narrow scope of Breast malignant tumours (SMQ).



# Detail Report

CR Number: 2024141043		Implementation Date: 28-May-24	Related CR: 2024141043	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Breast ablation	Approved as Requested	Proposed PT	
To SMQ	Breast tumours of unspecified malignancy (SMQ)		Breast ablation	10090883
Term scope	Narrow		To SMQ	
			Breast tumours of unspecified malignancy (SMQ)	20000199
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	

**MSSO Comment:** The proposal to add PT Breast ablation to Breast tumours of unspecified malignancy (SMQ) as a Narrow term is approved as requested. Ablative techniques used in breast cancer are cryoablation, radiofrequency ablation, microwave ablation, high-intensity focused ultrasound, and laser ablation. Breast ablation will be added in line with other therapeutic procedures to the narrow scope of Breast tumours of unspecified malignancy (SMQ)

CR Number: 2024141044		Implementation Date: 28-May-24	Related CR: 2024141044	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Intestinal neoplasm surgery	Approved as Requested	Proposed PT	
To SMQ	Malignancy related therapeutic and diagnostic procedures (SMQ)		Intestinal neoplasm surgery	10091049
Term scope	Narrow		To SMQ	
			Malignancy related therapeutic and diagnostic procedures (SMQ)	20000093
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	

**MSSO Comment:** The proposal to add PT Intestinal neoplasm surgery to Malignancy related therapeutic and diagnostic procedures (SMQ) as a Narrow term is approved as requested. Surgery is one of the main treatments for small intestine cancer. In some cases, it might be the only treatment from which to expect a curative outcome of an intestinal cancer. Intestinal neoplasm surgery meets the inclusion criteria of Malignancy related therapeutic and diagnostic procedures (SMQ), which only has narrow search terms.

# Detail Report

CR Number: 2024141045		Implementation Date: 28-May-24	Related CR: 2024141045	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Pharyngo-laryngo-oesophagectomy	Approved as Requested	Proposed PT	
To SMQ	Malignancy related therapeutic and diagnostic procedures (SMQ)		Pharyngo-laryngo-oesophagectomy	10090873
Term scope	Narrow		To SMQ	
			Malignancy related therapeutic and diagnostic procedures (SMQ)	20000093
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	

**MSSO Comment:** The proposal to add PT Pharyngo-laryngo-oesophagectomy to Malignancy related therapeutic and diagnostic procedures (SMQ) as a Narrow term is approved as requested. Esophageal invasion in hypopharyngeal cancer is an uncommon lesion with a poor prognosis, in which pharyngo-laryngo-esophagectomy is the most effective treatment option. Pharyngo-laryngo-oesophagectomy is a major surgical procedure and often done as cancer surgery. Pharyngo-laryngo-oesophagectomy meets the inclusion criteria and will be added to Malignancy related therapeutic and diagnostic procedures (SMQ), which only has narrow search terms.

CR Number: 2024141046		Implementation Date: 28-May-24	Related CR: 2024141046	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Breast ablation	Approved as Requested	Proposed PT	
To SMQ	Malignancy related therapeutic and diagnostic procedures (SMQ)		Breast ablation	10090883
Term scope	Narrow		To SMQ	
			Malignancy related therapeutic and diagnostic procedures (SMQ)	20000093
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	

**MSSO Comment:** The proposal to add PT Breast ablation to Malignancy related therapeutic and diagnostic procedures (SMQ) as a Narrow term is approved as requested. Ablative techniques used in breast cancer are cryoablation, radiofrequency ablation, microwave ablation, high-intensity focused ultrasound, and laser ablation. Breast ablation will be added to Malignancy related therapeutic and diagnostic procedures (SMQ), which has only narrow search terms.

# Detail Report

CR Number: 2024141047		Implementation Date: 28-May-24	Related CR: 2024141047	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Ureter biopsy abnormal</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Malignancy related therapeutic and diagnostic procedures (SMQ)</i>		<i>Ureter biopsy abnormal</i>	10091054
Term scope	<i>Narrow</i>		To SMQ	
			<i>Malignancy related therapeutic and diagnostic procedures (SMQ)</i>	20000093
			Term scope	
			<i>Narrow</i>	
			Term_category	
			A	
			Term_weight	
			0	

**MSSO Comment:** The proposal to add PT Ureter biopsy abnormal to Malignancy related therapeutic and diagnostic procedures (SMQ) as a Narrow term is approved as requested. The term matches the inclusion criteria of the SMQ and is in alignment with other anatomically qualified biopsy terms. Ureter biopsy abnormal will be added to Malignancy related therapeutic and diagnostic procedures (SMQ), which has only narrow search terms.

CR Number: 2024141048		Implementation Date: 28-May-24	Related CR: 2024141048	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Atypical Stevens-Johnson syndrome</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Drug reaction with eosinophilia and systemic symptoms syndrome (SMQ)</i>		<i>Atypical Stevens-Johnson syndrome</i>	10091034
Term scope	<i>Broad</i>		To SMQ	
			<i>Drug reaction with eosinophilia and systemic symptoms syndrome (SMQ)</i>	20000225
			Term scope	
			<i>Broad</i>	
			Term_category	
			B	
			Term_weight	
			0	

**MSSO Comment:** The proposal to add PT Atypical Stevens-Johnson syndrome to Drug reaction with eosinophilia and systemic symptoms syndrome (SMQ) as a Broad term is approved as requested. This term fits the inclusion criteria for this SMQ. Similar terms such as PT AGEP-DRESS overlap and PT SJS-TEN overlap are already included as broad scope terms. The syndrome is often seen in childhood associated with infective pathogens as well as certain drugs.

# Detail Report

CR Number: 2024141049		Implementation Date: 28-May-24	Related CR: 2024141049	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Immune-mediated mucositis	Approved as Requested	Proposed PT	
To SMQ	Drug reaction with eosinophilia and systemic symptoms syndrome (SMQ)		Immune-mediated mucositis	10090972
Term scope	Broad		To SMQ	
			Drug reaction with eosinophilia and systemic symptoms syndrome (SMQ)	20000225
			Term scope	
			Broad	
			Term_category	
			B	
			Term_weight	
			0	
MSSO Comment:	The proposal to add PT Immune-mediated mucositis to Drug reaction with eosinophilia and systemic symptoms syndrome (SMQ) as a Broad term is approved as requested. This term fits the inclusion criteria for this SMQ. Similar terms such as PT Immune-mediated dermatitis and PT Mucosal exfoliation are already included as broad scope terms.			

CR Number: 2024141050		Implementation Date: 28-May-24	Related CR: 2024141050	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Immune-mediated proctitis	Approved as Requested	Proposed PT	
To SMQ	Drug reaction with eosinophilia and systemic symptoms syndrome (SMQ)		Immune-mediated proctitis	10090982
Term scope	Broad		To SMQ	
			Drug reaction with eosinophilia and systemic symptoms syndrome (SMQ)	20000225
			Term scope	
			Broad	
			Term_category	
			B	
			Term_weight	
			0	
MSSO Comment:	The proposal to add PT Immune-mediated proctitis to Drug reaction with eosinophilia and systemic symptoms syndrome (SMQ) as a Broad term is approved as requested. This term fits the inclusion criteria for this SMQ. Similar terms such as PT Anal blister and PT Immune-mediated polyserositis are already included as broad scope terms.			

# Detail Report

<b>CR Number:</b> 2024141051		<b>Implementation Date:</b> 28-May-24	<b>Related CR:</b> 2024141051	
<u>Change Requested</u>	Add term to SMQ	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Hypothyroid cardiomyopathy</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Cardiomyopathy (SMQ)</i>		<i>Hypothyroid cardiomyopathy</i>	10090970
Term scope	<i>Narrow</i>		To SMQ	
			<i>Cardiomyopathy (SMQ)</i>	20000150
			Term scope	
			<i>Narrow</i>	
			Term_category	
			A	
			Term_weight	
			0	

**MSSO** The proposal to add PT Hypothyroid cardiomyopathy to Cardiomyopathy (SMQ) as a Narrow term is approved as requested. The PT Hypothyroid cardiomyopathy was  
**Comment:** added in v27.1 and will be included in this SMQ under the narrow scope in alignment with inclusion criteria for PTs containing "cardiomyopathy".

<b>CR Number:</b> 2024141052		<b>Implementation Date:</b> 28-May-24	<b>Related CR:</b> 2024141052	
<u>Change Requested</u>	Add term to SMQ	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Coronary slow flow phenomenon</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Other ischaemic heart disease (SMQ)</i>		<i>Coronary slow flow phenomenon</i>	10090933
Term scope	<i>Narrow</i>		To SMQ	
			<i>Other ischaemic heart disease (SMQ)</i>	20000168
			Term scope	
			<i>Narrow</i>	
			Term_category	
			A	
			Term_weight	
			0	

**MSSO** The proposal to add PT Coronary slow flow phenomenon to Other ischaemic heart disease (SMQ) as a Narrow term is approved as requested. The PT Coronary slow flow  
**Comment:** phenomenon was added in version 27.1 which is primarily seen during percutaneous coronary intervention in the setting of acute myocardial infarction. PT Coronary slow flow phenomenon will be added under Narrow scope in alignment with the existing PT Coronary no-reflow phenomenon.

# Detail Report

CR Number: 2024141053		Implementation Date: 28-May-24	Related CR: 2024141053	
<u>Change Requested</u>	Add term to SMQ	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Ileocecal valve lipoma</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Lipodystrophy (SMQ)</i>		<i>Ileocecal valve lipoma</i>	10090992 Current
Term scope	<i>Broad</i>		To SMQ	
			<i>Lipodystrophy (SMQ)</i>	20000177
			Term scope	
			<i>Broad</i>	
			Term_category	
			A	
			Term_weight	
			0	

**MSSO Comment:** The proposal to add PT Ileocecal valve lipoma to Lipodystrophy (SMQ) as a Broad term is approved as requested. The PT Ileocecal valve lipoma was added in v27.1 and is characterized by a diffuse infiltration of fatty tissue, most often in the submucous layer. PT Ileocecal valve lipoma will be added under broad scope in alignment with existing PTs such as Lipoma, Pleural lipoma and Lipoma of breast.

CR Number: 2024141054		Implementation Date: 28-May-24	Related CR: 2024141054	
<u>Change Requested</u>	Add term to SMQ	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Endometriosis surgical removal</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Fertility disorders (SMQ)</i>		<i>Endometriosis surgical removal</i>	10090975
Term scope	<i>Narrow</i>		To SMQ	
			<i>Fertility disorders (SMQ)</i>	20000210
			Term scope	
			<i>Narrow</i>	
			Term_category	
			A	
			Term_weight	
			0	

**MSSO Comment:** The proposal to add PT Endometriosis surgical removal to Fertility disorders (SMQ) as a Narrow term is approved as requested. This term fits the inclusion criteria for this SMQ. Similar term such as PT Endometrial scratching is already included as a narrow scope term. Endometriosis surgery (most often laparoscopic) aims to treat the structural causes of pain, infertility and other symptoms.

# Detail Report

CR Number: 2024141055		Implementation Date: 28-May-24	Related CR: 2024141055	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Exposed to maternal infection in utero	Approved as Requested	Proposed PT	
To SMQ	Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (SMQ)		Exposed to maternal infection in utero	10090881
Term scope	Narrow		To SMQ	
			Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (SMQ)	20000186
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	

**MSSO Comment:** The proposal to add PT Exposed to maternal infection in utero to Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (SMQ) as a Narrow term is approved as requested. This term fits the inclusion criteria for this SMQ which includes terms for conditions that increase the risk of pregnancy complication. Similar term such as PT Intrauterine infection is already included as a narrow scope term.

CR Number: 2024141056		Implementation Date: 28-May-24	Related CR: 2024141056	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Myelodysplastic syndrome/myeloproliferative neoplasm overlap syndrome	Approved as Requested	Proposed PT	
To SMQ	Blood premalignant disorders (SMQ)		Myelodysplastic syndrome/myeloproliferative neoplasm overlap syndrome	10090858
Term scope	Narrow		To SMQ	
			Blood premalignant disorders (SMQ)	20000086
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	

**MSSO Comment:** The proposal to add PT Myelodysplastic syndrome/myeloproliferative neoplasm overlap syndrome to Blood premalignant disorders (SMQ) as a Narrow term is approved as requested. Myelodysplastic syndrome/myeloproliferative neoplasm (MDS/MPN) overlap syndrome represents a chronic clonal myeloid malignancy in which there are features of both MDS and MPN at the time of presentation. Myelodysplastic syndrome/myeloproliferative neoplasm overlap syndrome matches the inclusion criteria and will be added to Blood premalignant disorders (SMQ), which has only narrow search terms.

# Detail Report

CR Number: 2024141057		Implementation Date: 28-May-24	Related CR: 2024141057	
<u>Change Requested</u>	Add term to SMQ	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Salivary stasis	Approved as Requested	Proposed PT	
To SMQ	Dehydration (SMQ)		Salivary stasis	10090924
Term scope	Broad		To SMQ	
			Dehydration (SMQ)	20000232
			Term scope	
		Broad		
		Term_category		
		A		
		Term_weight		
		0		

MSSO      The proposal to add PT Salivary stasis to Dehydration (SMQ) as a Broad term is approved as requested. This term fits the inclusion criteria for this SMQ. Similar terms  
Comment: such as PT Salivary hyosecretion and PT Dry mouth are already included as broad scope terms.

CR Number: 2024141058		Implementation Date: 28-May-24	Related CR: 2024141058	
<u>Change Requested</u>	Add term to SMQ	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Actinomyces bacteriaemia</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Opportunistic infections (SMQ)</i>		<i>Actinomyces bacteriaemia</i>	10091066
Term scope	<i>Narrow</i>		To SMQ	
			<i>Opportunistic infections (SMQ)</i>	20000235
			Term scope	
		<i>Narrow</i>		
		Term_category		
		<i>A</i>		
		Term_weight		
		<i>0</i>		

MSSO      The proposal to add PT Actinomyces bacteriaemia to Opportunistic infections (SMQ) as a Narrow term is approved as requested. Hematogenous dissemination is  
Comment: frequently the previous step to generalized infection, which occurs much more frequently in the immunosuppressed individual.



# Detail Report

CR Number: 2024141059		Implementation Date: 28-May-24	Related CR: 2024141059	
<u>Change Requested</u>	Add term to SMQ	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Disseminated Escherichia infection</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Opportunistic infections (SMQ)</i>		<i>Disseminated Escherichia infection</i>	10090996
Term scope	<i>Narrow</i>		To SMQ	
			<i>Opportunistic infections (SMQ)</i>	20000235
			Term scope	
			<i>Narrow</i>	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Disseminated Escherichia infection to Opportunistic infections (SMQ) as a Narrow term is approved as requested. While most strains of E. coli are harmless, in unusual circumstances some can cause serious illness, particularly if they enter the bloodstream or infect other tissues. Dissemination of infectious diseases as well as sepsis terms are generally in the narrow scope of this SMQ.

CR Number: 2024141060		Implementation Date: 28-May-24	Related CR: 2024141060	
<u>Change Requested</u>	Add term to SMQ	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Immune-mediated mucositis</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Immune-mediated/autoimmune disorders (SMQ)</i>		<i>Immune-mediated mucositis</i>	10090972
Term scope	<i>Narrow</i>		To SMQ	
			<i>Immune-mediated/autoimmune disorders (SMQ)</i>	20000236
			Term scope	
			<i>Narrow</i>	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Immune-mediated mucositis to Immune-mediated/autoimmune disorders (SMQ) as a Narrow term is approved as requested. Immune mediated mucositis refers to mucositis in patients treated with immunotherapeutic agents, which might stimulate an immune response leading to immune-mediated adverse events. Terms referring to immune-mediated and autoimmune disorders which may potentially be associated with immunotherapeutic agents or vaccines are added to the narrow scope of this SMQ.

# Detail Report

CR Number: 2024141061		Implementation Date: 28-May-24	Related CR: 2024141061	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Immune-mediated proctitis</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Immune-mediated/autoimmune disorders (SMQ)</i>		<i>Immune-mediated proctitis</i>	10090982
Term scope	<i>Narrow</i>		To SMQ	
			<i>Immune-mediated/autoimmune disorders (SMQ)</i>	20000236
			Term scope	
			<i>Narrow</i>	
			Term_category	
			A	
			Term_weight	
			0	
MSSO Comment:	The proposal to add PT Immune-mediated proctitis to Immune-mediated/autoimmune disorders (SMQ) as a Narrow term is approved as requested. Patients with immune checkpoint inhibitor colitis and proctitis present frequently with diarrhea. In those with more severe disease, diarrhea may be associated with cramping abdominal pain, urgency, and rectal bleeding. Terms referring to immune-mediated and autoimmune disorders which may potentially be associated with immunotherapeutic agents or vaccines are included in the narrow scope of this SMQ.			

CR Number: 2024141062		Implementation Date: 28-May-24	Related CR: 2024141062	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Adrenal antibody test positive</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Immune-mediated/autoimmune disorders (SMQ)</i>		<i>Adrenal antibody test positive</i>	10090927
Term scope	<i>Broad</i>		To SMQ	
			<i>Immune-mediated/autoimmune disorders (SMQ)</i>	20000236
			Term scope	
			<i>Broad</i>	
			Term_category	
			A	
			Term_weight	
			0	
MSSO Comment:	The proposal to add PT Adrenal antibody test positive to Immune-mediated/autoimmune disorders (SMQ) as a Broad term is approved as requested. Adrenal antibodies are serum antibodies to adrenal cortical cells, usually of all three zones, and are seen in 60% of patients with idiopathic Addison disease. Relevant investigation terms for immune-mediated processes including autoantibodies and immune response proteins are included as broad scope terms.			

# Detail Report

CR Number: 2024141063		Implementation Date: 28-May-24	Related CR: 2024141063	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Atypical Stevens-Johnson syndrome</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Immune-mediated/autoimmune disorders (SMQ)</i>		<i>Atypical Stevens-Johnson syndrome</i>	10091034
Term scope	<i>Broad</i>		To SMQ	
			<i>Immune-mediated/autoimmune disorders (SMQ)</i>	20000236
			Term scope	
			<i>Broad</i>	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Atypical Stevens-Johnson syndrome to Immune-mediated/autoimmune disorders (SMQ) as a Broad term is approved as requested. Atypical Stevens-Johnson syndrome (SJS) is a rare variation of SJS with a complete absence of or only a few cutaneous manifestations. It is usually seen in children infected by M. pneumoniae. Like the classical form of this syndrome, this term will be added to the broad scope of the SMQ.

CR Number: 2024141064		Implementation Date: 28-May-24	Related CR: 2024141064	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Anticholinergic effect</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Anticholinergic syndrome (SMQ)</i>		<i>Anticholinergic effect</i>	10090930
Term scope	<i>Broad</i>		To SMQ	
			<i>Anticholinergic syndrome (SMQ)</i>	20000048
			Term scope	
			<i>Broad</i>	
			Term_category	
			B	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Anticholinergic effect to Anticholinergic syndrome (SMQ) as a Broad term is approved as requested. This term fits the inclusion criteria for this SMQ. Similar terms such as PT Autonomic nervous system imbalance and PT Slow response to stimuli are already included as broad scope terms.

# Detail Report

CR Number: 2024141065		Implementation Date: 28-May-24	Related CR: 2024141065	
<u>Change Requested</u>	Add term to SMQ	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Actinomyces bacteraemia</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Sepsis (SMQ)</i>		<i>Actinomyces bacteraemia</i>	10091066
Term scope	<i>Broad</i>		To SMQ	
			<i>Sepsis (SMQ)</i>	20000234
			Term scope	
			<i>Broad</i>	
			Term_category	
			A	
			Term_weight	
			0	

MSSO      The proposal to add PT Actinomyces bacteraemia to Sepsis (SMQ) as a Broad term is approved as requested. This term fits the inclusion criteria for this SMQ. Similar  
Comment: terms such as PT Serratia bacteraemia and PT Escherichia bacteraemia are already included as broad scope terms.

CR Number: 2024141066		Implementation Date: 28-May-24	Related CR: 2024141066	
<u>Change Requested</u>	Add term to SMQ	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Disseminated Escherichia infection</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Sepsis (SMQ)</i>		<i>Disseminated Escherichia infection</i>	10090996
Term scope	<i>Broad</i>		To SMQ	
			<i>Sepsis (SMQ)</i>	20000234
			Term scope	
			<i>Broad</i>	
			Term_category	
			A	
			Term_weight	
			0	

MSSO      The proposal to add PT Disseminated Escherichia infection to Sepsis (SMQ) as a Broad term is approved as requested. This term fits the inclusion criteria for this SMQ.  
Comment: Similar terms such as PT Disseminated enteroviral infection and PT Disseminated mycobacterium avium complex infection are already included as broad scope terms.

# Detail Report

CR Number: 2024141067		Implementation Date: 28-May-24	Related CR: 2024141067	
<u>Change Requested</u>	Add term to SMQ	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Chronic kidney disease-associated pruritus	Approved as Requested	Proposed PT	
To SMQ	Chronic kidney disease (SMQ)		Chronic kidney disease-associated pruritus	10091062
Term scope	Narrow		To SMQ	
			Chronic kidney disease (SMQ)	20000213
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	

**MSSO Comment:** The proposal to add PT Chronic kidney disease-associated pruritus to Chronic kidney disease (SMQ) as a Narrow term is approved as requested. This term fits the inclusion criteria for this SMQ which includes terms related to the definition including signs and symptoms and long term consequences of chronic kidney disease. Similar term such as PT Chronic kidney disease-mineral and bone disorder is already included as narrow scope term.

CR Number: 2024141068		Implementation Date: 28-May-24	Related CR: 2024141068	
<u>Change Requested</u>	Add term to SMQ	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Metabolic dysfunction-associated steatohepatitis	Approved as Requested	Proposed PT	
To SMQ	Hepatic failure, fibrosis and cirrhosis and other liver damage-related conditions (SMQ)		Metabolic dysfunction-associated steatohepatitis	10090856
Term scope	Narrow		To SMQ	
			Hepatic failure, fibrosis and cirrhosis and other liver damage-related conditions (SMQ)	20000013
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	

**MSSO Comment:** The proposal to add PT Metabolic dysfunction-associated steatohepatitis to Hepatic failure, fibrosis and cirrhosis and other liver damage-related conditions (SMQ) as a Narrow term is approved as requested. After discussion with checkmate, we decided to finally add Metabolic dysfunction-associated steatohepatitis (MASH) which is defined as the presence of fat leading to lipotoxicity and inflammatory damage to hepatocytes. Differentiating simple steatosis from MASH can be difficult without a liver biopsy, and elevated liver enzymes are not a sensitive predictor for identifying MASH. Metabolic dysfunction-associated steatohepatitis is the most updated designation of the former PT Non-alcoholic steatohepatitis (with which it was swapped) and thus will be added to the narrow scope of this SMQ.

# Detail Report

CR Number: 2024141069		Implementation Date: 28-May-24	Related CR: 2024141069		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed PT	Metabolic dysfunction-associated steatohepatitis	Approved as Requested	Proposed PT		
To SMQ	Hepatitis, non-infectious (SMQ)		Metabolic dysfunction-associated steatohepatitis		10090856
Term scope	Narrow		To SMQ		
			Hepatitis, non-infectious (SMQ)		20000010
			Term scope		
			Narrow		
			Term_category		
			A		
			Term_weight		
			0		

**MSSO Comment:** The proposal to add PT Metabolic dysfunction-associated steatohepatitis to Hepatitis, non-infectious (SMQ) as a Narrow term is approved as requested. After discussion with checkmate, we decided to finally add Metabolic dysfunction-associated steatohepatitis (MASH) which is defined as the presence of fat leading to lipotoxicity and inflammatory damage to hepatocytes. Differentiating simple steatosis from MASH can be difficult without a liver biopsy, and elevated liver enzymes are not a sensitive predictor for identifying MASH. Metabolic dysfunction-associated steatohepatitis is the most updated designation of the former PT Non-alcoholic steatohepatitis (with which it was swapped) and thus will be added to the narrow scope of this SMQ.

CR Number: 2024141070		Implementation Date: 28-May-24	Related CR: 2024141070		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed PT	Hepatic vascular fistula	Approved as Requested	Proposed PT		
To SMQ	Hepatic failure, fibrosis and cirrhosis and other liver damage-related conditions (SMQ)		Hepatic vascular fistula		10090988
Term scope	Broad		To SMQ		
			Hepatic failure, fibrosis and cirrhosis and other liver damage-related conditions (SMQ)		20000013
			Term scope		
			Broad		
			Term_category		
			A		
			Term_weight		
			0		

**MSSO Comment:** The proposal to add PT Hepatic vascular fistula to Hepatic failure, fibrosis and cirrhosis and other liver damage-related conditions (SMQ) as a Broad term is approved as requested. After discussion with checkmate, we decided to finally add this term in the broad scope. Not only Intrahepatic portal hepatic venous fistula (the demoted LLT) but also other types of Hepatic vascular fistula (new PT), such as hepatic arterioportal fistulas are commonly caused by hepatocellular carcinoma and/or cirrhosis. Therefore the new PT should "inherit" the link to this SMQ "brought by" the demoted LLT Intrahepatic portal hepatic venous fistula.

# Detail Report

CR Number: 2024141071		Implementation Date: 28-May-24	Related CR: 2024141071	
<u>Change Requested</u>	Update MedDRA term_scope	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Gottron's papules</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Immune-mediated/autoimmune disorders (SMQ)</i>		<i>Gottron's papules</i>	10056954
Term scope	<i>Broad</i>		To SMQ	
			<i>Immune-mediated/autoimmune disorders (SMQ)</i>	20000236
			Term scope	
			<i>Broad</i>	

**MSSO Comment:** The proposal to change the scope of the PT Gottron's papules in Immune-mediated/autoimmune disorders (SMQ) to Broad is approved as requested. Though not entirely pathognomonic, Gottron's papules have a very strong correlation with dermatomyositis, an immune condition in the narrow reach from which Gottron's papules has been promoted. However, being a sign as it is, it will be better placed in the broad scope of the SMQ and thus moved accordingly.

CR Number: 2024141072		Implementation Date: 28-May-24	Related CR: 2024141072	
<u>Change Requested</u>	Add term to SMQ	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Chronic prostatitis/chronic pelvic pain syndrome</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Sexual dysfunction (SMQ)</i>		<i>Chronic prostatitis/chronic pelvic pain syndrome</i>	10091051
Term scope	<i>Broad</i>		To SMQ	
			<i>Sexual dysfunction (SMQ)</i>	20000238
			Term scope	
			<i>Broad</i>	
			Term_category	
			<i>A</i>	
			Term_weight	
			<i>0</i>	

**MSSO Comment:** The proposal to add PT Chronic prostatitis/chronic pelvic pain syndrome to Sexual dysfunction (SMQ) as a Broad term is approved as requested. As proposed by checkmate, Chronic prostatitis/chronic pelvic pain syndrome (CP/CPPS) is a clinical syndrome in males defined by pain or discomfort in the pelvic region, often accompanied by urologic symptoms or sexual dysfunction. The LLT Chronic pelvic pain syndrome is already in the broad scope of this SMQ though PT Pelvic pain. Therefore, this term will be added to the broad scope too.

# Detail Report

CR Number: 2024141073		Implementation Date: 28-May-24	Related CR: 2024141073	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Immune-mediated proctitis</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Noninfectious diarrhoea (SMQ)</i>		<i>Immune-mediated proctitis</i>	10090982
Term scope	<i>Broad</i>		To SMQ	
			<i>Noninfectious diarrhoea (SMQ)</i>	20000218
			Term scope	
			<i>Broad</i>	
			Term_category	
			A	
			Term_weight	
			0	

**MSSO Comment:** The proposal to add PT Immune-mediated proctitis to Noninfectious diarrhoea (SMQ) as a Broad term is approved as requested. As suggested by checkmate, patients with immune checkpoint inhibitor colitis and proctitis present frequently with diarrhea. In those with more severe disease, diarrhea may be associated with cramping abdominal pain, urgency, and rectal bleeding. Terms referring to immune-mediated and autoimmune disorders which may potentially be associated with immunotherapeutic agents or vaccines are included in the broad scope of this SMQ.

CR Number: 2024141074		Implementation Date: 28-May-24	Related CR: 2024141074	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Pentastomiasis</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Infective pneumonia (SMQ)</i>		<i>Pentastomiasis</i>	10090919
Term scope	<i>Broad</i>		To SMQ	
			<i>Infective pneumonia (SMQ)</i>	20000231
			Term scope	
			<i>Broad</i>	
			Term_category	
			A	
			Term_weight	
			0	

**MSSO Comment:** The proposal to add PT Pentastomiasis to Infective pneumonia (SMQ) as a Broad term is approved as requested. This terms fits the inclusion criteria for a broad scope term, for other pathogens that may be associated with pneumonia.



# Detail Report

CR Number: 2024141075		Implementation Date: 28-May-24	Related CR: 2024141075	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Tracheal aspirate culture positive	Approved as Requested	Proposed PT	
To SMQ	Infective pneumonia (SMQ)		Tracheal aspirate culture positive	10091047
Term scope	Broad		To SMQ	
			Infective pneumonia (SMQ)	20000231
			Term scope	
			Broad	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Tracheal aspirate culture positive to Infective pneumonia (SMQ) as a Broad term is approved as requested. This term fits the inclusion criteria for this SMQ for investigation terms closely related to infective pneumonia. Similar PT Aspiration tracheal abnormal is already included as a broad scope term.

CR Number: 2024141077		Implementation Date: 24-May-24	Related CR: 2024141077	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	Damp heat syndrome	Rejected		

MSSO Comment: The proposal to add a new term Damp heat syndrome is not approved. Damp heat syndrome is a concept used only in traditional Chinese medicine. Traditional Chinese medicine terms are not in the scope of MedDRA.

CR Number: 2024142000		Implementation Date: 24-May-24	Related CR: 2024142000	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	Comedonecrosis	Approved as Requested	Proposed LLT	
			Comedonecrosis	10091184 Current
			To PT	
			Necrosis	10028851

MSSO Comment: The proposal to add a new term Comedonecrosis is approved as requested. Comedonecrosis is an accumulation of a necrotic cells leftover with the subsequent attraction of other organic substances. This residual material often attracts calcium from the blood and can form calcium deposits which are visible in imaging tests, which is sometimes indication of the presence of cancer. Comedonecrosis will be added as an LLT to PT Necrosis.

# Detail Report

CR Number: 2024142001		Implementation Date: 24-May-24	Related CR: 2024142001	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	Mucosal schwann cell hamartomas	Approved Not as Requested	Proposed PT	
			Mucosal Schwann cell hamartoma	10091179
			HLT primary	
			Nervous system neoplasms benign NEC	10029210
			SOC primary	
			Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10029104
			HLT secondary	
			Nervous system neoplasms benign NEC	10029210
			SOC secondary	
			Nervous system disorders	10029205
MSSO Comment:	The proposal to add a new term Mucosal schwann cell hamartomas is approved but not as requested. Mucosal Schwann cell hamartomas are a group of neuronal polyps purely composed of S-100–positive Schwann cells which can be found incidentally during routine colonoscopy and for which there are currently no relation to inherited syndromes or malignancies. The proposed term will be modified in accordance with MedDRA capitalization conventions and added as PT Mucosal Schwann cell hamartoma to bi-axial HLT Nervous system neoplasms benign NEC (primary SOC Neoplasms benign, malignant and unspecified (incl cysts and polyps) and to secondary SOC Nervous system disorders) and secondary HLT Benign neoplasms gastrointestinal (excl oral cavity).			

CR Number: 2024145053		Implementation Date: 24-May-24	Related CR: 2024142001	
<a href="#">Change Requested</a>	Link a PT to a HLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Mucosal Schwann cell hamartoma	Approved as Requested	Proposed PT	
To HLT	Benign neoplasms gastrointestinal (excl oral cavity)		Mucosal Schwann cell hamartoma	10091179
			To HLT	
			Benign neoplasms gastrointestinal (excl oral cavity)	10017988
MSSO Comment:				

# Detail Report

<b>CR Number:</b> 2024142002		<b>Implementation Date:</b> 24-May-24	<b>Related CR:</b> 2024142002	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Knee subchondroplasty</i>	Approved as Requested	Proposed PT <i>Knee subchondroplasty</i>	10091180
			HLT primary <i>Bone therapeutic procedures NEC</i>	10006000
			SOC primary <i>Surgical and medical procedures</i>	10042613

**MSSO Comment:** The proposal to add a new term Knee subchondroplasty is approved as requested. Knee subchondroplasty is a minimally invasive technique to apply a synthetic bone substitute (calcium phosphate-based) into the bone marrow lesions to reduce pain, improve function and delay the need for a knee replacement in the following years. Knee subchondroplasty will be added as a PT to the HLT Bone therapeutic procedures NEC.

<b>CR Number:</b> 2024142003		<b>Implementation Date:</b> 24-May-24	<b>Related CR:</b> 2024142003	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Bobble-head doll syndrome</i>	Approved as Requested	Proposed PT <i>Bobble-head doll syndrome</i>	10091182
			HLT primary <i>Dyskinesias and movement disorders NEC</i>	10013929
			SOC primary <i>Nervous system disorders</i>	10029205

**MSSO Comment:** The proposal to add a new term Bobble-head doll syndrome is approved as requested. The bobble head doll syndrome is a rare neurological disorder characterized by repetitive and involuntary movement of the head that typically appears in childhood. It is usually associated with the dilatation of the third ventricle and one or more cystic lesions that can be treated surgically. Bobble-head doll syndrome will be added as PT to the HLT Dyskinesias and movement disorders NEC.

# Detail Report

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<b>CR Number:</b> 2024142004		<b>Implementation Date:</b> 24-May-24	<b>Related CR:</b> 2024142004	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Cystatin C decreased</i>	Approved as Requested	Proposed PT <i>Cystatin C decreased</i>	10091183
			HLT primary <i>Renal function analyses</i>	10038454
			SOC primary <i>Investigations</i>	10022891

**MSSO Comment:** The proposal to add a new term Cystatin C decreased is approved as requested. Cystatin C is a useful marker of acute kidney injury which may detect it 1 or 2 days earlier than serum creatinine. Cystatin C decreased will be added as PT to the HLT Renal function analyses, representing a missing qualified outcome of Cystatin C test.

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<b>CR Number:</b> 2024142005		<b>Implementation Date:</b> 24-May-24	<b>Related CR:</b> 2024142005	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Dysfunctional tear syndrome</i>	Approved as Requested	Proposed PT <i>Dysfunctional tear syndrome</i>	10091181
			HLT primary <i>Lacrimation disorders</i>	10072989
			SOC primary <i>Eye disorders</i>	10015919

**MSSO Comment:** The proposal to add a new term Dysfunctional tear syndrome is approved as requested. Dysfunctional tear syndrome represents any alteration in the quantity and/or quality of the tear film. It is a chronic condition with multiple subtypes that include dry eye disease and associated tear film disorders. Dysfunctional tear syndrome will be added as a PT to HLT Lacrimation disorders.

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<b>CR Number:</b> 2024142013		<b>Implementation Date:</b> 24-May-24	<b>Related CR:</b> 2024142013	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Monorhinal</i>	Rejected		

**MSSO Comment:** The proposal to add a new LLT Monorhinal is not approved. Proposed term is generally an adjective meaning using or having one nasal orifice. Please provide context for the use of this term either as an anomaly or in relation to a disorder.

# Detail Report

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<b>CR Number:</b> 2024142014	<b>Implementation Date:</b> 24-May-24	<b>Related CR:</b> 2024142014	<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>
Proposed Term	<i>Split tongue procedure</i>	Rejected	

**MSSO Comment:** The proposal to add a new term Split tongue procedure is not approved. The proposed concept is never a therapeutic procedure (like other plastic surgeries, which could be both cosmetic and therapeutic). The proposed concept may be represented by existing LLT Deliberate tongue bifurcation represented under PT Body modification in SOC Social circumstances.

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<b>CR Number:</b> 2024142015	<b>Implementation Date:</b> 24-May-24	<b>Related CR:</b> 2024142015	<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>
Proposed Term	<i>Phlegmon of toe</i>	Rejected	

**MSSO Comment:** The proposal to add a new term Phlegmon of toe is not approved. To avoid the overpopulation of MedDRA, it is not possible to add an anatomically qualified term including phlegmon. Please consider using the existing synonym cellulitis with existing anatomic qualifiers.

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<b>CR Number:</b> 2024142016	<b>Implementation Date:</b> 24-May-24	<b>Related CR:</b> 2024142016	<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>
Proposed LLT	<i>Near miss</i>	Rejected	
To PT	<i>Intercepted medication error</i>		

**MSSO Comment:** The proposal to add a new LLT Near miss to PT Intercepted medication error is not approved. In the healthcare setting a near miss is an event that could have resulted in patient harm but did not, either by chance or through timely intervention. Near miss can be used in contexts other than medication errors, such as surgical errors or errors in transfusion medicine, patient identification and others. Limiting the term to medication errors could be misleading.

# Detail Report

<b>CR Number:</b> 2024142017		<b>Implementation Date:</b> 24-May-24	<b>Related CR:</b> 2024142017		
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed LLT	<i>Near miss during product dispensing</i>	Rejected			
To PT	<i>Intercepted product dispensing error</i>				
<b>MSSO Comment:</b> The proposal to add a new LLT Near miss during product dispensing to PT Intercepted product dispensing error is not approved. The proposed term is colloquial and somewhat ambiguous. The more precise existing "intercepted" term is more appropriate.					

<b>CR Number:</b> 2024142018		<b>Implementation Date:</b> 24-May-24	<b>Related CR:</b> 2024142018		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed LLT	<i>Near miss in product prescribing</i>	Rejected			
To PT	<i>Intercepted product prescribing error</i>				
<b>MSSO Comment:</b> The proposal to add a new LLT <i>Near miss in product prescribing</i> to PT <i>Intercepted product prescribing error</i> is not approved. The proposed term is colloquial and somewhat ambiguous. The more precise existing "intercepted" term is more appropriate.					

<b>CR Number:</b> 2024142022		<b>Implementation Date:</b> 28-May-24	<b>Related CR:</b> 2024142022		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Promote an LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed LLT	<i>Non-proliferative diabetic retinopathy</i>	Rejected			
From PT	<i>Diabetic retinopathy</i>				
<b>MSSO Comment:</b> The proposal to promote the LLT Non-proliferative diabetic retinopathy from PT Diabetic retinopathy is not approved. Non-proliferative diabetic retinopathy is the early stage of the disease and is less severe. The degree of severity is generally presented in MedDRA at the LLT level. Promoting the LLT would create two closely related concepts at PT level which may result in signal dilution. Although the main analyses are conducted on PT level, in case of need the analysis will need to be conducted on LLT level. Internal data management conventions of one's organization may help to standardize the use of related retinopathy concepts and provide coding consistency. In a related change, four LLTs will be moved from PT Diabetic retinopathy to PT Non-proliferative retinopathy: LLT Background retinopathy, unspecified; LLT Retinopathy background; LLT Simple retinopathy; and non-current LLT Other background retinopathy and retinal vascular changes.					

# Detail Report

CR Number: 2024149092		Implementation Date: 28-May-24	Related CR: 2024142022	
<a href="#">Change Requested</a>	Link (move) an LLT to another PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Simple retinopathy	Approved as Requested	Proposed LLT	10067460 Current
From PT	Diabetic retinopathy		Simple retinopathy	
To PT	Non-proliferative retinopathy		From PT	
			Diabetic retinopathy	10012689
			To PT	
			Non-proliferative retinopathy	10081568
MSSO Comment:				

CR Number: 2024149091		Implementation Date: 28-May-24	Related CR: 2024142022	
<a href="#">Change Requested</a>	Link (move) an LLT to another PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Retinopathy background	Approved as Requested	Proposed LLT	10038924 Current
From PT	Diabetic retinopathy		Retinopathy background	
To PT	Non-proliferative retinopathy		From PT	
			Diabetic retinopathy	10012689
			To PT	
			Non-proliferative retinopathy	10081568
MSSO Comment:				

# Detail Report

CR Number: 2024149090		Implementation Date: 28-May-24	Related CR: 2024142022	
<a href="#">Change Requested</a>	Link (move) an LLT to another PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Background retinopathy, unspecified	Approved as Requested	Proposed LLT	
From PT	Diabetic retinopathy		Background retinopathy, unspecified	10003996 Current
To PT	Non-proliferative retinopathy		From PT	
			Diabetic retinopathy	10012689
			To PT	
			Non-proliferative retinopathy	10081568

MSSO  
Comment:

CR Number: 2024149093		Implementation Date: 28-May-24	Related CR: 2024142022	
<a href="#">Change Requested</a>	Link (move) an LLT to another PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Other background retinopathy and retinal vascular changes	Approved as Requested	Proposed LLT	
From PT	Diabetic retinopathy		Other background retinopathy and retinal vascular changes	10031676 Non-Current
To PT	Non-proliferative retinopathy		From PT	
			Diabetic retinopathy	10012689
			To PT	
			Non-proliferative retinopathy	10081568

MSSO  
Comment:



# Detail Report

<b>CR Number:</b> 2024142023		<b>Implementation Date:</b> 28-May-24	<b>Related CR:</b> 2024142023		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Promote an LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed LLT	<i>Proliferative diabetic retinopathy</i>	Rejected			
From PT	<i>Diabetic retinopathy</i>				

**MSSO Comment:** The proposal to promote the LLT Proliferative diabetic retinopathy from PT Diabetic retinopathy is not approved. Proliferative retinopathy is the severe form of diabetic retinopathy. The degree of severity is generally presented in MedDRA at the LLT level. Promoting the LLT would create two closely related concepts at PT level which may result in signal dilution. Although the main analyses are conducted on PT level, in case of need the analysis will need to be conducted on LLT level. Internal data management conventions of one's organization may help to standardize the use of related retinopathy concepts and provide coding consistency.

<b>CR Number:</b> 2024142024		<b>Implementation Date:</b> 28-May-24	<b>Related CR:</b> 2024142024		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Promote an LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed LLT	<i>Proliferative vitreoretinopathy</i>	Approved as Requested	Proposed LLT		
From PT	<i>Retinopathy proliferative</i>		<i>Proliferative vitreoretinopathy</i>		10057896
			From PT		
			<i>Retinopathy proliferative</i>		10038934
			HLT primary		
			<i>Retinopathies NEC</i>		10038932
			SOC primary		
			<i>Eye disorders</i>		10015919
			HLT secondary		
			<i>Ocular vascular disorders NEC</i>		10030067
			SOC secondary		
			<i>Vascular disorders</i>		10047065

**MSSO Comment:** The proposal to promote the LLT Proliferative vitreoretinopathy from PT Retinopathy proliferative is approved as requested. Proliferative vitreoretinopathy is a complication that can occur after retinal detachment or retinal surgery. It involves the growth of membranes on both surfaces of the retina and within the vitreous cavity, leading to retinal traction and potentially causing the retina to detach again. Proliferative vitreoretinopathy will be promoted from under PT Retinopathy proliferative to PT level linked to primary HLT Retinopathies NEC, to secondary HLT Ocular vascular disorders NEC and to secondary HLT Eye and ear procedural complications.

# Detail Report

<b>CR Number:</b> 2024149094		<b>Implementation Date:</b> 28-May-24	<b>Related CR:</b> 2024142024	
<a href="#">Change Requested</a>	Link a PT to a HLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Proliferative vitreoretinopathy</i>	Approved as Requested	Proposed PT	
To HLT	<i>Eye and ear procedural complications</i>		<i>Proliferative vitreoretinopathy</i>	10057896
			To HLT	
			<i>Eye and ear procedural complications</i>	10015908

MSSO  
Comment:

<b>CR Number:</b> 2024143000		<b>Implementation Date:</b> 28-May-24	<b>Related CR:</b> 2024143000	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Spinal prosthesis user</i>	Approved Not as Requested	Proposed PT	
			<i>Spinal prosthesis user</i>	10091190
			HLT primary	
			<i>Disability issues</i>	10057171
			SOC primary	
			<i>Social circumstances</i>	10041244

MSSO  
Comment: The proposal to add a new LLT Spinal prosthesis user is approved but not as requested. Development of prosthesis for the spine, generally follow two paths. One, is for the treatment of less advanced degeneration, the "nucleus prosthesis", wherein only the core of the disc is replaced, resulting in an anatomic reconstruction. The other, is for the more serious degeneration requiring complete or total disc prosthesis, wherein, in addition to the core, the fibrous ring is also removed and new joint components are implanted. Individuals with spinal cord injuries need new options for negotiating architectural barriers as well as completing many essential daily tasks. Spinal prosthesis user will be added as new PT under HLT Disability issues.

<b>CR Number:</b> 2024143001		<b>Implementation Date:</b> 28-May-24	<b>Related CR:</b> 2024143001	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Excess post-exercise oxygen consumption</i>	Rejected		

MSSO  
Comment: The proposal to add a new LLT Excess post-exercise oxygen consumption is not approved. Excess post-exercise oxygen consumption (EPOC) is the result of an elevation in oxygen consumption and metabolism (Resting Energy Expenditure), which occurs after exercise as the body recovers, repairs, and returns to its pre-exercise state. This can happen for up to 24 hours, according to some sources. This phenomenon, also known as "afterburn" is a normal physiologic process after strenuous exercise and generally normal processes are not added in MedDRA.

# Detail Report

<b>CR Number:</b> 2024143002		<b>Implementation Date:</b> 28-May-24	<b>Related CR:</b> 2024143002	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	YAG laser capsulotomy	Approved as Requested	Proposed LLT	
To PT	Posterior lens capsulotomy		YAG laser capsulotomy	10091192 Current
			To PT	
			Posterior lens capsulotomy	10073047
<b>MSSO Comment:</b>	The proposal to add a new LLT YAG laser capsulotomy to PT Posterior lens capsulotomy is approved as requested. Posterior capsulotomy (or YAG laser capsulotomy) is laser surgery sometimes needed after cataract surgery. A special laser, called the YAG laser, is used to make an opening in the posterior capsule allowing light to pass through the clouded capsule for better vision.			

<b>CR Number:</b> 2024143003		<b>Implementation Date:</b> 28-May-24	<b>Related CR:</b> 2024143003	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Arteriovenous malformation radiosurgery	Rejected		
<b>MSSO Comment:</b>	The proposal to add a new LLT Arteriovenous malformation radiosurgery is not approved. It is not possible to have a term for ever anatomic malformation and therapy term combination. This is a multiple concept term which can be coded using more than one MedDRA term. Please refer to Section 3.5 of the MedDRA Term Selection: Points to Consider Document regarding the coding of combination terms.			

<b>CR Number:</b> 2024143004		<b>Implementation Date:</b> 28-May-24	<b>Related CR:</b> 2024143004	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Encephalomyosynangiosis	Approved as Requested	Proposed LLT	
			Encephalomyosynangiosis	10091191 Current
			To PT	
			Cerebral revascularisation	10071508
<b>MSSO Comment:</b>	The proposal to add a new LLT Encephalomyosynangiosis is approved as requested. Proposed concept already exists as LLT Encephalo-myo-synangiosis under PT Cerebral revascularisation but will be added without hyphens for easier retrieval as LLT Encephalomyosynangiosis to PT Cerebral revascularisation.			

# Detail Report

<b>CR Number:</b> 2024143005		<b>Implementation Date:</b> 24-May-24	<b>Related CR:</b> 2024143005	
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Upshaw-Schulman syndrome</i>	Approved as Requested	Proposed LLT <i>Upshaw-Schulman syndrome</i>	10091188 Current
			To PT <i>Congenital thrombotic thrombocytopenic purpura</i>	10091107
<b>MSSO Comment:</b> The proposal to add a new PT Upshaw-Schulman syndrome is approved as requested. Upshaw-Schulman syndrome, also called hereditary thrombotic thrombocytopenic purpura refers to a severe deficiency of the ADAMTS13 protease due to biallelic germline pathogenic variants in the ADAMTS13 gene. ADAMTS13 activity is typically undetectable. Upshaw-Schulman syndrome will be added as the eponymous LLT to PT Congenital thrombotic thrombocytopenic purpura, added in change request 2024128005.				

<b>CR Number:</b> 2024143006		<b>Implementation Date:</b> 24-May-24	<b>Related CR:</b> 2024143006	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Monosomy X</i>	Approved as Requested	Proposed LLT <i>Monosomy X</i>	10091187 Current
To PT	<i>Turner's syndrome</i>		To PT <i>Turner's syndrome</i>	10045181
<b>MSSO Comment:</b> The proposal to add a new LLT Monosomy X to PT Turner's syndrome is approved as requested. Monosomy X is a synonym of Turner's syndrome.				

<b>CR Number:</b> 2024143007		<b>Implementation Date:</b> 24-May-24	<b>Related CR:</b> 2024143007	
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>BCR-ABL1 level decreased</i>	Approved Not as Requested	Proposed LLT <i>BCR-ABL1 level decreased</i>	10091186 Current
			To PT <i>Philadelphia chromosome negative</i>	10075645
<b>MSSO Comment:</b> The proposal to add a new PT BCR-ABL1 level decreased is approved but not as requested. Assessment of BCR-ABL1 at 3 months has been demonstrated to be the only indicator for predicting prognosis of patients with chronic myeloid leukemia. BCR-ABL1 level decreased will be added as LLT to PT Philadelphia chromosome negative, as the test result counterpart of existing LLT BCR-ABL1 level increased.				

# Detail Report

<b>CR Number:</b> 2024143008		<b>Implementation Date:</b> 24-May-24	<b>Related CR:</b> 2024143008	
<u>Change Requested</u>	Add a New PT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Vasoreactivity test	Approved as Requested	Proposed PT Vasoreactivity test	10091185
			HLT primary Vascular tests NEC (incl blood pressure)	10047110
			SOC primary Investigations	10022891

**MSSO Comment:** The proposal to add a new PT Vasoreactivity test is approved as requested. Vasoreactivity to inhaled nitric oxide with oxygen is a test which predicts long-term survival in pulmonary arterial hypertension. Vasoreactivity test will be added as a PT to the HLT Vascular tests NEC (incl blood pressure).

<b>CR Number:</b> 2024143009		<b>Implementation Date:</b> 28-May-24	<b>Related CR:</b> 2024143009	
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	CT scan guided Liver Biopsy	Approved Not as Requested	Proposed LLT CT scan-guided liver biopsy	10091193 Current
			To PT Biopsy liver	10004791

**MSSO Comment:** The proposal to add a new LLT CT scan guided Liver Biopsy is approved but not as requested. A CT scan-guided liver biopsy is a medical procedure in which a small sample of liver tissue is removed for examination under the guidance of a computed tomography scan. The proposed term will be modified for MedDRA capitalization rules and added as LLT CT scan-guided liver biopsy to PT Biopsy liver, aligned with existing LLT Ultrasound guided liver biopsy.

<b>CR Number:</b> 2024143010		<b>Implementation Date:</b> 28-May-24	<b>Related CR:</b> 2024143010	
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Anicteric hepatitis	Approved as Requested	Proposed LLT Anicteric hepatitis	10091194 Current
			To PT Hepatitis	10019717

**MSSO Comment:** The proposal to add a new LLT Anicteric hepatitis is approved as requested. Anicteric hepatitis implies the absence of clinical jaundice. Anicteric hepatitis will be added as LLT to PT Hepatitis in line with LLT Hepatitis non-icteric.

# Detail Report

CR Number: 2024143011		Implementation Date: 28-May-24	Related CR: 2024143011		
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed LLT	Intergluteal itching	Rejected			

MSSO Comment: The proposal to add a new LLT Intergluteal itching is not approved. To avoid the overpopulation of MedDRA, it is not feasible to accommodate terms relating to every possible anatomical location for pruritus.

CR Number: 2024143012		Implementation Date: 28-May-24	Related CR: 2024143012		
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed Term	Koolen-de Vries syndrome (KdVS)	Approved Not as Requested	Proposed PT Koolen-de Vries syndrome	10091195	
			HLT primary Musculoskeletal and connective tissue disorders of face, neck and jaw congenital	10028380	
			SOC primary Congenital, familial and genetic disorders	10010331	
			HLT secondary Musculoskeletal and connective tissue disorders of face, neck and jaw congenital	10028380	
			SOC secondary Musculoskeletal and connective tissue disorders	10028395	

MSSO Comment: The proposal to add a new term Koolen-de Vries syndrome (KdVS) is approved but not as requested. Koolen-de Vries syndrome, also known as 17q21.31 microdeletion syndrome, is a rare genetic disorder caused by the deletion of a small piece of chromosome 17 at the q21.31 region or mutations in the KANSL1 gene within this region. This syndrome is characterized by a variety of physical, developmental, and behavioral features. Affected individuals often have distinctive facial features. The proposed term will be modified to delete the acronym and added as new PT Koolen-de Vries syndrome to bi-axial primary HLT Musculoskeletal and connective tissue disorders of face, neck and jaw congenital (primary SOC Congenital, familial and genetic disorders and secondary SOC Musculoskeletal and connective tissue disorders) and secondary HLT Intellectual disabilities.

# Detail Report

<b>CR Number:</b> 2024149095		<b>Implementation Date:</b> 28-May-24	<b>Related CR:</b> 2024143012	
<a href="#">Change Requested</a>	Link a PT to a HLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Koolen-de Vries syndrome</i>	Approved as Requested	Proposed PT	
To HLT	<i>Intellectual disabilities</i>		<i>Koolen-de Vries syndrome</i>	10091195
			To HLT	
			<i>Intellectual disabilities</i>	10077548

MSSO  
Comment:

<b>CR Number:</b> 2024143013		<b>Implementation Date:</b> 24-May-24	<b>Related CR:</b> 2024143013	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Persistent Hyperplastic Primary Vitreous</i>	Approved Not as Requested	Proposed LLT	
			<i>Persistent hyperplastic primary vitreous</i>	10091189 Current
			To PT	
			<i>Congenital vitreous anomaly</i>	10061085

MSSO  
Comment:

The proposal to add a new LLT Persistent Hyperplastic Primary Vitreous is approved but not as requested. Anterior persistent hyperplastic primary vitreous is a rare congenital ocular anomaly characterized by the presence of fibrovascular tissue in the anterior chamber of the eye, connecting the iris and/or lens with the pupillary region. This condition results from the persistence and abnormal proliferation of embryonic primary vitreous tissue, which should normally return during fetal development. The proposed term will be modified in accordance with MedDRA capitalization conventions and added as the LLT Persistent hyperplastic primary vitreous to the PT Congenital vitreous anomaly.

<b>CR Number:</b> 2024143014		<b>Implementation Date:</b> 28-May-24	<b>Related CR:</b> 2024143014	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Head fixation</i>	Approved as Requested	Proposed PT	
			<i>Head fixation</i>	10091196
			HLT primary	
			<i>Patient positioning</i>	10075883
			SOC primary	
			<i>Surgical and medical procedures</i>	10042613

MSSO  
Comment:

The proposal to add a new term Head fixation is approved as requested. Cranial fixation or head fixation is essential for neurosurgical procedures, in which intraoperative precision depends on reference stability fixed to the patient's head. Head fixation will be added as a new PT under HLT Patient positioning.

# Detail Report

<b>CR Number:</b> 2024143015		<b>Implementation Date:</b> 28-May-24	<b>Related CR:</b> 2024143015	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Implantable cardioverter defibrillator battery change</i>	Approved Not as Requested	Proposed LLT <i>Implantable cardioverter defibrillator battery replacement</i>	10091197 Current
To PT	<i>Implantable defibrillator replacement</i>		To PT <i>Implantable defibrillator replacement</i>	10057459

**MSSO Comment:** The proposal to add a new LLT Implantable cardioverter defibrillator battery change to PT Implantable defibrillator replacement is approved but not as requested. The batteries in an Implantable cardioverter defibrillator (ICD) typically last 6 to 12 years. Replacing the ICD usually requires a simple procedure in which a repeat incision is made, the older ICD is removed, and a new ICD is implanted and joined with the existing leads. Proposed term will be modified for better alignment and added as LLT Implantable cardioverter defibrillator battery replacement under PT Implantable defibrillator replacement.

<b>CR Number:</b> 2024143017		<b>Implementation Date:</b> 29-May-24	<b>Related CR:</b> 2024143017	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Anterior choroidal artery infarction</i>	Approved as Requested	Proposed LLT <i>Anterior choroidal artery infarction</i>	10091209 Current
			To PT <i>Cerebral infarction</i>	10008118

**MSSO Comment:** The proposal to add a new LLT Anterior choroidal artery infarction is approved as requested. The anterior choroidal artery supplies several crucial anatomical structures of the brain important for vision and motor control. The clinical spectrum of anterior choroidal artery infarction is increasing and may manifest as hemiparesis, or hemianesthesia, and/or hemianopia. Anterior choroidal artery infarction will be added as sub-concept LLT to PT Cerebral infarction.

<b>CR Number:</b> 2024143018		<b>Implementation Date:</b> 28-May-24	<b>Related CR:</b> 2024143018	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Lower limb arteriosclerosis</i>	Rejected		

**MSSO Comment:** The proposal to add a new LLT Lower limb arteriosclerosis is not approved. Lower limb arteriosclerosis, also known as peripheral arterial disease, is chronic arterial occlusive disease of the lower extremities caused by atherosclerosis. The concept is already represented by LLT Obstructive arteriosclerosis of lower extremities, or any appropriate LLT under PT Peripheral arterial occlusive disease can be considered for your specific scenario.



# Detail Report

<b>CR Number:</b> 2024144001		<b>Implementation Date:</b> 28-May-24	<b>Related CR:</b> 2024144001	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Influenza A virus subtype H9N2</i>	Approved Not as Requested	Proposed LLT <i>H9N2 influenza</i>	10091199 Current
			To PT <i>Avian influenza</i>	10064097
<b>MSSO Comment:</b> The proposal to add a new LLT Influenza A virus subtype H9N2 is approved but not as requested. Most human cases of infection with avian influenza A(H9N2) viruses are exposed to the virus through contact with infected poultry or contaminated environments. Results from recent ferret research on the H9N2 subtype has demonstrated an increased theoretical threat to humans from the potential emergence of novel subtypes of avian influenza. Proposed term will be modified for better alignment as a subtype and added as LLT H9N2 influenza to PT Avian influenza.				

<b>CR Number:</b> 2024144002		<b>Implementation Date:</b> 28-May-24	<b>Related CR:</b> 2024144002	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Circulating vaccine-derived poliovirus type 2</i>	Rejected		
<b>MSSO Comment:</b> The proposal to add a new LLT Circulating vaccine-derived poliovirus type 2 is not approved. The proposed term is an epidemiological concept term, referring the spread of the vaccine-derived poliovirus in a given population. Please resubmit with clarification whether you need an investigation term or disease concept term.				

<b>CR Number:</b> 2024144003		<b>Implementation Date:</b> 28-May-24	<b>Related CR:</b> 2024144003	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Drug-resistant Shigella sonnei infection</i>	Approved Not as Requested	Proposed LLT <i>Extensively drug-resistant Shigella sonnei infection</i>	10091201 Current
			To PT <i>Shigella infection</i>	10054178
<b>MSSO Comment:</b> The proposal to add a new LLT Drug-resistant Shigella sonnei infection is approved but not as requested. The Centers for Disease Control and Prevention (CDC) has been monitoring an increase in extensively drug-resistant (XDR) Shigella infections (shigellosis) reported through national surveillance systems. Although most infections with S. sonnei result in a short duration of disease and low case fatality, multi-drug resistant (MDR) and XDR shigellosis is a public health concern since treatment options are very limited for moderate to severe cases. Proposed term will be modified to the most referenced concept in literature and added as LLT Extensively drug-resistant Shigella sonnei infection under PT Shigella infection. In a related change, Extensively drug-resistant Shigella infection will also be added as an LLT to PT Shigella infection.				

# Detail Report

<b>CR Number:</b> 2024149096		<b>Implementation Date:</b> 28-May-24	<b>Related CR:</b> 2024144003		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed LLT	<i>Extensively drug-resistant Shigella infection</i>	Approved as Requested	Proposed LLT		
To PT	<i>Shigella infection</i>		<i>Extensively drug-resistant Shigella infection</i>	10091203	Current
			To PT		
			<i>Shigella infection</i>	10054178	

MSSO  
Comment:

<b>CR Number:</b> 2024144004		<b>Implementation Date:</b> 28-May-24	<b>Related CR:</b> 2024144004		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed LLT	<i>Mayaro virus disease</i>	Approved Not as Requested	Proposed PT		
			<i>Mayaro virus disease</i>	10091198	
			HLT primary		
			<i>Arboviral infections NEC</i>	10057198	
			SOC primary		
			<i>Infections and infestations</i>	10021881	

MSSO  
Comment: The proposal to add a new LLT Mayaro virus disease is approved but not as requested. Mayaro virus is an arbovirus that is endemic to tropical forests in Central and South America, particularly within the Amazon basin. Mayaro virus is spread to people through the bite of an infected mosquito. Most people with Mayaro virus disease have mild illness. Common symptoms include fever, headache, muscle aches, joint aches, chills, and rash. Mayaro virus disease will be added as new PT under HLT Arboviral infections NEC.

<b>CR Number:</b> 2024144005		<b>Implementation Date:</b> 28-May-24	<b>Related CR:</b> 2024144005		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed LLT	<i>Guinea worm disease</i>	Approved as Requested	Proposed LLT		
To PT	<i>Dracunculiasis</i>		<i>Guinea worm disease</i>	10091202	Current
			To PT		
			<i>Dracunculiasis</i>	10013618	

MSSO  
Comment: The proposal to add a new LLT Guinea worm disease to PT Dracunculiasis is approved as requested. Dracunculiasis, also called Guinea-worm disease, is a parasitic infection by the Guinea worm, *Dracunculus medinensis*. A person becomes infected by drinking water contaminated with Guinea-worm larvae that reside inside copepods (a type of small crustacean).

# Detail Report

<b>CR Number:</b> 2024144006		<b>Implementation Date:</b> 28-May-24	<b>Related CR:</b> 2024144006	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Seoul virus infection	Approved as Requested	Proposed LLT Seoul virus infection	10091200 Current
			To PT Haemorrhagic fever with renal syndrome	10075015

**MSSO Comment:** The proposal to add a new LLT Seoul virus infection is approved as requested. Reports from several Western countries, including the United States, have described an ill-known hantavirus disease, commonly called hemorrhagic fever with renal syndrome, induced by Seoul orthohantavirus and spread by infected wild, laboratory, and pet rats. Seoul virus infection will be added as LLT under PT Haemorrhagic fever with renal syndrome.

<b>CR Number:</b> 2024144007		<b>Implementation Date:</b> 28-May-24	<b>Related CR:</b> 2024144007	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	Lacrimon apparatus syringing	Approved as Requested	Proposed PT Lacrimon apparatus syringing	10091204
			HLT primary Lacrimon apparatus therapeutic procedures	10023617
			SOC primary Surgical and medical procedures	10042613

**MSSO Comment:** The proposal to add a new term Lacrimon apparatus syringing is approved as requested. Lacrimon syringing is performed to assess the patency of the lacrimon system, flush debris from the system – which can improve epiphora symptoms - and elucidate the level of blockage where the system is found to be non-patent. Lacrimon apparatus syringing will be added as PT to the HLT Lacrimon apparatus therapeutic procedures.

<b>CR Number:</b> 2024144008		<b>Implementation Date:</b> 28-May-24	<b>Related CR:</b> 2024144008	
<a href="#">Change Requested</a>	Promote an LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Anaphylactic reaction to food	Rejected		
From PT	Anaphylactic reaction			

**MSSO Comment:** The proposal to promote the LLT Anaphylactic reaction to food from PT Anaphylactic reaction is not approved. In general, queries should be built at the PT level and/or at grouping term level. Analysis may also need to be performed at LLT level depending on the specificity of the analysis.

# Detail Report

<b>CR Number:</b> 2024144009		<b>Implementation Date:</b> 28-May-24	<b>Related CR:</b> 2024144009	
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Post-ERCP acute pancreatitis	Approved Not as Requested	Proposed LLT Post-ERCP acute pancreatitis	10091206 Current
			To PT Procedural pancreatitis	10091205
<b>MSSO Comment:</b> The proposal to add a new PT Post-ERCP acute pancreatitis is approved but not as requested. Acute pancreatitis remains the most common complication of endoscopic retrograde cholangiopancreatography. Post-ERCP acute pancreatitis will be added as an LLT to a new PT Procedural pancreatitis, which will be added, in a related change to primary HLT Acute and chronic pancreatitis and to secondary HLT Gastrointestinal and hepatobiliary procedural complications.				

<b>CR Number:</b> 2024149097		<b>Implementation Date:</b> 28-May-24	<b>Related CR:</b> 2024144009	
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Procedural pancreatitis	Approved as Requested	Proposed PT Procedural pancreatitis	10091205
HLT primary	Acute and chronic pancreatitis		HLT primary Acute and chronic pancreatitis	10033646
SOC primary	Gastrointestinal disorders		SOC primary Gastrointestinal disorders	10017947
			HLT secondary Gastrointestinal and hepatobiliary procedural complications	10017927
			SOC secondary Injury, poisoning and procedural complications	10022117

MSSO  
Comment:

# Detail Report

<b>CR Number:</b> 2024144010		<b>Implementation Date:</b> 28-May-24	<b>Related CR:</b> 2024144010	
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Human metapneumovirus infection	Approved Not as Requested	Proposed LLT	
HLT primary	Respiratory syncytial viral infections		Human metapneumovirus infection	10091207 Current
SOC primary	Infections and infestations		To PT	
			Metapneumovirus infection	10066226
<b>MSSO Comment:</b> The proposal to add a new PT Human metapneumovirus infection to primary HLT Respiratory syncytial viral infections in SOC Infections and infestations is approved but not as requested. Human metapneumovirus (HMPV) infection is a respiratory illness caused by the human metapneumovirus. It was first identified in 2001 and is known to cause respiratory tract infections primarily in children, though it can affect people of all ages. HMPV is the specific strain of metapneumovirus that infects humans. Human metapneumovirus infection will be added as LLT to PT Metapneumovirus infection.				

<b>CR Number:</b> 2024144012		<b>Implementation Date:</b> 30-May-24	<b>Related CR:</b> 2024144012	
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Myoepithelial carcinoma of salivary gland	Approved as Requested	Proposed PT	
HLT primary	Salivary gland neoplasms malignant		Myoepithelial carcinoma of salivary gland	10091222
SOC primary	Neoplasms benign, malignant and unspecified (incl cysts and polyps)		HLT primary	
			Salivary gland neoplasms malignant	10039396
			SOC primary	
			Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10029104
			HLT secondary	
			Malignant oral cavity neoplasms	10026660
			SOC secondary	
			Gastrointestinal disorders	10017947

**MSSO Comment:** The proposal to add a new PT Myoepithelial carcinoma of salivary gland to primary HLT Salivary gland neoplasms malignant in SOC Neoplasms benign, malignant and unspecified (incl cysts and polyps) and secondary HLT Malignant oral cavity neoplasms in SOC Gastrointestinal disorders is approved as requested. Myoepithelial carcinoma is an invasive malignant salivary gland neoplasm that is almost exclusively composed of myoepithelial cells. Myoepithelial carcinoma may arise de novo or within a pre-existing pleomorphic adenoma and is the second most common histological subtype of carcinoma excluding pleomorphic adenoma.

# Detail Report

<b>CR Number:</b> 2024144013		<b>Implementation Date:</b> 30-May-24	<b>Related CR:</b> 2024144013	
<u>Change Requested</u>	Link (move) an LLT to another PT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Intramedullary femoral nailing</i>	Approved as Requested	Proposed LLT	
From PT	<i>Internal fixation of fracture</i>		<i>Intramedullary femoral nailing</i>	10090654 Current
To PT	<i>Intramedullary rod insertion</i>		From PT	
			<i>Internal fixation of fracture</i>	10022576
			To PT	
			<i>Intramedullary rod insertion</i>	10069066
<b>MSSO Comment:</b> The proposal to move the LLT Intramedullary femoral nailing from PT Internal fixation of fracture to PT Intramedullary rod insertion is approved as requested. Prophylactic femoral nailing is a procedure to stabilize the femoral bone that has become weak due to the presence of a tumor. Therefore, the LLT Intramedullary femoral nailing is better aligned under the PT Intramedullary rod insertion, since this new placement is in accordance with the use of this technique in both repair and prophylaxis of fractures.				

<b>CR Number:</b> 2024144014		<b>Implementation Date:</b> 28-May-24	<b>Related CR:</b> 2024144014	
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Skin blush</i>	Approved Not as Requested	Proposed LLT	
To PT	<i>Erythema</i>		<i>Skin blush</i>	10091208 Current
			To PT	
			<i>Flushing</i>	10016825
<b>MSSO Comment:</b> The proposal to add a new LLT Skin blush to PT Erythema is approved but not as requested. Erythema is simply the term for any reddening of the skin, as defined by Dorland's Medical Dictionary: "Redness of the skin produced by congestion of the capillaries". Skin blushing or flushing (used synonymously) is a sudden reddening of the face, neck, or upper chest due to increased blood flow, primarily a physiological response to emotional stimuli but can also occur due to certain physical conditions. Skin blush will be added as LLT to PT Flushing aligned with LLT Skin flushed and LLT Facial flushing.				

<b>CR Number:</b> 2024144015		<b>Implementation Date:</b> 28-May-24	<b>Related CR:</b> 2024144015	
<u>Change Requested</u>	Add a New PT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Skin haematoma</i>	Rejected		
<b>MSSO Comment:</b> The proposal to add a new PT Skin haematoma is not approved. The proposed concept maybe represented by existing LLT/PT Subcutaneous haematoma or other LLTs under PT Haematoma, depending upon your specific scenario.				

# Detail Report

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<b>CR Number:</b> 2024144016		<b>Implementation Date:</b> 28-May-24	<b>Related CR:</b> 2024144016		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed PT	<i>Respiratory constriction</i>	Rejected			

MSSO Comment: The proposal to add a new PT Respiratory constriction is not approved. The proposed term is an ambiguous concept and non-specific.

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<b>CR Number:</b> 2024144017		<b>Implementation Date:</b> 29-May-24	<b>Related CR:</b> 2024144017		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed LLT	<i>Plasma homovanillic acid increased</i>	Approved as Requested	Proposed LLT <i>Plasma homovanillic acid increased</i> To PT <i>Homovanillic acid increased</i>	10091215	Current  10091214

MSSO Comment: The proposal to add a new LLT Plasma homovanillic acid increased is approved as requested. Plasma levels of homovanillic acid (pHVA), a major metabolite of dopamine, have been used as a peripheral measure of dopaminergic activity in the central nervous system. Although a relatively small part of pHVA has been indicated as central origin, there have been reports of the usefulness of pHVA as a peripheral indicator of central dopaminergic activity. Since specimen-related investigation terms are usually represented at the LLT level in MedDRA, Plasma homovanillic acid increased will be added as an LLT to a new non-specimen-specific PT Homovanillic acid increased, which will be added, in a related change to HLT Chemistry analyses NEC.

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<b>CR Number:</b> 2024150004		<b>Implementation Date:</b> 29-May-24	<b>Related CR:</b> 2024144017		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed PT	<i>Homovanillic acid increased</i>	Approved as Requested	Proposed PT <i>Homovanillic acid increased</i>	10091214	
HLT primary	<i>Chemistry analyses NEC</i>		HLT primary <i>Chemistry analyses NEC</i>	10008431	
SOC primary	<i>Investigations</i>		SOC primary <i>Investigations</i>	10022891	

MSSO Comment:

# Detail Report

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<b>CR Number:</b> 2024144018		<b>Implementation Date:</b> 05-Jun-24	<b>Related CR:</b> 2024144018		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed LLT	<i>Plasma vanillyl mandelic acid increased</i>	Rejected After Suspension			

**MSSO Comment:** The proposal to add a new LLT Plasma vanillyl mandelic acid increased is not approved after suspension. Please refer change request 2024150002.

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<b>CR Number:</b> 2024145047		<b>Implementation Date:</b> 28-May-24	<b>Related CR:</b> 2024145047		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed LLT	<i>Renal or Kidney Lesion</i>	Rejected			

**MSSO Comment:** The proposal to add a new LLT Renal or Kidney Lesion is not approved. As Section 5.1 of the MedDRA Introductory Guide states: Lesion terms may be considered for inclusion in MedDRA when the word "lesion" is part of a medical concept, e.g., PT Glomerulonephritis minimal lesion or a well documented medical concept, e.g., LLT Brain lesion. However, the term will not be added when adding a broad "lesion" term only adds an additional imprecise term to existing "disorder" concepts, e.g., "renal lesion," when one could use for coding the existing LLT Renal disorder under PT Renal disorder.

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<b>CR Number:</b> 2024145048		<b>Implementation Date:</b> 29-May-24	<b>Related CR:</b> 2024145048		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed PT	<i>Pescetarian diet</i>	Approved as Requested	Proposed PT		
HLT primary	<i>Dietary and nutritional issues</i>		<i>Pescetarian diet</i>		10091216
SOC primary	<i>Social circumstances</i>		HLT primary		
			<i>Dietary and nutritional issues</i>		10012776
			SOC primary		
			<i>Social circumstances</i>		10041244

**MSSO Comment:** The proposal to add a new PT Pescetarian diet to primary HLT Dietary and nutritional issues in SOC Social circumstances is approved as requested. A pescetarian diet is a type of dietary practice that combines aspects of vegetarianism with the inclusion of seafood. People who follow a pescetarian diet primarily eat plant-based foods but also include fish and other seafood in their meals.



# Detail Report

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<b>CR Number:</b> 2024145049		<b>Implementation Date:</b> 29-May-24	<b>Related CR:</b> 2024145049	
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Low histamine diet</i>	Approved Not as Requested	Proposed LLT	
HLT primary	<i>Dietary and nutritional issues</i>		<i>Low histamine diet</i>	10091218 Current
SOC primary	<i>Social circumstances</i>		To PT	
			<i>Medical diet</i>	10027087
<b>MSSO Comment:</b> The proposal to add a new PT Low histamine diet to primary HLT Dietary and nutritional issues in SOC Social circumstances is approved but not as requested. Low histamine diet excludes foods known to contain high levels of histamine or to contain chemicals that can promote the physiological release of histamine and is designed to help individuals who are sensitive to histamine or who suffer from conditions like histamine intolerance. Low histamine diet will be added as LLT to PT Medical diet.				

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<b>CR Number:</b> 2024145050		<b>Implementation Date:</b> 29-May-24	<b>Related CR:</b> 2024145050	
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Difficulty eating</i>	Rejected		
<b>MSSO Comment:</b> The proposal to add a new PT Difficulty eating is not approved. The proposed term is ambiguous as difficulty eating may be due to multiple causes ranging from psychological to functional or other. The underlying reason of the difficulty eating may be represented by a more precise existing LLT/PT.				

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<b>CR Number:</b> 2024145051		<b>Implementation Date:</b> 29-May-24	<b>Related CR:</b> 2024145051	
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Emotional dysregulation</i>	Approved Not as Requested	Proposed LLT	
HLT primary	<i>Emotional and mood disturbances NEC</i>		<i>Emotional dysregulation</i>	10091217 Current
SOC primary	<i>Psychiatric disorders</i>		To PT	
			<i>Emotional disorder</i>	10014551
<b>MSSO Comment:</b> The proposal to add a new PT Emotional dysregulation to primary HLT Emotional and mood disturbances NEC in SOC Psychiatric disorders is approved but not as requested. Emotional dysregulation is characterized by an inability in flexibly responding to and managing emotional states, resulting in intense and prolonged emotional reactions that deviate from social norms, given the nature of the environmental stimuli encountered. Emotional dysregulation will be added as an LLT to the PT Emotional disorder.				

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# Detail Report

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<b>CR Number:</b> 2024145052		<b>Implementation Date:</b> 29-May-24	<b>Related CR:</b> 2024145052		
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed LLT	Off label use in unapproved sex	Approved as Requested	Proposed LLT		
To PT	Off label use		Off label use in unapproved sex	10091219	Current
			To PT		
			Off label use	10053762	
<b>MSSO Comment:</b> The proposal to add a new LLT Off label use in unapproved sex to PT Off label use is approved as requested. Off label use in unapproved sex occurs when a product authorized for one sex is used off label for the other sex.					

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<b>CR Number:</b> 2024145054		<b>Implementation Date:</b> 29-May-24	<b>Related CR:</b> 2024145054		
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>	
Proposed LLT	<i>Near miss medication error</i>	Rejected			
To PT	<i>Intercepted medication error</i>				
<b>MSSO Comment:</b> The proposal to add a new LLT Near miss medication error to PT Intercepted medication error is not approved. The proposed term is only an alternative expression of "intercepted medication error" and appears in quotations in EMA's "Good Practice Guide on Recording, Coding, Reporting and Assessment of Medication Errors" document and may lead to confusion and overpopulation of synonym terms.					

<b>CR Number:</b> 2024145055		<b>Implementation Date:</b> 29-May-24	<b>Related CR:</b> 2024145055		
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed LLT	<i>Near miss medication error during product dispensing</i>	Rejected			
To PT	<i>Intercepted medication error</i>				
<b>MSSO Comment:</b> The proposal to add a new LLT Near miss medication error during product dispensing to PT Intercepted medication error is not approved. This concept is already represented by the PT Intercepted product dispensing error.					

# Detail Report

CR Number: 2024145056		Implementation Date: 29-May-24		Related CR: 2024145056			
<a href="#">Change Requested</a>	Add a New LLT		<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		<a href="#">MedDRA Code #</a>	
Proposed LLT	Near miss medication error in product prescribing		Rejected				
To PT	Intercepted medication error						
MSSO Comment:	The proposal to add a new LLT Near miss medication error in product prescribing to PT Intercepted medication error is not approved. This concept is already represented by the PT Intercepted product prescribing error.						

CR Number: 2024146000		Implementation Date: 29-May-24	Related CR: 2024146000		
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed LLT	<i>Ventricular diverticulum</i>	Approved Not as Requested	Proposed PT		
			<i>Cardiac ventricular diverticulum</i>	10091212	
			HLT primary		
			<i>Cardiac disorders congenital NEC</i>	10007542	
			SOC primary		
			<i>Congenital, familial and genetic disorders</i>	10010331	
			HLT secondary		
			<i>Congenital cardiac structural defects NEC</i>	10010397	
			SOC secondary		
			<i>Cardiac disorders</i>	10007541	
MSSO Comment:	The proposal to add a new LLT Ventricular diverticulum is approved but not as requested. Cardiac ventricular diverticulum is a rare congenital ventricular outpouching. The disease is often diagnosed during childhood because it is frequently associated with midline thoracoabdominal defects and other congenital cardiac anomalies. Most cases are asymptomatic and often discovered incidentally. The proposed term will be modified for clarity to Cardiac ventricular diverticulum and will be added as PT to primary HLT Cardiac disorders congenital NEC and secondary HLT Congenital cardiac structural defects NEC.				

# Detail Report

<b>CR Number:</b> 2024146001		<b>Implementation Date:</b> 29-May-24	<b>Related CR:</b> 2024146001	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Amsler grid test	Approved Not as Requested	Proposed PT	
To PT	Visual field tests		Amsler grid test	10091211
			HLT primary	
			Ophthalmic function diagnostic procedures	10030864
			SOC primary	
			Investigations	10022891

**MSSO Comment:** The proposal to add a new LLT Amsler grid test to PT Visual field tests is approved but not as requested. Amsler grid test is a simple grid pattern test used to detect distortions or abnormalities in the central visual field used primarily for monitoring macular degeneration and other central vision issues. Amsler grid test will be added as a PT to HLT Ophthalmic function diagnostic procedures.

<b>CR Number:</b> 2024146002		<b>Implementation Date:</b> 29-May-24	<b>Related CR:</b> 2024146002	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Lupus retinopathy	Approved Not as Requested	Proposed PT	
			Lupus retinopathy	10091210
			HLT primary	
			Retinopathies NEC	10038932
			SOC primary	
			Eye disorders	10015919
			HLT secondary	
			Lupus erythematosus and associated conditions	10025136
			SOC secondary	
			Immune system disorders	10021428

**MSSO Comment:** The proposal to add a new LLT Lupus retinopathy is approved but not as requested. Retinal vasculitis is an under-recognized manifestation of systemic lupus erythematosus (SLE). Mild and visually nonthreatening manifestations are common, consisting of cotton-wool spots with or without hemorrhages. They are observed in 3 to 30 percent of ambulatory and hospitalized patients with SLE, respectively. Lupus retinopathy will be added as PT to primary HLT Retinopathies NEC, secondary HLT Lupus erythematosus and associated conditions and secondary HLT Lupus erythematosus (incl subtypes).

# Detail Report

<b>CR Number:</b> 2024150003		<b>Implementation Date:</b> 29-May-24	<b>Related CR:</b> 2024146002	
<a href="#">Change Requested</a>	Link a PT to a HLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Lupus retinopathy</i>	Approved as Requested	Proposed PT	
To HLT	<i>Lupus erythematosus (incl subtypes)</i>		<i>Lupus retinopathy</i>	10091210
			To HLT	
			<i>Lupus erythematosus (incl subtypes)</i>	10025135

MSSO  
Comment:

<b>CR Number:</b> 2024146003		<b>Implementation Date:</b> 29-May-24	<b>Related CR:</b> 2024146003	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Intracellular dehydration</i>	Approved as Requested	Proposed LLT	
			<i>Intracellular dehydration</i>	10091213 Current
			To PT	
			<i>Dehydration</i>	10012174

MSSO  
Comment: The proposal to add a new LLT Intracellular dehydration is approved as requested. Intracellular dehydration refers to the condition in which there is a deficit of water within the cells closely related to hyperosmotic or hypertonic dehydration. Intracellular dehydration will be added as LLT to PT Dehydration.

<b>CR Number:</b> 2024148000		<b>Implementation Date:</b> 29-May-24	<b>Related CR:</b> 2024148000	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Spinal dysraphism</i>	Approved as Requested	Proposed LLT	
			<i>Spinal dysraphism</i>	10091220 Current
			To PT	
			<i>Neural tube defect</i>	10052046

MSSO  
Comment: The proposal to add a new LLT Spinal dysraphism is approved as requested. Spinal dysraphism, or neural tube defect, is a broad term encompassing a heterogeneous group of congenital spinal anomalies that result from defective closure of the neural tube early in fetal life and anomalous development of the caudal cell mass. Spinal dysraphism will be added as sub-concept LLT to PT Neural tube defect.

# Detail Report

<b>CR Number:</b> 2024148003		<b>Implementation Date:</b> 31-May-24	<b>Related CR:</b> 2024148003	
<u>Change Requested</u>	Add a New PT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Bicameral gallbladder</i>	Approved as Requested	Proposed PT	
HLT primary	<i>Gallbladder disorders NEC</i>		<i>Bicameral gallbladder</i>	10091223
SOC primary	<i>Hepatobiliary disorders</i>		HLT primary	
			<i>Gallbladder disorders NEC</i>	10017629
			SOC primary	
			<i>Hepatobiliary disorders</i>	10019805

**MSSO Comment:** The proposal to add a new PT Bicameral gallbladder to primary HLT Gallbladder disorders NEC in SOC Hepatobiliary disorders is approved as requested. Bicameral gallbladder, often due - but not only - to the presence of segmental adenomyomatosis, is an anomaly in which the gallbladder lumen is partitioned, often nearly completely, into two chambers. When oral cholecystography is performed for bicameral gallbladders, the contrast medium tends to concentrate only in the ductal chamber.

<b>CR Number:</b> 2024148004		<b>Implementation Date:</b> 31-May-24	<b>Related CR:</b> 2024148004	
<u>Change Requested</u>	Add a New Term	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	<i>Chronic drug use</i>	Rejected		

**MSSO Comment:** The proposal to add a new term Chronic drug use is not approved. The proposed term is ambiguous as it may represent multiple incompatible scenarios, ranging from the chronic use (and often subsequent substance abuse) of an illegal drug, to a long duration of prescribed treatment.

<b>CR Number:</b> 2024148005		<b>Implementation Date:</b> 31-May-24	<b>Related CR:</b> 2024148005	
<u>Change Requested</u>	Rename PT/LLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Term to modify	<i>Parietal pain</i>	Approved Not as Requested	Proposed LLT	
Replacement term	<i>Parietal peritoneal pain</i>		<i>Parietal abdominal pain</i>	10091225 Current
			To PT	
			<i>Abdominal pain</i>	10000081

**MSSO Comment:** The proposal to rename PT/LLT Parietal pain to Parietal peritoneal pain is approved but not as requested. Except for minor modifications, MedDRA cannot rename terms which are already in use by subscribers. To address this request, a new LLT Parietal abdominal pain will be added to the PT Abdominal pain. The qualifier "abdominal" is preferred to the one proposed ("peritoneal"), since this term may be used for pains originated in layers of the abdominal wall different than peritoneum. In a related change, the LLT Parietal pain added in version 27.0 will be made non-current.

# Detail Report

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<b>CR Number:</b> 2024152031		<b>Implementation Date:</b> 31-May-24	<b>Related CR:</b> 2024148005		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Change Status of LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
LLT to change	<i>Parietal pain</i>	Approved as Requested	LLT to change		
Status	<i>Non-current</i>		<i>Parietal pain</i>	10089956	Non-Current
			Status		
			<i>Non-current</i>		

MSSO  
Comment:

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<b>CR Number:</b> 2024148006		<b>Implementation Date:</b> 31-May-24	<b>Related CR:</b> 2024148006		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed Term	<i>Gonococcal tysonitis</i>	Approved as Requested	Proposed PT		
			<i>Gonococcal tysonitis</i>	10091224	
			HLT primary		
			<i>Neisseria infections</i>	10028909	
			SOC primary		
			<i>Infections and infestations</i>	10021881	
			HLT secondary		
			<i>Penile and scrotal infections and inflammations</i>	10021854	
			SOC secondary		
			<i>Reproductive system and breast disorders</i>	10038604	

MSSO  
Comment: The proposal to add a new term Gonococcal tysonitis is approved as requested. Although Tyson's abscess is a rare entity when compared to other complications of acute gonorrhea, infection of Tyson's glands may occur causing a protruding cystic globoid enlargement either unilaterally or bilaterally. Gonococcal tysonitis will be added as a PT with a primary link to HLT Neisseria infections and a secondary link to HLT Penile and scrotal infections and inflammations.

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# Detail Report

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<b>CR Number:</b> 2024148013		<b>Implementation Date:</b> 30-May-24	<b>Related CR:</b> 2024148013		
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed Term	<i>Exudative pancreatitis</i>	Approved as Requested	Proposed LLT <i>Exudative pancreatitis</i>	10091221	Current
			To PT <i>Pancreatitis acute</i>	10033647	

**MSSO Comment:** The proposal to add a new term Exudative pancreatitis is approved as requested. Exudative pancreatitis describes a local complication of acute pancreatitis with pancreatic and peripancreatic fluid collections. Exudative pancreatitis will be added as an LLT to PT Pancreatitis acute.

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<b>CR Number:</b> 2024148014		<b>Implementation Date:</b> 04-Jun-24	<b>Related CR:</b> 2024148014		
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed Term	<i>Product data issue</i>	Approved Not as Requested After Suspension	Proposed LLT <i>Database system product information issue</i>	10091269	Current
			To PT <i>Circumstance or information capable of leading to medication error</i>	10064385	

**MSSO Comment:** The proposal to add a new term Product data issue is approved but not as requested after suspension. Product information is an important component of clinical decision support data systems. Any issue with this information may lead to medication errors. The proposed term will be modified for clarity accordingly and added as LLT Database system product information issue under PT Circumstance or information capable of leading to medication error.

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<b>CR Number:</b> 2024148015		<b>Implementation Date:</b> 30-May-24	<b>Related CR:</b> 2024148015		
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed Term	<i>Informations in summary of product characteristics and patient leaflet differ</i>	Suspended			

**MSSO Comment:** The proposal to add a new term Informations in summary of product characteristics and patient leaflet differ is suspended. The MSSO would like to take additional time to study this proposed change. You will be notified once a decision has been made on the disposition of your request.



# Detail Report

<b>CR Number:</b> 2024148016		<b>Implementation Date:</b> 30-May-24	<b>Related CR:</b> 2024148016	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Round lung focus	Rejected		
To PT	Pulmonary mass			

**MSSO Comment:** The proposal to add a new LLT Round lung focus to PT Pulmonary mass is not approved. The translation for "Lungenrundherd" is pulmonary or lung nodule, with available LLT Lung nodule linked to the proposed PT. Internal translation change request 2024151008 has been submitted to address the proposed term "Round lung focus" in this change request.

<b>CR Number:</b> 2024148024		<b>Implementation Date:</b> 31-May-24	<b>Related CR:</b> 2024148024	
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Verrucous carcinoma	Approved Not as Requested	Proposed LLT Verrucous squamous cell carcinoma	10091240 Current
			To PT Squamous cell carcinoma	10041823

**MSSO Comment:** The proposal to add a new PT Verrucous carcinoma is approved but not as requested. Verrucous squamous cell carcinoma is a rare, well-differentiated type of cutaneous squamous cell carcinoma as well as can be found on mucosal surfaces; it has a characteristically undulant architecture and often exhibits locally aggressive behaviour, yet has low potential for metastasis. The proposed term will be modified to its more frequent and clear representation in literature and will be added as LLT Verrucous squamous cell carcinoma to the PT Squamous cell carcinoma.

<b>CR Number:</b> 2024148025		<b>Implementation Date:</b> 31-May-24	<b>Related CR:</b> 2024148025	
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Corneal sub-epithelial infiltrates	Approved Not as Requested	Proposed LLT Corneal subepithelial infiltrates	10091237 Current
			To PT Corneal infiltrates	10011022

**MSSO Comment:** The proposal to add a new PT Corneal sub-epithelial infiltrates is approved but not as requested. Subepithelial corneal infiltrates can develop and persist for months or even years in patients with epidemic keratoconjunctivitis. Although usually minimally symptomatic, these infiltrates can cause significant ocular morbidity, reduced vision, photophobia, glare, halos, and foreign body sensation. The proposed term will be modified to its non-hyphenated spelling and added as the LLT Corneal subepithelial infiltrates to the PT Corneal infiltrates.

# Detail Report

CR Number: 2024148026		Implementation Date: 31-May-24	Related CR: 2024148026	
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	BASDAI score	Approved as Requested	Proposed PT BASDAI score	10091235
			HLT primary Musculoskeletal and soft tissue tests NEC	10028394
			SOC primary Investigations	10022891
<div>MSSO</div> <div>Comment:</div> <div>The proposal to add a new PT BASDAI score is approved as requested. The Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) Score Calculator is a tool used to assess disease activity in Ankylosing Spondylitis (AS) patients. The numeric score reflects the severity of disease activity in AS patients and aids healthcare professionals in making treatment decisions and monitoring the progression of the condition. BASDAI score will be added as new PT under HLT Musculoskeletal and soft tissue tests NEC.</div>				

CR Number: 2024148027		Implementation Date: 31-May-24	Related CR: 2024148027	
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	BASDAI score increased	Approved as Requested	Proposed PT BASDAI score increased	10091236
			HLT primary Musculoskeletal and soft tissue tests NEC	10028394
			SOC primary Investigations	10022891
<div>MSSO</div> <div>Comment:</div> <div>The proposal to add a new PT BASDAI score increased is approved as requested. The Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) Score Calculator is a tool used to assess disease activity in Ankylosing Spondylitis (AS) patients. The numeric score reflects the severity of disease activity in AS patients and aids healthcare professionals in making treatment decisions and monitoring the progression of the condition. BASDAI score increased will be added as new PT under HLT Musculoskeletal and soft tissue tests NEC.</div>				

# Detail Report

<b>CR Number:</b> 2024148028		<b>Implementation Date:</b> 31-May-24	<b>Related CR:</b> 2024148028	
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	BASDAI score decreased	Approved as Requested	Proposed PT	
			BASDAI score decreased	10091234
			HLT primary	
			Musculoskeletal and soft tissue tests NEC	10028394
			SOC primary	
			Investigations	10022891

**MSSO Comment:** The proposal to add a new PT BASDAI score decreased is approved as requested. The Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) Score Calculator is a tool used to assess disease activity in Ankylosing Spondylitis (AS) patients. The numeric score reflects the severity of disease activity in AS patients and aids healthcare professionals in making treatment decisions and monitoring the progression of the condition. BASDAI score decreased will be added as new PT under HLT Musculoskeletal and soft tissue tests NEC.

<b>CR Number:</b> 2024148029		<b>Implementation Date:</b> 31-May-24	<b>Related CR:</b> 2024148029	
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	HAQ score	Approved Not as Requested	Proposed LLT	
			HAQ score	10091242 Current
			To PT	
			Health assessment questionnaire score	10091232

**MSSO Comment:** The proposal to add a new PT HAQ score is approved but not as requested. The Health assessment questionnaire (HAQ) score is one of the first self-report functional status (disability) measures and has become the dominant instrument in many disease areas, including arthritis. It is widely used throughout the world and has become a mandated outcome measure for clinical trials in rheumatoid arthritis and some other joint related diseases. HAQ score will be added as LLT under a new PT Health assessment questionnaire score. In a related change, new PT Health assessment questionnaire score will be added under HLT Musculoskeletal and soft tissue tests NEC.

<b>CR Number:</b> 2024152027		<b>Implementation Date:</b> 31-May-24	<b>Related CR:</b> 2024148029	
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Health assessment questionnaire score	Approved as Requested	Proposed PT	
			Health assessment questionnaire score	10091232
HLT primary	Musculoskeletal and soft tissue tests NEC		HLT primary	
			Musculoskeletal and soft tissue tests NEC	10028394
SOC primary	Investigations		SOC primary	
			Investigations	10022891

**MSSO Comment:**

# Detail Report

<b>CR Number:</b> 2024148030		<b>Implementation Date:</b> 31-May-24	<b>Related CR:</b> 2024148030	
<u>Change Requested</u>	Add a New PT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	HAQ score increased	Approved Not as Requested	Proposed LLT HAQ score increased	10091241 Current
			To PT Health assessment questionnaire score increased	10091233

**MSSO**  
**Comment:** The proposal to add a new PT HAQ score increased is approved but not as requested. The Health assessment questionnaire (HAQ) score is one of the first self-report functional status (disability) measures and has become the dominant instrument in many disease areas, including arthritis. It is widely used throughout the world and has become a mandated outcome measure for clinical trials in rheumatoid arthritis and some other joint related diseases. HAQ score increased will be added as LLT under a new PT Health assessment questionnaire score increased. In a related change, new PT Health assessment questionnaire score increased will be added under HLT Musculoskeletal and soft tissue tests NEC.

<b>CR Number:</b> 2024152028		<b>Implementation Date:</b> 31-May-24	<b>Related CR:</b> 2024148030	
<u>Change Requested</u>	Add a New PT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Health assessment questionnaire score increased	Approved as Requested	Proposed PT Health assessment questionnaire score increased	10091233
HLT primary	Musculoskeletal and soft tissue tests NEC		HLT primary Musculoskeletal and soft tissue tests NEC	10028394
SOC primary	Investigations		SOC primary Investigations	10022891

**MSSO**  
**Comment:**

# Detail Report

<b>CR Number:</b> 2024148031		<b>Implementation Date:</b> 31-May-24	<b>Related CR:</b> 2024148031	
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	HAQ score decreased	Approved Not as Requested	Proposed LLT HAQ score decreased	10091239 Current
			To PT Health assessment questionnaire score decreased	10091231

**MSSO**  
**Comment:** The proposal to add a new PT HAQ score decreased is approved but not as requested. The Health assessment questionnaire (HAQ) score is one of the first self-report functional status (disability) measures and has become the dominant instrument in many disease areas, including arthritis. It is widely used throughout the world and has become a mandated outcome measure for clinical trials in rheumatoid arthritis and some other joint related diseases. HAQ score decreased will be added as LLT under a new PT Health assessment questionnaire score decreased. In a related change, new PT Health assessment questionnaire score decreased will be added under HLT Musculoskeletal and soft tissue tests NEC.

<b>CR Number:</b> 2024152029		<b>Implementation Date:</b> 31-May-24	<b>Related CR:</b> 2024148031	
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Health assessment questionnaire score decreased	Approved as Requested	Proposed PT Health assessment questionnaire score decreased	10091231
HLT primary	Musculoskeletal and soft tissue tests NEC		HLT primary Musculoskeletal and soft tissue tests NEC	10028394
SOC primary	Investigations		SOC primary Investigations	10022891

**MSSO**  
**Comment:**

<b>CR Number:</b> 2024148032		<b>Implementation Date:</b> 31-May-24	<b>Related CR:</b> 2024148032	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Ciliochoroidal effusion	Approved as Requested	Proposed LLT Ciliochoroidal effusion	10091238 Current
			To PT Choroidal effusion	10063970

**MSSO**  
**Comment:** The proposal to add a new LLT Ciliochoroidal effusion is approved as requested. Ciliochoroidal or uveal effusion is an abnormal accumulation of serous fluid from the choriocapillaris into the potential space between the sclera externally and the choroid or ciliary body internally, which often results in detachments of the choroidal and ciliary body. Ciliochoroidal effusion will be added as LLT to PT Choroidal effusion as a synonym of the existing LLT Uveal effusion syndrome. In a related change, the PT Choroidal effusion will receive a secondary link to HLT Eye and ear procedural complications, since it is frequently the consequence of ophthalmic surgery.

# Detail Report

CR Number: 2024152030		Implementation Date: 31-May-24	Related CR: 2024148032	
<a href="#">Change Requested</a>	Link a PT to a HLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Choroidal effusion	Approved as Requested	Proposed PT	
To HLT	Eye and ear procedural complications		Choroidal effusion	10063970
			To HLT	
			Eye and ear procedural complications	10015908

MSSO  
Comment:

CR Number: 2024149040		Implementation Date: 30-May-24	Related CR: 2024149040	
<a href="#">Change Requested</a>	Change Status of LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
LLT to change	Unintentional therapeutic error with medication	Rejected		
Status	non-current			

MSSO Comment: The proposal to change status of LLT Unintentional therapeutic error with medication to non-current is not approved. In some regulatory databases, unintentional is synonymous to accidental, and thus to facilitate communication with organizations dealing with safety information such as toxicology reports, the term was added.

CR Number: 2024149041		Implementation Date: 31-May-24	Related CR: 2024149041	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Catheter angiography	Rejected		

MSSO Comment: The proposal to add a new LLT Catheter angiography is not approved. There are multiple terms in MedDRA to represent both the general angiography and those related to specific organs. Contrast for angiographies is delivered by a catheter, which is something inherent to this imaging technique and makes the proposed term of little additional value.

# Detail Report

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<b>CR Number:</b> 2024149042		<b>Implementation Date:</b> 31-May-24	<b>Related CR:</b> 2024149042	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Scapulectomy	Approved Not as Requested	Proposed PT Scapulectomy	10091226
			HLT primary Limb therapeutic procedures	10024502
			SOC primary Surgical and medical procedures	10042613

**MSSO Comment:** The proposal to add a new LLT Scapulectomy is approved but not as requested. Scapulectomy and limb-salvage surgery are indicated for low and high-grade tumors of the scapula and soft-tissue sarcomas that secondarily invade the bone. Scapulectomy will be added as PT to the HLT Limb therapeutic procedures.

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<b>CR Number:</b> 2024149043		<b>Implementation Date:</b> 31-May-24	<b>Related CR:</b> 2024149043	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Soft tissue flap reconstruction	Rejected		

**MSSO Comment:** The proposal to add a new LLT Soft tissue flap reconstruction is not approved. This concept is already represented in LLT/PT Soft tissue flap operation.

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<b>CR Number:</b> 2024149044		<b>Implementation Date:</b> 31-May-24	<b>Related CR:</b> 2024149044	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Chrome allergy	Approved Not as Requested	Proposed LLT Chromium allergy	10091227 Current
			To PT Allergy to metals	10066414

**MSSO Comment:** The proposal to add a new LLT Chrome allergy is approved but not as requested. Chrome allergy presents with a contact allergic dermatitis. It is due to a delayed hypersensitivity reaction to chromium salts, particularly Cr(III) and Cr(VI). The proposed term will be modified to represent the more accurate name of this metal, and added as the LLT Chromium allergy to the PT Allergy to metals.

# Detail Report

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<b>CR Number:</b> 2024149098		<b>Implementation Date:</b> 31-May-24	<b>Related CR:</b> 2024149098		
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed LLT	<i>Atypical Enostoses</i>	Rejected			

**MSSO Comment:** The proposal to add a new LLT Atypical Enostoses is not approved. The proposed term is not a well-defined medical concept found widely in medical literature.

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<b>CR Number:</b> 2024149099		<b>Implementation Date:</b> 31-May-24	<b>Related CR:</b> 2024149099		
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed LLT	<i>Atypical Clubfoot</i>	Approved Not as Requested	Proposed LLT <i>Atypical clubfoot</i>	10091243	Current
			To PT <i>Talipes</i>	10043101	

**MSSO Comment:** The proposal to add a new LLT Atypical Clubfoot is approved but not as requested. Atypical clubfeet have severe equinus and plantarflexion of all metatarsals and a short hyperextended great toe and are challenging to treat. Proposed term will be modified for MedDRA capitalization conventions and added as LLT Atypical clubfoot to PT Talipes aligned with existing LLT Clubfoot.

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<b>CR Number:</b> 2024149100		<b>Implementation Date:</b> 31-May-24	<b>Related CR:</b> 2024149100		
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed LLT	<i>Complex Clubfoot</i>	Approved Not as Requested	Proposed LLT <i>Complex clubfoot</i>	10091245	Current
			To PT <i>Talipes</i>	10043101	

**MSSO Comment:** The proposal to add a new LLT Complex Clubfoot is approved but not as requested. Atypical clubfeet or complex clubfeet are defined by Ponseti as "having rigid equinus, severe plantar flexion of all metatarsals, a deep crease above the heel, a transverse crease in the sole of the foot, and a short hyperextended first toe. Proposed term will be modified for MedDRA capitalization conventions and added as LLT Complex clubfoot to PT Talipes aligned with existing LLT Clubfoot.



# Detail Report

<b>CR Number:</b> 2024149101		<b>Implementation Date:</b> 31-May-24	<b>Related CR:</b> 2024149101	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Recurrent varicella	Approved as Requested	Proposed LLT Recurrent varicella	10091244 Current
			To PT Varicella	10046980

**MSSO** The proposal to add a new LLT Recurrent varicella is approved as requested. Although a single Varicella-zoster virus infection typically confers protection against its  
**Comment:** reactivation, recurrent varicella rarely is reported, particularly in immunocompetent patients. Recurrent varicella will be added as subconcept LLT under PT Varicella.

<b>CR Number:</b> 2024150000		<b>Implementation Date:</b> 31-May-24	<b>Related CR:</b> 2024150000	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	MAGnetic Expansion adjustment	Approved Not as Requested	Proposed PT Spinal rod adjustment	10091228
			HLT primary Spine and spinal cord therapeutic procedures	10041590
			SOC primary Surgical and medical procedures	10042613

**MSSO** The proposal to add a new LLT MAGnetic Expansion adjustment is approved but not as requested. Spinal rod adjustment refers to the process of modifying the position, tension, or configuration of spinal rods that have been surgically implanted to correct spinal deformities or stabilize the spine. These rods are typically made of metal and are used in various spinal surgeries, including scoliosis correction, spinal fusion, and treatment of fractures or degenerative spine conditions. Since MedDRA does not include tradenames, the proposed term will be modified and added as a PT Spinal rod adjustment to HLT Spine and spinal cord therapeutic procedures. In a related change, LLT Spinal growing rod adjustment and LLT Spinal magnetic rod adjustment will both be added under new PT Spinal rod adjustment. Furthermore, LLT Spinal rod insertion will be promoted from PT Spinal implantation to PT level and linked to HLT Spine and spinal cord therapeutic procedures.

<b>CR Number:</b> 2024152025		<b>Implementation Date:</b> 31-May-24	<b>Related CR:</b> 2024150000	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Spinal magnetic rod adjustment	Approved as Requested	Proposed LLT Spinal magnetic rod adjustment	10091230 Current
To PT	Spinal rod adjustment		To PT Spinal rod adjustment	10091228

**MSSO**  
**Comment:**

# Detail Report

CR Number: 2024152024		Implementation Date: 31-May-24	Related CR: 2024150000		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed LLT	Spinal growing rod adjustment	Approved as Requested	Proposed LLT		
To PT	Spinal rod adjustment		Spinal growing rod adjustment	10091229	Current
			To PT		
			Spinal rod adjustment	10091228	

MSSO  
Comment:

CR Number: 2024152026		Implementation Date: 31-May-24	Related CR: 2024150000		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Promote an LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed LLT	Spinal rod insertion	Approved as Requested	Proposed LLT		
From PT	Spinal implantation		Spinal rod insertion	10053002	
HLT primary	Spine and spinal cord therapeutic procedures		From PT		
			Spinal implantation	10088845	
			HLT primary		
			Spine and spinal cord therapeutic procedures	10041590	
			SOC primary		
			Surgical and medical procedures	10042613	

MSSO  
Comment:

CR Number: 2024150001		Implementation Date: 31-May-24	Related CR: 2024150001		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed LLT	Fundus lesion	Rejected			

MSSO  
Comment: The proposal to add a new LLT Fundus lesion is not approved. The proposed term is highly ambiguous, since it can be interpreted as the bottom or base of multiple hollow organs, such as stomach, eye, gallbladder or uterus.

# Detail Report

<b>CR Number:</b> 2024150002		<b>Implementation Date:</b> 05-Jun-24	<b>Related CR:</b> 2024150002	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Plasma vanillyl mandelic acid increased	Approved After Suspension	Proposed LLT Plasma vanillyl mandelic acid increased	10091301 Current
			To PT Vanillyl mandelic acid increased	10091300
<b>MSSO Comment:</b> The proposal to add a new LLT Plasma vanillyl mandelic acid increased is approved as requested after suspension. Vanillylmandelic acid (VMA), a metabolic by-product of norepinephrine and epinephrine, can be used to detect neuroblastoma and other tumors of neural crest origin. Plasma vanillyl mandelic acid increased will be added as an LLT to a new PT Vanillyl mandelic acid increased linked to HLT Adrenal medulla tests. In a related change, the qualified existing PT Vanillyl mandelic acid urine increased will be demoted to LLT level under new PT Vanillyl mandelic acid increased. Furthermore, new PT Vanillyl mandelic acid will be added under HLT Adrenal medulla tests and existing PT Vanillyl mandelic acid urine will be demoted under new PT Vanillyl mandelic acid. In addition, new PT Vanillyl mandelic acid decreased will be added under HLT Adrenal medulla tests and existing PT Vanillyl mandelic acid urine decreased will be demoted under new PT Vanillyl mandelic acid decreased.				

<b>CR Number:</b> 2024157014		<b>Implementation Date:</b> 05-Jun-24	<b>Related CR:</b> 2024150002	
<a href="#">Change Requested</a>	Demote a PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
PT to merge	Vanillyl mandelic acid urine increased	Approved as Requested	PT to merge Vanillyl mandelic acid urine increased	10049528 Current
To PT	Vanillyl mandelic acid increased		To PT Vanillyl mandelic acid increased	10091300

MSSO  
Comment:

<b>CR Number:</b> 2024157016		<b>Implementation Date:</b> 05-Jun-24	<b>Related CR:</b> 2024150002	
<a href="#">Change Requested</a>	Demote a PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
PT to merge	Vanillyl mandelic acid urine	Approved as Requested	PT to merge Vanillyl mandelic acid urine	10050833 Current
To PT	Vanillyl mandelic acid		To PT Vanillyl mandelic acid	10091299

MSSO  
Comment:

# Detail Report

CR Number: 2024157015		Implementation Date: 05-Jun-24	Related CR: 2024150002	
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Vanillyl mandelic acid</i>	Approved as Requested	Proposed PT	
HLT primary	<i>Adrenal medulla tests</i>		<i>Vanillyl mandelic acid</i>	10091299
SOC primary	<i>Investigations</i>		HLT primary	
			<i>Adrenal medulla tests</i>	10001373
			SOC primary	
			<i>Investigations</i>	10022891

MSSO  
Comment:

CR Number: 2024157017		Implementation Date: 05-Jun-24	Related CR: 2024150002	
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Vanillyl mandelic acid decreased</i>	Approved as Requested	Proposed PT	
HLT primary	<i>Adrenal medulla tests</i>		<i>Vanillyl mandelic acid decreased</i>	10091298
SOC primary	<i>Investigations</i>		HLT primary	
			<i>Adrenal medulla tests</i>	10001373
			SOC primary	
			<i>Investigations</i>	10022891

MSSO  
Comment:

CR Number: 2024157018		Implementation Date: 05-Jun-24	Related CR: 2024150002	
<a href="#">Change Requested</a>	Demote a PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
PT to merge	<i>Vanillyl mandelic acid urine decreased</i>	Approved as Requested	PT to merge	
To PT	<i>Vanillyl mandelic acid decreased</i>		<i>Vanillyl mandelic acid urine decreased</i>	10050836 Current
			To PT	
			<i>Vanillyl mandelic acid decreased</i>	10091298

MSSO  
Comment:

# Detail Report

CR Number: 2024157013		Implementation Date: 05-Jun-24	Related CR: 2024150002	
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Vanillyl mandelic acid increased	Approved as Requested	Proposed PT	
HLT primary	Adrenal medulla tests		Vanillyl mandelic acid increased	10091300
SOC primary	Investigations		HLT primary	
			Adrenal medulla tests	10001373
			SOC primary	
			Investigations	10022891

MSSO  
Comment:

CR Number: 2024150005		Implementation Date: 03-Jun-24	Related CR: 2024150005	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	Hydroxybutyrate dehydrogenase increased	Rejected		

MSSO  
Comment: The proposal to add a new term Hydroxybutyrate dehydrogenase increased is not approved. There are several different enzymes including hydroxybutyrate dehydrogenase in their name, which catalyze for different reactions and are used in different clinical settings. For example, Serum  $\alpha$ -hydroxybutyrate dehydrogenase ( $\alpha$ -HBDH) is an isoenzyme of lactate dehydrogenase (LDH), and is used in the diagnosis of myocardial infarction or liver disease; while beta hydroxybutyrate dehydrogenase participates in the synthesis and degradation of ketone bodies and the metabolism of butyric acid. The proposed term will not be added based on its ambiguity.

CR Number: 2024151000		Implementation Date: 03-Jun-24	Related CR: 2024151000	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	Thoracic sympathectomy	Approved as Requested	Proposed LLT	
			Thoracic sympathectomy	10091248 Current
			To PT	
			Sympathectomy	10042738

MSSO  
Comment: The proposal to add a new term Thoracic sympathectomy is approved as requested. Patients with primary hyperhidrosis have the option of undergoing a surgical procedure called thoracoscopic sympathectomy. The procedure interrupts the sympathetic chain, preventing the nerve signals that originate in the spine from reaching and stimulating the sweat glands. Thoracic sympathectomy will be added as LLT under PT Sympathectomy.

# Detail Report

<b>CR Number:</b> 2024151001		<b>Implementation Date:</b> 03-Jun-24	<b>Related CR:</b> 2024151001	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	Left ventricular (LV) hypertrabeculation	Approved Not as Requested	Proposed LLT Left ventricular hypertrabeculation To PT Non-compaction cardiomyopathy	10091247 Current  10079253
MSSO Comment:	The proposal to add a new term Left ventricular (LV) hypertrabeculation is approved but not as requested. Left ventricular hypertrabeculation/non-compaction (LVHT) is a cardiac abnormality, characterised by >3 trabeculations apically to the papillary muscles and intertrabecular spaces. LVHT may occur with other cardiac abnormalities, heart failure, electrocardiographic abnormalities and neuromuscular disorders. Proposed term will be modified without acronym and added as LLT Left ventricular hypertrabeculation under PT Non-compaction cardiomyopathy aligned with existing synonym LLT Left ventricular noncompaction cardiomyopathy.			

<b>CR Number:</b> 2024151002		<b>Implementation Date:</b> 03-Jun-24	<b>Related CR:</b> 2024151002	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	Catamenial epilepsy	Approved as Requested	Proposed PT Catamenial epilepsy HLT primary Seizures and seizure disorders NEC SOC primary Nervous system disorders HLT secondary Menstruation and uterine bleeding NEC SOC secondary Reproductive system and breast disorders	10091246  10039912  10029205  10027335  10038604
MSSO Comment:	The proposal to add a new term Catamenial epilepsy is approved as requested. Catamenial epilepsy describes a worsening of seizures in relation to the menstrual cycle and may affect around 40% of women with epilepsy. Catamenial epilepsy will be added as new PT under primary HLT Seizures and seizure disorders NEC and secondary HLT Menstruation and uterine bleeding NEC.			

# Detail Report

<b>CR Number:</b> 2024151003		<b>Implementation Date:</b> 03-Jun-24	<b>Related CR:</b> 2024151003		
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed Term	Urinary syndrome	Rejected			

**MSSO Comment:** The proposal to add a new term Urinary syndrome is not approved. The proposed concept is not well established in medical literature and can only be found in other language (Ukrainian) references.

<b>CR Number:</b> 2024151004		<b>Implementation Date:</b> 03-Jun-24	<b>Related CR:</b> 2024151004		
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed Term	Partial anterior circulation infarct (PACI)	Approved Not as Requested	Proposed LLT Partial cerebral anterior circulation infarct To PT Cerebral infarction	10091249	Current  10008118

**MSSO Comment:** The proposal to add a new term Partial anterior circulation infarct (PACI) is approved but not as requested. Partial anterior circulation infarct is a type of cerebral infarction affecting part of the anterior circulation supplying one side of the brain. The proposed term will be modified without acronym, with qualifier and added as LLT Partial cerebral anterior circulation infarct under PT Cerebral infarction aligned with LLT Total anterior circulation infarct.

<b>CR Number:</b> 2024151005		<b>Implementation Date:</b> 03-Jun-24	<b>Related CR:</b> 2024151005		
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed Term	Unilateral sciatica	Rejected			

**MSSO Comment:** The proposal to add a new term Unilateral sciatica is not approved. Patients with sciatica usually experience unilateral pain in the lumbar spine. It is not possible to qualify every concept with laterality unless clinically significant. As well, the LLT R Sciatica has been in MedDRA since version 2.1.

# Detail Report

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<b>CR Number:</b> 2024151006		<b>Implementation Date:</b> 03-Jun-24	<b>Related CR:</b> 2024151006		
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed Term	<i>Bodily distress syndrome</i>	Approved as Requested	Proposed LLT <i>Bodily distress syndrome</i>	10091250	Current
			To PT <i>Somatic dysfunction</i>	10077554	

**MSSO Comment:** The proposal to add a new term Bodily distress syndrome is approved as requested. Bodily distress syndrome represents a new conceptualization around somatic dysfunctions in people who experience daily bothersome physical symptoms. Typical symptoms are headache, pains in the back, muscles or joints, stomach trouble, breathlessness, excessive fatigue and many more. Bodily distress syndrome will be added as LLT under PT Somatic dysfunction.

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<b>CR Number:</b> 2024151007		<b>Implementation Date:</b> 03-Jun-24	<b>Related CR:</b> 2024151007		
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed Term	<i>Hypersensitive c reactive protein increased</i>	Rejected			

**MSSO Comment:** The proposal to add a new term Hypersensitive c reactive protein increased is not approved. This concept already exists in LLT hs-CRP increased and LLT High-sensitivity C-reactive protein increased. For clinical and medical contexts, it is more accurate and appropriate to use the term "high-sensitivity C-reactive protein (hs-CRP)" when referring to this specific test.

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<b>CR Number:</b> 2024151009		<b>Implementation Date:</b> 04-Jun-24	<b>Related CR:</b> 2024151009		
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed LLT	<i>Basal joint arthritis</i>	Approved Not as Requested	Proposed LLT <i>Basal thumb arthritis</i>	10091253	Current
			To PT <i>Arthritis</i>	10003246	

**MSSO Comment:** The proposal to add a new LLT Basal joint arthritis is approved but not as requested. Basal thumb arthritis is common with aging and occurs when cartilage wears away in the carpometacarpal joint. The proposed term will be modified for greater clarity and added as LLT Basal thumb arthritis to the PT Arthritis.

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# Detail Report

<b>CR Number:</b> 2024151010		<b>Implementation Date:</b> 04-Jun-24	<b>Related CR:</b> 2024151010	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Hyaluronic acid injection</i>	Approved Not as Requested	Proposed PT <i>Hyaluronic acid injection</i>	10091252
			HLT primary <i>Therapeutic procedures NEC</i>	10027700
			SOC primary <i>Surgical and medical procedures</i>	10042613

**MSSO Comment:** The proposal to add a new LLT Hyaluronic acid injection is approved but not as requested. Hyaluronic acid injection is used to treat joint pain caused by osteoarthritis in patients. Hyaluronic acid injection is also used for cosmetic purposes. Hyaluronic acid injection will be added as PT to the HLT Therapeutic procedures NEC.

<b>CR Number:</b> 2024151011		<b>Implementation Date:</b> 04-Jun-24	<b>Related CR:</b> 2024151011	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Excisional biopsy</i>	Approved as Requested	Proposed LLT <i>Excisional biopsy</i>	10091254 Current
To PT	<i>Biopsy</i>		To PT <i>Biopsy</i>	10004720

**MSSO Comment:** The proposal to add a new LLT Excisional biopsy to PT Biopsy is approved as requested. An excisional biopsy is the procedure when the entire tumor is removed, in comparison to an incisional biopsy when only a portion of the tumor is removed.

<b>CR Number:</b> 2024151012		<b>Implementation Date:</b> 04-Jun-24	<b>Related CR:</b> 2024151012	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Sterilized partner</i>	Approved as Requested	Proposed LLT <i>Sterilized partner</i>	10091255 Current
			To PT <i>Sterilised partner</i>	10091251

**MSSO Comment:** The proposal to add a new LLT Sterilized partner is approved as requested. Living with a sterile partner is a social circumstance which may have implications in sexual life. The concept represents when a partner has undergone any procedure by which the partner is made incapable of reproduction. Sterilized partner will be added as LLT to a new PT Sterilised partner representing the British spelling of the concept. In a related change, PT Sterilised partner will be added to the HLT Sexuality issues.

# Detail Report

CR Number: 2024156001		Implementation Date: 04-Jun-24	Related CR: 2024151012	
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Sterilised partner</i>	Approved as Requested	Proposed PT	
HLT primary	<i>Sexuality issues</i>		<i>Sterilised partner</i>	10091251
SOC primary	<i>Social circumstances</i>		HLT primary	
			<i>Sexuality issues</i>	10040489
			SOC primary	
			<i>Social circumstances</i>	10041244

MSSO  
Comment:

CR Number: 2024151013		Implementation Date: 04-Jun-24	Related CR: 2024151013		
<a href="#">Change Requested</a>	Reassign Primary SOC	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed PT	<i>Dermatomyositis</i>	Approved as Requested	Proposed PT		
Old Primary SOC	<i>Skin and subcutaneous tissue disorders</i>		<i>Dermatomyositis</i>	10012503	
New Primary SOC	<i>Musculoskeletal and connective tissue disorders</i>		Old Primary SOC		
			<i>Skin and subcutaneous tissue disorders</i>	10040785	
			New Primary SOC		
			<i>Musculoskeletal and connective tissue disorders</i>	10028395	

MSSO  
Comment: The proposal to reassign the primary SOC of PT Dermatomyositis from current SOC Skin and subcutaneous tissue disorders to SOC Musculoskeletal and connective tissue disorders is approved as requested. Dermatomyositis is an immune-mediated myopathy, characterized by proximal skeletal muscle weakness and evidence of muscle inflammation, with additional association of a variety of characteristic skin manifestations. For alignment with other myositis subtypes the primary SOC allocation for PT Dermatomyositis will be changed from SOC Skin and subcutaneous tissue disorders to SOC Musculoskeletal and connective tissue disorders. In a related change, the primary link of PT Paraneoplastic dermatomyositis will be changed from SOC Skin and subcutaneous tissue disorders to SOC Musculoskeletal and connective tissue disorders.

# Detail Report

<b>CR Number:</b> 2024156003		<b>Implementation Date:</b> 04-Jun-24	<b>Related CR:</b> 2024151013	
<a href="#">Change Requested</a>	Reassign Primary SOC	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Paraneoplastic dermatomyositis</i>	Approved as Requested	Proposed PT	
Old Primary SOC	<i>Skin and subcutaneous tissue disorders</i>		<i>Paraneoplastic dermatomyositis</i>	10066267
New Primary SOC	<i>Musculoskeletal and connective tissue disorders</i>		Old Primary SOC	
			<i>Skin and subcutaneous tissue disorders</i>	10040785
			New Primary SOC	
			<i>Musculoskeletal and connective tissue disorders</i>	10028395

MSSO  
Comment:

<b>CR Number:</b> 2024151014		<b>Implementation Date:</b> 04-Jun-24	<b>Related CR:</b> 2024151014	
<a href="#">Change Requested</a>	Reassign Primary SOC	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Dermatomyositis</i>	Rejected		
Old Primary SOC	<i>Skin and subcutaneous tissue disorders</i>			
New Primary SOC	<i>Musculoskeletal and connective tissue disorders</i>			

MSSO  
Comment: The proposal to reassign the primary SOC of PT Dermatomyositis from current SOC Skin and subcutaneous tissue disorders to SOC Musculoskeletal and connective tissue disorders is not approved. The proposed change has been addressed in change request 2024151013.

<b>CR Number:</b> 2024152000		<b>Implementation Date:</b> 06-Jun-24	<b>Related CR:</b> 2024152000	
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Portosinusoidal vascular disease</i>	Rejected		

MSSO  
Comment: The proposal to add a new PT Portosinusoidal vascular disease is not approved. The proposed concept has been added as LLT Porto-sinusoidal vascular disorder in change request 2024135005. However, in a related change, the LLT Porto-sinusoidal vascular disorder will be promoted from PT Venooclusive liver disease to PT Level and placed under primary HLT Hepatic vascular disorders and to secondary HLT Portal hypertensions. The term "porto-sinusoidal vascular disorder" is proposed to fill the diagnostic gap represented by patients with histological lesions suggesting porto-sinusoidal vascular disorder without necessarily having portal hypertension. Moreover, this entity includes patients with a diagnosis of portal vein thrombosis and/or chronic liver disease, under the condition that cirrhosis is absent.

# Detail Report

CR Number: 2024158001		Implementation Date: 06-Jun-24	Related CR: 2024152000	
<a href="#">Change Requested</a>	Promote an LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Porto-sinusoidal vascular disorder</i>	Approved as Requested	Proposed LLT	
From PT	<i>Venoocclusive liver disease</i>		<i>Porto-sinusoidal vascular disorder</i>	10091148
HLT primary	<i>Hepatic vascular disorders</i>		From PT	
			<i>Venoocclusive liver disease</i>	10047216
			HLT primary	
			<i>Hepatic vascular disorders</i>	10019712
			SOC primary	
			<i>Hepatobiliary disorders</i>	10019805
			HLT secondary	
			<i>Portal hypertension</i>	10036201
			SOC secondary	
			<i>Vascular disorders</i>	10047065

MSSO  
Comment:

CR Number: 2024152001		Implementation Date: 04-Jun-24	Related CR: 2024152001	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Acute ischemic stroke</i>	Rejected		
To PT	<i>Ischaemic stroke</i>			

MSSO      The proposal to add a new LLT Acute ischemic stroke to PT Ischaemic stroke is not approved. By definition strokes are a heterogeneous group of disorders involving sudden, focal interruption of cerebral blood flow that causes neurologic deficit. As such, there is no need for the qualified "acute" term.

# Detail Report

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<b>CR Number:</b> 2024152002		<b>Implementation Date:</b> 05-Jun-24	<b>Related CR:</b> 2024152002		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed Term	<i>Osteoplasty</i>	Approved as Requested	Proposed PT <i>Osteoplasty</i>		10091271
			HLT primary <i>Bone therapeutic procedures NEC</i>		10006000
			SOC primary <i>Surgical and medical procedures</i>		10042613

**MSSO Comment:** The proposal to add a new term Osteoplasty is approved as requested. Osteoplasty is a surgical procedure for bone reshaping, either for removing protruding bony surfaces or by injecting bone cement or bone graft into a painful bone lesion, such as in painful bone metastasis which are refractory to conventional therapy. Osteoplasty will be added as a PT to the HLT Bone therapeutic procedures NEC.

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<b>CR Number:</b> 2024152003		<b>Implementation Date:</b> 05-Jun-24	<b>Related CR:</b> 2024152003		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed Term	<i>Wrist arthritis</i>	Approved as Requested	Proposed LLT <i>Wrist arthritis</i>		10091274 Current
			To PT <i>Arthritis</i>		10003246

**MSSO Comment:** The proposal to add a new term Wrist arthritis is approved as requested. In inflammatory or degenerative conditions, the wrist movements may be limited and painful. Wrist arthritis will be added as LLT to PT Arthritis.

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<b>CR Number:</b> 2024152004		<b>Implementation Date:</b> 05-Jun-24	<b>Related CR:</b> 2024152004		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed Term	<i>Periodic limb movements of sleep</i>	Rejected			

**MSSO Comment:** The proposal to add a new term Periodic limb movements of sleep is not approved. Please clarify the distinction between existing PT Periodic limb movement disorder and proposed term in more detail to justify as a separate concept. As well, your need for the proposed term.

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# Detail Report

CR Number: 2024152005		Implementation Date: 05-Jun-24	Related CR: 2024152005		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed Term	Metabolic dysfunction associated steatotic liver disease	Rejected			

MSSO Comment: The proposal to add a new term Metabolic dysfunction associated steatotic liver disease is not approved. The proposed concept exists in PT Metabolic dysfunction-associated steatohepatitis which was added in change request 2024043055 and will be available in version 27.1 in September 2024.

CR Number: 2024152006		Implementation Date: 05-Jun-24	Related CR: 2024152006		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed Term	Ear stones	Rejected			

MSSO Comment: The proposal to add a new term Ear stones is not approved. The proposed concept is represented in PT Otolithiasis.

CR Number: 2024152007		Implementation Date: 05-Jun-24	Related CR: 2024152007		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed Term	Fistulectomy	Approved as Requested	Proposed LLT Fistulectomy	10091273	Current
			To PT Fistula repair	10053697	

MSSO Comment: The proposal to add a new term Fistulectomy is approved as requested. Fistulectomy is a surgical procedure where a fistula is completely removed. Fistulectomy will be added as an LLT under PT Fistula repair. In a related change, the PT Fistulotomy - where a fistula is cut open but not completely removed - will be demoted under Fistula repair.

# Detail Report

CR Number: 2024157003		Implementation Date: 05-Jun-24	Related CR: 2024152007	
<a href="#">Change Requested</a>	Demote a PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
PT to merge	<i>Fistulotomy</i>	Approved as Requested	PT to merge	
To PT	<i>Fistula repair</i>		<i>Fistulotomy</i>	10079194 Current
			To PT	
			<i>Fistula repair</i>	10053697
MSSO Comment:				

CR Number: 2024152008		Implementation Date: 05-Jun-24	Related CR: 2024152008	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Onychoptosis</i>	Approved as Requested	Proposed LLT	
			<i>Onychoptosis</i>	10091272 Current
			To PT	
			<i>Onychomadesis</i>	10049274
MSSO Comment: The proposal to add a new term Onychoptosis is approved as requested. Onychoptosis is the periodic shedding and falling of one or more nails, in whole or part. It can be seen after fever, trauma, adverse reaction to medications, and in systemic illnesses including syphilis. Onychoptosis will be added as synonym LLT to PT Onychomadesis.				

# Detail Report

CR Number: 2024152009		Implementation Date: 05-Jun-24	Related CR: 2024152009	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	Mullerian duct cyst	Approved as Requested	Proposed PT Mullerian duct cyst	10091270
			HLT primary Male reproductive tract disorders congenital	10025517
			SOC primary Congenital, familial and genetic disorders	10010331
			HLT secondary Congenital male reproductive tract disorders	10010447
			SOC secondary Reproductive system and breast disorders	10038604

**MSSO Comment:** The proposal to add a new term Mullerian duct cyst is approved as requested. Müllerian duct cyst is a congenital anomaly that originates from an abnormality in the degradation of the Müllerian system and remnants of the Müllerian duct. It may originate from any part of the Müllerian ducts and may be associated with renal agenesis. Mullerian duct cyst will be added as PT with a primary link to HLT Male reproductive tract disorders congenital and secondary link to HLT Congenital male reproductive tract disorders.

CR Number: 2024152010		Implementation Date: 04-Jun-24	Related CR: 2024152010	
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Macular pigmentary changes	Approved as Requested	Proposed PT Macular pigmentary changes	10091257
			HLT primary Retinal structural change, deposit and degeneration	10038896
			SOC primary Eye disorders	10015919

**MSSO Comment:** The proposal to add a new PT Macular pigmentary changes is approved as requested. Macular pigmentary changes refer to alterations in the macula's pigmentation. These changes can be indicative of various retinal conditions and are often observed through retinal imaging techniques such as fundus photography, optical coherence tomography, or autofluorescence imaging. PT Macular pigmentary changes will be added to HLT Retinal structural change, deposit and degeneration. In a related change, PT Macular pigmentation will be demoted under new PT Macular pigmentary changes and then made non-current to avoid confusion as a normal finding.



# Detail Report

<b>CR Number:</b> 2024156004		<b>Implementation Date:</b> 04-Jun-24	<b>Related CR:</b> 2024152010	
<a href="#">Change Requested</a>	Demote a PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
PT to merge	Macular pigmentation	Approved as Requested	PT to merge	
To PT	Macular pigmentary changes		Macular pigmentation	10071041 Non-Current
			To PT	
			Macular pigmentary changes	10091257

MSSO  
Comment:

<b>CR Number:</b> 2024156005		<b>Implementation Date:</b> 04-Jun-24	<b>Related CR:</b> 2024152010	
<a href="#">Change Requested</a>	Change Status of LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
LLT to change	Macular pigmentation	Approved as Requested	LLT to change	
Status	Non-current		Macular pigmentation	10071041 Non-Current
			Status	
			Non-current	

MSSO  
Comment:

<b>CR Number:</b> 2024152011		<b>Implementation Date:</b> 04-Jun-24	<b>Related CR:</b> 2024152011	
<a href="#">Change Requested</a>	Link (move) an LLT to another PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Laser surgery	Approved Not as Requested	Proposed LLT	
From PT	Surgery		Laser surgery	10090499
To PT	Laser therapy		From PT	
			Surgery	10042609
			HLT primary	
			Therapeutic procedures NEC	10027700
			SOC primary	
			Surgical and medical procedures	10042613

MSSO  
Comment: The proposal to move the LLT Laser surgery from PT Surgery to PT Laser therapy is approved but not as requested. Laser surgery offers several benefits over traditional surgery, including precision, reduced invasiveness, less bleeding, and a lower risk of infection. Laser surgery will be promoted from PT Surgery to a PT level and added to HLT Therapeutic procedures NEC. In a related change, LLT YAG laser surgery will be moved from PT Laser therapy to PT Laser surgery.

# Detail Report

CR Number: 2024156006		Implementation Date: 04-Jun-24	Related CR: 2024152011	
<a href="#">Change Requested</a>	Link (move) an LLT to another PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	YAG laser surgery	Approved as Requested	Proposed LLT	
From PT	Laser therapy		YAG laser surgery	10070189 Current
To PT	Laser surgery		From PT	
			Laser therapy	10062035
			To PT	
			Laser surgery	10090499

MSSO  
Comment:

CR Number: 2024152012		Implementation Date: 04-Jun-24	Related CR: 2024152012	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	Agnathia	Approved as Requested	Proposed PT	
			Agnathia	10091259
			HLT primary	
			Musculoskeletal and connective tissue disorders of face, neck and jaw congenital	10028380
			SOC primary	
			Congenital, familial and genetic disorders	10010331
			HLT secondary	
			Musculoskeletal and connective tissue disorders of face, neck and jaw congenital	10028380
			SOC secondary	
			Musculoskeletal and connective tissue disorders	10028395

MSSO  
Comment: The proposal to add a new term Agnathia is approved as requested. Agnathia is a rare congenital condition characterized by the absence or severe underdevelopment of the lower jaw. This anomaly can lead to significant facial deformities and is often associated with other craniofacial abnormalities. Agnathia will be added as PT to bi-axial HLT Musculoskeletal and connective tissue disorders of face, neck and jaw congenital (primary SOC Congenital, familial and genetic disorders and secondary SOC Musculoskeletal and connective tissue disorders).

# Detail Report

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<b>CR Number:</b> 2024152013	<b>Implementation Date:</b> 04-Jun-24	<b>Related CR:</b> 2024152013	<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>
Proposed Term	EARS CRYSTALS	Rejected	

**MSSO Comment:** The proposal to add a new term EARS CRYSTALS is not approved. Ear crystals, also known as otoconia or otoliths, are tiny calcium carbonate structures located within the inner ear, specifically in the utricle and saccule of the vestibular system. These crystals play a crucial role in the body's ability to sense gravity and movement. They are a normal anatomical structure. For disorders related to otoliths, MedDRA includes LLT/PT Otolithiasis.

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<b>CR Number:</b> 2024152014	<b>Implementation Date:</b> 04-Jun-24	<b>Related CR:</b> 2024152014	<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>
Proposed Term	Mesenteric duplex ultrasound	Rejected	

**MSSO Comment:** The proposal to add a new term Mesenteric duplex ultrasound is not approved. To avoid the overpopulation of MedDRA, it is not feasible to accommodate terms for all specific anatomical locations for doppler ultrasound investigations.

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<b>CR Number:</b> 2024152015	<b>Implementation Date:</b> 04-Jun-24	<b>Related CR:</b> 2024152015	<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>
Proposed Term	Persistent Airflow Limitation	Rejected	

**MSSO Comment:** The proposal to add a new term Persistent Airflow Limitation is not approved. Persistent and chronic, although having different nuances in meaning are often used interchangeably. Please consider existing LLT Chronic airflow limitation. In a related change, LLT Chronic airflow limitation will be moved from PT Chronic obstructive pulmonary disease to PT Obstructive airways disorder in order to be represented under a broader concept.

# Detail Report

<b>CR Number:</b> 2024156007		<b>Implementation Date:</b> 04-Jun-24	<b>Related CR:</b> 2024152015	
<a href="#">Change Requested</a>	Link (move) an LLT to another PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	<i>Chronic airflow limitation</i>	Approved as Requested	Proposed LLT	
From PT	<i>Chronic obstructive pulmonary disease</i>		<i>Chronic airflow limitation</i>	10008828 Current
To PT	<i>Obstructive airways disorder</i>		From PT	
			<i>Chronic obstructive pulmonary disease</i>	10009033
			To PT	
			<i>Obstructive airways disorder</i>	10061877

MSSO  
Comment:

<b>CR Number:</b> 2024152016		<b>Implementation Date:</b> 04-Jun-24	<b>Related CR:</b> 2024152016	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>B-cell leukemia/lymphoma panel</i>	Approved as Requested	Proposed LLT	
			<i>B-cell leukemia/lymphoma panel</i>	10091267 Current
			To PT	
			<i>B-cell leukaemia/lymphoma panel</i>	10091264

MSSO  
Comment: The proposal to add a new term B-cell leukemia/lymphoma panel is approved as requested. B-cell leukemia/lymphoma panel is a blood test that looks for certain markers on the surface of B-lymphocytes for their immunophenotyping in order to help in the diagnose of leukemia or lymphoma. B-cell leukemia/lymphoma panel will be added as an LLT to the British English spelled new PT B-cell leukaemia/lymphoma panel. In a related change, PT B-cell leukaemia/lymphoma panel will be added under the HLT Cell marker analyses.

<b>CR Number:</b> 2024156008		<b>Implementation Date:</b> 04-Jun-24	<b>Related CR:</b> 2024152016	
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>B-cell leukaemia/lymphoma panel</i>	Approved as Requested	Proposed PT	
HLT primary	<i>Cell marker analyses</i>		<i>B-cell leukaemia/lymphoma panel</i>	10091264
SOC primary	<i>Investigations</i>		HLT primary	
			<i>Cell marker analyses</i>	10072981
			SOC primary	
			<i>Investigations</i>	10022891

MSSO  
Comment:

# Detail Report

CR Number: 2024152017		Implementation Date: 04-Jun-24	Related CR: 2024152017	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Sepsis-Associated Acute Kidney Injury</i>	Approved Not as Requested	Proposed PT	
			<i>Sepsis associated acute kidney injury</i>	10091260
			HLT primary	
			<i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i>	10040054
			SOC primary	
			<i>Infections and infestations</i>	10021881
			HLT secondary	
			<i>Renal failure and impairment</i>	10038443
			SOC secondary	
			<i>Renal and urinary disorders</i>	10038359

**MSSO Comment:** The proposal to add a new term Sepsis-Associated Acute Kidney Injury is approved but not as requested. Sepsis-associated acute kidney injury is common in critically ill patients and is strongly associated with adverse outcomes, including an increased risk of chronic kidney disease, cardiovascular events and death. The proposed term will be de-hyphenated and modified according to MedDRA capitalization conventions to be added as the PT Sepsis associated acute kidney injury with a primary link to HLT Sepsis, bacteraemia, viraemia and fungaemia NEC and a secondary link to the HLT Renal failure and impairment.

CR Number: 2024152018		Implementation Date: 04-Jun-24	Related CR: 2024152018	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Catheterisation of the auditory tube</i>	Approved Not as Requested	Proposed PT	
			<i>Auditory tube catheterisation</i>	10091258
			HLT primary	
			<i>Middle ear therapeutic procedures</i>	10027588
			SOC primary	
			<i>Surgical and medical procedures</i>	10042613

**MSSO Comment:** The proposal to add a new term Catheterisation of the auditory tube is approved but not as requested. Catheterisation of the auditory tube is a medical procedure during which a Hartmann cannula is inserted into the Eustachian tube. The special catheter has the appearance of a flexible metal tube, with a funnel-shaped expansion on it. Catheterisation of the auditory tube is performed for both diagnostic and therapeutic purposes. The proposed term will be modified and added in the natural word order as PT Auditory tube catheterisation to the HLT Middle ear therapeutic procedures. In a related change, the American English spelled counterpart LLT Auditory tube catheterization will also be added to new PT Auditory tube catheterisation.

# Detail Report

CR Number: 2024156009		Implementation Date: 04-Jun-24	Related CR: 2024152018		
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed LLT	Auditory tube catheterization	Approved as Requested	Proposed LLT		
To PT	Auditory tube catheterisation		Auditory tube catheterization	10091265	Current
			To PT		
			Auditory tube catheterisation	10091258	

MSSO  
Comment:

CR Number: 2024152019		Implementation Date: 04-Jun-24	Related CR: 2024152019		
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed Term	Dual-chamber rate-modulated (DDDR) pacing	Approved Not as Requested	Proposed LLT		
			Dual chamber rate modulated pacing	10091266	Current
			To PT		
			Pacemaker generated rhythm	10059831	

MSSO  
Comment:

The proposal to add a new term Dual-chamber rate-modulated (DDDR) pacing is approved but not as requested. Dual-chamber rate-modulated pacing is a mode that is programmed into a pacemaker for patients with atrioventricular block and sinus node dysfunction. During exercise, the pacemaker is capable of tracking not only the patient's intrinsic P wave but also the AV sequential sensor-indicated rate response. The proposed term will be de-hyphenated and modified according to MedDRA capitalization rules and added as the LLT Dual chamber rate modulated pacing to the PT Pacemaker generated rhythm.

CR Number: 2024152020		Implementation Date: 04-Jun-24	Related CR: 2024152020		
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed Term	Sextuple Bypass Surgery	Rejected			

MSSO  
Comment:

The proposal to add a new term Sextuple Bypass Surgery is not approved. Please use existing LLT Multiple vessel bypass for your scenario.

# Detail Report

<b>CR Number:</b> 2024152021		<b>Implementation Date:</b> 04-Jun-24	<b>Related CR:</b> 2024152021	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	Duraplasty	Approved as Requested	Proposed PT	
			Duraplasty	10091261
			HLT primary	
			Skull and brain therapeutic procedures	10040957
			SOC primary	
			Surgical and medical procedures	10042613

**MSSO Comment:** The proposal to add a new term Duraplasty is approved as requested. Duraplasty is a type of repair or expansion of dura when it has been cut open during surgery. It is often closed with another compatible soft tissue material taken from another part of the body. Duraplasty can also be constructed from inorganic material. Duraplasty will be added as PT under HLT Skull and brain therapeutic procedures.

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<b>CR Number:</b> 2024152022		<b>Implementation Date:</b> 04-Jun-24	<b>Related CR:</b> 2024152022	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Eyeball cerclage</i>	Approved as Requested	Proposed PT	
			<i>Eyeball cerclage</i>	10091262
			HLT primary	
			<i>Orbit and globe therapeutic procedures</i>	10031028
			SOC primary	
			<i>Surgical and medical procedures</i>	10042613

**MSSO Comment:** The proposal to add a new term Eyeball cerclage is approved as requested. Eyeball cerclage is a surgical procedure performed both for preventing retinal detachment in pathological conditions of the retina at particular risk of developing a detachment, and for the treatment of retinal detachment, when this has already occurred. It is performed by applying a solid band of silicone, around the eyeball, in order to bring the part closer to the detached retina, occlude any holes or breaks, and then repair the retinal detachment by restoring the retina back to its normal state of adhesion. Eyeball cerclage will be added as a PT under HLT Orbit and globe therapeutic procedures.

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# Detail Report

CR Number: 2024152023		Implementation Date: 04-Jun-24	Related CR: 2024152023		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed Term	<i>EUS-guided hepaticogastrostomy or hepaticogastrostomy</i>	Approved Not as Requested	Proposed LLT <i>EUS-guided hepaticogastrostomy</i>	10091268	Current
			To PT <i>Endoscopic ultrasound-guided hepaticogastrostomy</i>	10091263	

**MSSO**  
**Comment:** The proposal to add a new term EUS-guided hepaticogastrostomy or hepaticogastrostomy is approved but not as requested. Hepaticogastrostomy is the surgical creation of a communication between the hepatic duct and the stomach. Endoscopic Ultrasound (EUS)-guided hepaticogastrostomy is an option to treat obstructive jaundice when Endoscopic retrograde cholangiopancreatography (ERCP) drainage fails. These procedures represent alternatives to surgery and percutaneous transhepatic biliary drainage and have been made possible through the continuous development and improvement of EUS scopes and accessories. Proposed term will be modified by truncating and added as LLT EUS-guided hepaticogastrostomy under new PT Endoscopic ultrasound-guided hepaticogastrostomy. In a related change, the spelled-out term will be added as new PT Endoscopic ultrasound-guided hepaticogastrostomy under HLT Biliary tract and gallbladder therapeutic procedures.

CR Number: 2024156010		Implementation Date: 04-Jun-24	Related CR: 2024152023		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed PT	<i>Endoscopic ultrasound-guided hepaticogastrostomy</i>	Approved as Requested	Proposed PT <i>Endoscopic ultrasound-guided hepaticogastrostomy</i>	10091263	
HLT primary	<i>Biliary tract and gallbladder therapeutic procedures</i>		HLT primary <i>Biliary tract and gallbladder therapeutic procedures</i>	10004675	
SOC primary	<i>Surgical and medical procedures</i>		SOC primary <i>Surgical and medical procedures</i>	10042613	

**MSSO**  
**Comment:**



# Detail Report

<b>CR Number:</b> 2024152032		<b>Implementation Date:</b> 04-Jun-24	<b>Related CR:</b> 2024152032	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Parotid calcification	Approved Not as Requested	Proposed PT Parotid calcification	10091256
			HLT primary Salivary gland disorders NEC	10039407
			SOC primary Gastrointestinal disorders	10017947

**MSSO Comment:** The proposal to add a new LLT Parotid calcification is approved but not as requested. Parotid gland calcifications can be incidental findings on computed tomography and have been reported to be associated with chronic inflammatory conditions. Parotid calcification will be added as a PT to HLT Salivary gland disorders NEC.

<b>CR Number:</b> 2024152033		<b>Implementation Date:</b> 04-Jun-24	<b>Related CR:</b> 2024152033	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Maternal exposure via partner before pregnancy	Rejected		

**MSSO Comment:** The proposal to add a new LLT Maternal exposure via partner before pregnancy is not approved. The proposed term is a combination concept. Section 3.5 of the MedDRA Term Selection Points to Consider (MTS:PTC) document provides coding guidance. Please consider existing Maternal exposure term concepts in combination with partner/father exposure terms to capture your specific scenario.

<b>CR Number:</b> 2024152034		<b>Implementation Date:</b> 04-Jun-24	<b>Related CR:</b> 2024152034	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Maternal exposure via partner	Rejected		

**MSSO Comment:** The proposal to add a new LLT Maternal exposure via partner is not approved. The proposed term is a combination concept. Section 3.5 of the MedDRA Term Selection Points to Consider (MTS:PTC) document provides coding guidance. Please consider existing Maternal exposure term concepts in combination with partner/father exposure terms to capture your specific scenario.

# Detail Report

<b>CR Number:</b> 2024153000		<b>Implementation Date:</b> 05-Jun-24	<b>Related CR:</b> 2024153000		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed LLT	<i>Percutaneous occlusive balloon angioplasty with stenting</i>	Rejected			
To PT	<i>Stent placement</i>				

**MSSO Comment:** The proposal to add a new LLT Percutaneous occlusive balloon angioplasty with stenting to PT Stent placement is not approved. While proposed concept is an accepted abbreviation representing two techniques, the concepts exist in MedDRA and may be captured with combination coding. Please refer to Section 3.5 of the MedDRA Term Selection Points to Consider (MTS:PTC) document which defines these as "combination terms" and provides coding guidance.

<b>CR Number:</b> 2024153001		<b>Implementation Date:</b> 05-Jun-24	<b>Related CR:</b> 2024153001		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed PT	<i>Cardiothoracic ratio decreased</i>	Approved as Requested	Proposed PT		
HLT primary	<i>Cardiac imaging procedures</i>		<i>Cardiothoracic ratio decreased</i>		10091275
SOC primary	<i>Investigations</i>		HLT primary		
			<i>Cardiac imaging procedures</i>		10007574
			SOC primary		
			<i>Investigations</i>		10022891

**MSSO Comment:** The proposal to add a new PT Cardiothoracic ratio decreased to primary HLT Cardiac imaging procedures in SOC Investigations is approved as requested. Cardiothoracic ratio (CTR) is the ratio of the transverse diameter of the heart to the internal diameter of the chest at its widest point just above the level of the dome of the respiratory diaphragm, such as on radiographic examination. A decreased CTR is defined as <42%/0.42 when assessed on a PA chest radiograph and is often called small heart syndrome.

<b>CR Number:</b> 2024153002		<b>Implementation Date:</b> 05-Jun-24	<b>Related CR:</b> 2024153002		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Demote a PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
PT to merge	<i>Gonorrhoea</i>	Rejected			
To PT	<i>Gonococcal infection</i>				

**MSSO Comment:** The proposal to demote the PT Gonorrhoea under PT Gonococcal infection is not approved. Besides gonorrhoea, Neisseria gonorrhoeae infection or the concept PT Gonococcal infection, can lead to a variety of wider clinical symptoms and signs, such as arthritis or arthralgias, tenosynovitis, and multiple skin lesions. Gonorrhoea generally involves the penis, vagina, anus, or mouth and is appropriately placed at PT level.

# Detail Report

CR Number: 2024153008		Implementation Date: 05-Jun-24	Related CR: 2024153008	
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Dural arteriovenous fistula embolisation	Approved Not as Requested	Proposed LLT	
HLT primary	Vascular therapeutic procedures NEC		Arteriovenous fistula embolisation	10091278 Current
SOC primary	Surgical and medical procedures		To PT	
			Therapeutic embolisation	10057335
MSSO Comment:	The proposal to add a new PT Dural arteriovenous fistula embolisation to primary HLT Vascular therapeutic procedures NEC in SOC Surgical and medical procedures is approved but not as requested. Endovascular embolization is the most common form of treatment for an arteriovenous fistula. Arteriovenous fistula embolisation and the American spelled counterpart Arteriovenous fistula embolization will both be added as LLTs to PT Therapeutic embolisation.			

CR Number: 2024157004		Implementation Date: 05-Jun-24	Related CR: 2024153008	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Arteriovenous fistula embolization	Approved as Requested	Proposed LLT	
To PT	Therapeutic embolisation		Arteriovenous fistula embolization	10091279 Current
			To PT	
			Therapeutic embolisation	10057335
MSSO Comment:				

# Detail Report

CR Number: 2024153009		Implementation Date: 05-Jun-24	Related CR: 2024153009	
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Interface fluid syndrome	Approved as Requested	Proposed PT	
HLT primary	Eye and ear procedural complications		Interface fluid syndrome	10091276
SOC primary	Injury, poisoning and procedural complications		HLT primary	
			Eye and ear procedural complications	10015908
			SOC primary	
			Injury, poisoning and procedural complications	10022117
			HLT secondary	
			Corneal structural change, deposit and degeneration	10011049
			SOC secondary	
			Eye disorders	10015919

**MSSO Comment:** The proposal to add a new PT Interface fluid syndrome to primary HLT Eye and ear procedural complications in SOC Injury, poisoning and procedural complications is approved as requested. Interface fluid syndrome is a complication associated with laser in situ keratomileusis surgery where a fluid pocket in the corneal stroma decreases visual acuity. PT Interface fluid syndrome will also be linked to secondary HLT Corneal structural change, deposit and degeneration.

CR Number: 2024153010		Implementation Date: 05-Jun-24	Related CR: 2024153010	
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Coeliac artery dilatation	Rejected		
HLT primary	Gastrointestinal vascular malformations			
SOC primary	Gastrointestinal disorders			

**MSSO Comment:** The proposal to add a new PT Coeliac artery dilatation to primary HLT Gastrointestinal vascular malformations in SOC Gastrointestinal disorders is not approved. The proposed term seems to be a morphological description of an imaging test rather than a lesser degree of coeliac artery aneurysm.

# Detail Report

<b>CR Number:</b> 2024153011		<b>Implementation Date:</b> 05-Jun-24	<b>Related CR:</b> 2024153011	
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Filar lipoma</i>	Approved Not as Requested	Proposed LLT	
HLT primary	<i>Nervous system neoplasms benign NEC</i>		<i>Filar lipoma</i>	10091277 Current
SOC primary	<i>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</i>		To PT	
			<i>Spinal cord lipoma</i>	10064898
<b>MSSO Comment:</b> The proposal to add a new PT Filar lipoma to primary HLT Nervous system neoplasms benign NEC in SOC Neoplasms benign, malignant and unspecified (incl cysts and polyps) is approved but not as requested. The filum terminale is a slender, thread-like structure in the spinal cord. The filum terminale extends from the conus medullaris down to the coccyx and helps to anchor the spinal cord in place within the vertebral column. Lipoma of the filum terminale, also known as fatty filum terminale or filar lipoma, is a relatively common finding on imaging of the lumbar spine, and in most cases is an incidental finding of no clinical concern. Filar lipoma will be added as a sub-concept LLT to PT Spinal cord lipoma.				

<b>CR Number:</b> 2024153012		<b>Implementation Date:</b> 05-Jun-24	<b>Related CR:</b> 2024153012	
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Desquamative inflammatory vaginitis</i>	Approved as Requested	Proposed PT	
			<i>Desquamative inflammatory vaginitis</i>	10091280
			HLT primary	
			<i>Vaginal and vulval infections and inflammations</i>	10021886
			SOC primary	
			<i>Reproductive system and breast disorders</i>	10038604
<b>MSSO Comment:</b> The proposal to add a new term Desquamative inflammatory vaginitis is approved as requested. Desquamative inflammatory vaginitis is an uncommon chronic clinical syndrome of unknown etiology that usually occurs in perimenopausal females. Patients present with purulent vaginal discharge, vulvovaginal burning or irritation, dyspareunia, and vulvar and vaginal erythema. Desquamative inflammatory vaginitis is believed to be a relatively nonspecific form of immuno-inflammatory or reactive vaginitis that is multifactorial in etiology. Desquamative inflammatory vaginitis will be added as a PT to HLT Vaginal and vulval infections and inflammations.				

# Detail Report

<b>CR Number:</b> 2024153013		<b>Implementation Date:</b> 05-Jun-24	<b>Related CR:</b> 2024153013	
<u>Change Requested</u>	Add a New PT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Human papillomavirus reactivation	Approved as Requested	Proposed PT	
HLT primary	Papilloma viral infections		Human papillomavirus reactivation	10091281
SOC primary	Infections and infestations		HLT primary	
			Papilloma viral infections	10033724
			SOC primary	
			Infections and infestations	10021881

**MSSO Comment:** The proposal to add a new PT Human papillomavirus reactivation to primary HLT Papilloma viral infections in SOC Infections and infestations is approved as requested. Women with a history of cervical human papilloma virus infection may be at risk of reactivation of latent viral infection even in the absence of sexual activity, and this risk is higher in women with HIV infection.

<b>CR Number:</b> 2024153014		<b>Implementation Date:</b> 05-Jun-24	<b>Related CR:</b> 2024153014	
<u>Change Requested</u>	Add a New PT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Gastrointestinal autonomic nerve tumour	Approved as Requested	Proposed PT	
			Gastrointestinal autonomic nerve tumour	10091282
			HLT primary	
			Gastrointestinal neoplasms malignant NEC	10017992
			SOC primary	
			Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10029104
			HLT secondary	
			Gastrointestinal neoplasms NEC	10017993
			SOC secondary	
			Gastrointestinal disorders	10017947

**MSSO Comment:** The proposal to add a new PT Gastrointestinal autonomic nerve tumour is approved as requested. Gastrointestinal autonomic nerve tumors (GANT) are extremely rare tumors that are related to gastrointestinal autonomic nervous plexuses. They are distinguished from stromal tumors by their unique ultrastructural features. Hence, their diagnosis is usually made on electron microscopy and immunohistochemical analyses. Although they are apparently slow-growing tumors, they run an aggressive clinical course and often associated with poor prognosis which eventually leads to death. Gastrointestinal autonomic nerve tumour will be added as PT linked to primary HLT Gastrointestinal neoplasms malignant NEC and secondary HLT Gastrointestinal neoplasms NEC. In a related change the American English counterpart will be added as LLT Gastrointestinal autonomic nerve tumor to new PT Gastrointestinal autonomic nerve tumour.

# Detail Report

<b>CR Number:</b> 2024157005		<b>Implementation Date:</b> 05-Jun-24	<b>Related CR:</b> 2024153014		
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed LLT	Gastrointestinal autonomic nerve tumor	Approved as Requested	Proposed LLT		
To PT	Gastrointestinal autonomic nerve tumour		Gastrointestinal autonomic nerve tumor	10091288	Current
			To PT		
			Gastrointestinal autonomic nerve tumour	10091282	

MSSO  
Comment:

<b>CR Number:</b> 2024153015		<b>Implementation Date:</b> 05-Jun-24	<b>Related CR:</b> 2024153015		
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed LLT	Top surgery	Approved Not as Requested	Proposed LLT		
To PT	Transgender operation		Gender-affirming top surgery	10091287	Current
			To PT		
			Transgender operation	10064733	

MSSO  
Comment:

The proposal to add a new LLT Top surgery to PT Transgender operation is approved but not as requested. Top surgery is a term commonly used to refer to gender-affirming chest surgery for transgender individuals. This surgery is often part of the medical transition process for transgender people, helping them align their physical appearance with their gender identity. There are two main types of top surgery, chest masculinization surgery or "female-to-male" top surgery and breast augmentation surgery also referred to as "male-to-female" top surgery. The proposed term will be clarified for context and added as LLT Gender-affirming top surgery to PT Transgender operation.

<b>CR Number:</b> 2024153016		<b>Implementation Date:</b> 05-Jun-24	<b>Related CR:</b> 2024153016		
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed LLT	Sodium 18F-fluoride positron emission tomography	Approved as Requested	Proposed LLT		
To PT	Positron emission tomogram		Sodium 18F-fluoride positron emission tomography	10091286	Current
			To PT		
			Positron emission tomogram	10036220	

MSSO  
Comment:

The proposal to add a new LLT Sodium 18F-fluoride positron emission tomography to PT Positron emission tomogram is approved as requested. Sodium 18F-fluoride positron emission tomography is a positron emission tomography (PET) scan using a specific radiotracer. Sodium fluoride is a bone-seeking agent, which gets incorporated into hydroxyapatite in the bone by replacing hydroxyl groups. Therefore, this radiotracer is primarily used in imaging of bone metastases, providing a high level of detail on bone turnover and abnormalities.

# Detail Report

CR Number: 2024153017		Implementation Date: 05-Jun-24	Related CR: 2024153017		
<a href="#">Change Requested</a>	Add a New Term	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed Term	15q21.3q22.2 deletion syndrome	Rejected			

MSSO      The proposal to add a new term 15q21.3q22.2 deletion syndrome is not approved. MedDRA cannot accommodate such specific microdeletions as deletions may span several bands. As well, we need details on the phenotype of such affected individuals. In addition, please propose a broader concept for such genetic alterations.

Comment:

CR Number: 2024153018		Implementation Date: 05-Jun-24	Related CR: 2024153018		
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed PT	Ice pack test	Approved as Requested	Proposed PT		
			Ice pack test	10091283	
			HLT primary		
			Neurologic diagnostic procedures	10029285	
			SOC primary		
			Investigations	10022891	

MSSO      The proposal to add a new PT Ice pack test is approved as requested. The ice pack test is a simple and non-invasive diagnostic procedure used primarily to assess and help diagnose myasthenia gravis, a neuromuscular disorder characterized by weakness and rapid fatigue of voluntary muscles. The test is particularly useful in cases of ptosis. Cold temperatures can inhibit the activity of acetylcholinesterase, the enzyme that breaks down acetylcholine at the neuromuscular junction. Ice pack test will be added as a PT linked to HLT Neurologic diagnostic procedures.

Comment:



# Detail Report

CR Number: 2024153019		Implementation Date: 05-Jun-24	Related CR: 2024153019	
<u>Change Requested</u>	Add a New PT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Adrenal-renal fusion anomaly	Approved as Requested	Proposed PT	
			Adrenal-renal fusion anomaly	10091285
			HLT primary	
			Adrenal disorders congenital	10001349
			SOC primary	
			Congenital, familial and genetic disorders	10010331
			HLT secondary	
			Adrenal gland disorders NEC	10001354
			SOC secondary	
			Endocrine disorders	10014698

MSSO  
Comment: The proposal to add a new PT Adrenal-renal fusion anomaly is approved as requested. Adrenal-renal fusion is a rare entity wherein the capsule of the adrenal gland is fused to the kidney. The condition is usually found incidentally and has no clinical significance. Adrenal-renal fusion anomaly will be added as PT linked to primary HLT Adrenal disorders congenital, secondary HLT Adrenal gland disorders NEC and secondary HLT Renal structural abnormalities and trauma.

CR Number: 2024157006		Implementation Date: 05-Jun-24	Related CR: 2024153019	
<u>Change Requested</u>	Link a PT to a HLT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Adrenal-renal fusion anomaly	Approved as Requested	Proposed PT	
To HLT	Renal structural abnormalities and trauma		Adrenal-renal fusion anomaly	10091285
			To HLT	
			Renal structural abnormalities and trauma	10038529

MSSO  
Comment:

# Detail Report

<b>CR Number:</b> 2024153020		<b>Implementation Date:</b> 05-Jun-24	<b>Related CR:</b> 2024153020	
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Functional status test</i>	Approved Not as Requested	Proposed PT <i>Activities of daily living assessment</i>	10091284
			HLT primary <i>Investigations NEC</i>	10022892
			SOC primary <i>Investigations</i>	10022891

**MSSO Comment:** The proposal to add a new PT Functional status test is approved but not as requested. Tests for Activities of Daily Living (ADLs) are used to assess an individual's ability to perform basic self-care tasks and more complex activities necessary for independent living. These tests are essential in various settings, including clinical, rehabilitation, and geriatric care, to determine the level of assistance required. The proposed term will be modified for specificity and added as PT Activities of daily living assessment linked to HLT Investigations NEC.

<b>CR Number:</b> 2024153021		<b>Implementation Date:</b> 05-Jun-24	<b>Related CR:</b> 2024153021	
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Arrhythmia induced cardiomyopathy</i>	Approved Not as Requested	Proposed PT <i>Arrhythmia induced cardiomyopathy</i>	10091289
HLT primary	<i>Cardiomyopathies</i>		HLT primary <i>Cardiomyopathies</i>	10007635
SOC primary	<i>Cardiac disorders</i>		SOC primary <i>Cardiac disorders</i>	10007541

**MSSO Comment:** The proposal to add a new PT Arrhythmia induced cardiomyopathy to primary HLT Cardiomyopathies in SOC Cardiac disorders is approved but not as requested. Arrhythmias frequently accompany heart failure and left ventricular dysfunction. Tachycardias, atrial fibrillation, and premature ventricular contractions can induce a reversible form of dilated cardiomyopathy known as arrhythmia-induced (AiCM). Proposed term will be modified for spelling and added as PT Arrhythmia induced cardiomyopathy under HLT Cardiomyopathies. In a related change, PT Tachycardia induced cardiomyopathy will be demoted under PT Arrhythmia induced cardiomyopathy.

# Detail Report

<b>CR Number:</b> 2024157007		<b>Implementation Date:</b> 05-Jun-24	<b>Related CR:</b> 2024153021	
<a href="#">Change Requested</a>	Demote a PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
PT to merge	<i>Tachycardia induced cardiomyopathy</i>	Approved as Requested	PT to merge	
To PT	<i>Arrhythmia induced cardiomyopathy</i>		<i>Tachycardia induced cardiomyopathy</i>	10074269 Current
			To PT	
			<i>Arrhythmia induced cardiomyopathy</i>	10091289

MSSO  
Comment:

<b>CR Number:</b> 2024153022		<b>Implementation Date:</b> 05-Jun-24	<b>Related CR:</b> 2024153022	
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Prurigo strophulus</i>	Approved Not as Requested	Proposed PT	
HLT primary	<i>Allergic conditions NEC</i>		<i>Prurigo strophulus</i>	10091291
SOC primary	<i>Immune system disorders</i>		HLT primary	
			<i>Dermatitis and eczema</i>	10012435
			SOC primary	
			<i>Skin and subcutaneous tissue disorders</i>	10040785
			HLT secondary	
			<i>Allergic conditions NEC</i>	10027654
			SOC secondary	
			<i>Immune system disorders</i>	10021428

MSSO  
Comment: The proposal to add a new PT Prurigo strophulus to primary HLT Allergic conditions NEC in SOC Immune system disorders is approved but not as requested. Prurigo strophulus is an inflammatory dermatosis related to a delayed hypersensitivity reaction to arthropod bites, occurring mainly in children. Papule-vesicle lesions are the most frequent signs. It is usually found in exposed areas of the body. Prurigo strophulus will be added as new PT under primary HLT Dermatitis and eczema and secondary HLT Allergic conditions NEC.

# Detail Report

CR Number: 2024153023		Implementation Date: 05-Jun-24	Related CR: 2024153023	
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Metabolic bone disease of prematurity</i>	Approved Not as Requested	Proposed PT	
			<i>Neonatal metabolic bone disease</i>	10091290
			HLT primary	
			<i>Metabolic bone disorders</i>	10027425
			SOC primary	
			<i>Musculoskeletal and connective tissue disorders</i>	10028395
			HLT secondary	
			<i>Neonatal metabolic and endocrine disorders</i>	10028961
			SOC secondary	
			<i>Pregnancy, puerperium and perinatal conditions</i>	10036585

MSSO  
Comment: The proposal to add a new PT Metabolic bone disease of prematurity is approved but not as requested. Bone mineralization begins during embryonic phase of human development, but the large part of this process occurs in the third trimester of gestation, when the 80% of the mineral content is stored. Metabolic bone disease (MBD) of prematurity is a multifactorial disorder commonly observed in very low birth weight newborns, with a greater incidence in those of extremely low birth weight. MBD is characterized by biochemical and radiological findings related to bone demineralization. Proposed term will be modified for better alignment and added as PT Neonatal metabolic bone disease under primary HLT Metabolic bone disorders, secondary HLT Neonatal metabolic and endocrine disorders and secondary HLT Bone metabolism disorders. In a related change, Metabolic bone disease of prematurity will be added as LLT under new PT Neonatal metabolic bone disease.

CR Number: 2024157008		Implementation Date: 05-Jun-24	Related CR: 2024153023	
<a href="#">Change Requested</a>	Link a PT to a HLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Neonatal metabolic bone disease</i>	Approved as Requested	Proposed PT	
To HLT	<i>Bone metabolism disorders</i>		<i>Neonatal metabolic bone disease</i>	10091290
			To HLT	
			<i>Bone metabolism disorders</i>	10005992

MSSO  
Comment:

# Detail Report

CR Number: 2024157009		Implementation Date: 05-Jun-24	Related CR: 2024153023		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed LLT	Metabolic bone disease of prematurity	Approved as Requested	Proposed LLT		
To PT	Neonatal metabolic bone disease		Metabolic bone disease of prematurity	10091294	Current
			To PT		
			Neonatal metabolic bone disease	10091290	

MSSO  
Comment:

CR Number: 2024153024		Implementation Date: 05-Jun-24	Related CR: 2024153024		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New PT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed PT	WT1 gene analysis	Approved Not as Requested	Proposed LLT		
HLT primary	Gene analyses		WT1 gene analysis	10091297	Current
SOC primary	Investigations		To PT		
			Wilms' tumour gene analysis	10091295	

MSSO  
Comment: The proposal to add a new PT WT1 gene analysis to primary HLT Gene analyses in SOC Investigations is approved but not as requested. The WT1 gene, located on chromosome 11p13, plays a critical role in normal development and cell differentiation, particularly in the genitourinary system and hematopoietic system. Mutations or dysregulation of the WT1 gene have been implicated in various diseases. WT1 gene analysis will be added as an LLT to new PT Wilms' tumour gene analysis. In a related change PT Wilms' tumour gene analysis will be added to HLT Gene analyses. Furthermore, the American English spelled counterpart LLT Wilms' tumor gene analysis will be added to PT Wilms' tumour gene analysis.

CR Number: 2024157011		Implementation Date: 05-Jun-24	Related CR: 2024153024		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed LLT	Wilms' tumor gene analysis	Approved as Requested	Proposed LLT		
To PT	Wilms' tumour gene analysis		Wilms' tumor gene analysis	10091296	Current
			To PT		
			Wilms' tumour gene analysis	10091295	

MSSO  
Comment:

# Detail Report

<b>CR Number:</b> 2024157010		<b>Implementation Date:</b> 05-Jun-24	<b>Related CR:</b> 2024153024	
<u>Change Requested</u>	Add a New PT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Wilms' tumour gene analysis</i>	Approved as Requested	Proposed PT	
HLT primary	<i>Gene analyses</i>		<i>Wilms' tumour gene analysis</i>	10091295
SOC primary	<i>Investigations</i>		HLT primary	
			<i>Gene analyses</i>	10071950
			SOC primary	
			<i>Investigations</i>	10022891

MSSO  
Comment:

<b>CR Number:</b> 2024153025		<b>Implementation Date:</b> 05-Jun-24	<b>Related CR:</b> 2024153025	
<u>Change Requested</u>	Add a New PT	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Urinary tract dilatation</i>	Approved Not as Requested	Proposed PT	
			<i>Foetal urinary tract dilatation</i>	10091292
			HLT primary	
			<i>Urinary tract signs and symptoms NEC</i>	10046591
			SOC primary	
			<i>Renal and urinary disorders</i>	10038359
			HLT secondary	
			<i>Foetal complications NEC</i>	10016850
			SOC secondary	
			<i>Pregnancy, puerperium and perinatal conditions</i>	10036585

MSSO  
Comment: The proposal to add a new PT Urinary tract dilatation is approved but not as requested. Urinary tract dilatation, which refers to the abnormal dilation of the urinary collection system, is the most common finding on prenatal ultrasound and presents with varying severity, presentation, etiology, and prognosis. Prenatal classification and risk stratification aim to prevent postnatal complications, such as urinary tract infections and further kidney dysfunction. The proposed term will be modified for clarity and added as PT Foetal urinary tract dilatation under primary HLT Urinary tract signs and symptoms NEC and secondary HLT Foetal complications NEC. In a related change, the American English spelled counterpart LLT Fetal urinary tract dilatation will be added to new PT Foetal urinary tract dilatation.

# Detail Report

CR Number: 2024157012		Implementation Date: 05-Jun-24	Related CR: 2024153025	
<a href="#">Change Requested</a>	Add a New LLT	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed LLT	Fetal urinary tract dilatation	Approved as Requested	Proposed LLT	10091293 Current
To PT	Foetal urinary tract dilatation		Fetal urinary tract dilatation	
			To PT	
			Foetal urinary tract dilatation	10091292

MSSO  
Comment:

CR Number: 2024155000		Implementation Date: 06-Jun-24	Related CR: 2024155000	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Bell's palsy	Approved Not as Requested	Proposed PT	10004223
To SMQ	Immune-mediated/autoimmune disorders (SMQ)		Bell's palsy	
Term scope	Narrow		To SMQ	
			Immune-mediated/autoimmune disorders (SMQ)	20000236
			Term scope	
			Broad	
			Term_category	
			A	
			Term_weight	
			0	

MSSO  
Comment: The proposal to add PT Bell's palsy to Immune-mediated/autoimmune disorders (SMQ) as a narrow term is approved but not as requested. Bell's palsy, although initially reported as idiopathic, is considered strongly associated with viral infections, especially herpes simplex. However, there are cases attributed to an immune-mediated pathogenesis, and of these, there are some associated with the administration of vaccines, especially influenza. The appendix to the second inclusion criterion for this SMQ establishes that immune-mediated cranial neuropathies should be included in the broad scope. PT Bell's palsy will be added to Immune-mediated/autoimmune disorders (SMQ) in the Broad scope.

# Detail Report

CR Number: 2024156002		Implementation Date: 06-Jun-24	Related CR: 2024156002	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Facial paralysis	Approved Not as Requested	Proposed PT	
To SMQ	Immune-mediated/autoimmune disorders (SMQ)		Facial paralysis	10016062
Term scope	Narrow		To SMQ	
			Immune-mediated/autoimmune disorders (SMQ)	20000236
			Term scope	
			Broad	
			Term_category	
			A	
			Term_weight	
			0	
MSSO Comment:	The proposal to add PT Facial paralysis to Immune-mediated/autoimmune disorders (SMQ) as a narrow term is approved but not as requested. Facial paralysis has multiple etiologies, one of which is Bell's palsy, which in turn is associated, in some cases, with an immune-mediated reaction following the administration of vaccines. Paralytic or pathetic disorders associated with cranial nerves appear within the broad scope of this SMQ. This is also in accordance with the appendix of its second inclusion criterion. PT Facial paralysis will be added to Immune-mediated/autoimmune disorders (SMQ) in the Broad scope.			

CR Number: 2024180001		Implementation Date: 10-Jul-24	Related CR: 2024180001	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Procedural pancreatitis	Approved as Requested	Proposed PT	
To SMQ	Acute pancreatitis (SMQ)		Procedural pancreatitis	10091205
Term scope	Narrow		To SMQ	
			Acute pancreatitis (SMQ)	20000022
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	
MSSO Comment:	The proposal to add PT Procedural pancreatitis to Acute pancreatitis (SMQ) as a narrow term is approved as requested. This PT fits the inclusion criteria for this SMQ. Procedural pancreatitis is a form of acute pancreatitis.			



# Detail Report

CR Number: 2024180003		Implementation Date: 01-Jul-24	Related CR: 2024180003	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Gastrointestinal autonomic nerve tumour	Approved as Requested	Proposed PT	
To SMQ	Non-haematological malignant tumours (SMQ)		Gastrointestinal autonomic nerve tumour	10091282
Term scope	Narrow		To SMQ	
			Non-haematological malignant tumours (SMQ)	20000228
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	
MSSO Comment:	The proposal to add PT Gastrointestinal autonomic nerve tumour to Non-haematological malignant tumours (SMQ) as a narrow term is approved as requested. Gastrointestinal autonomic nerve tumors are extremely rare tumors that are related to gastrointestinal autonomic nervous plexuses. They are distinguished from stromal tumors by their unique ultrastructural features. Hence, their diagnosis is usually made on electron microscopy and immunohistochemical analyses. Although they are apparently slow-growing tumors, they run an aggressive clinical course and are often associated with poor prognosis which eventually leads to death. The term matches the inclusion criteria of the Non-haematological malignant tumours (SMQ) which only has narrow search terms.			

CR Number: 2024180004		Implementation Date: 01-Jul-24	Related CR: 2024180004	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Myoepithelial carcinoma of salivary gland	Approved as Requested	Proposed PT	
To SMQ	Non-haematological malignant tumours (SMQ)		Myoepithelial carcinoma of salivary gland	10091222
Term scope	Narrow		To SMQ	
			Non-haematological malignant tumours (SMQ)	20000228
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	
MSSO Comment:	The proposal to add PT Myoepithelial carcinoma of salivary gland to Non-haematological malignant tumours (SMQ) as a narrow term is approved as requested. Myoepithelial carcinoma is an invasive malignant salivary gland neoplasm that is almost exclusively composed of myoepithelial cells. Myoepithelial carcinoma may arise de novo or within a pre-existing pleomorphic adenoma and is the second most common histological subtype of carcinoma excluding pleomorphic adenoma. Myoepithelial carcinoma of salivary gland matches the inclusion criteria and will be added to Non-haematological malignant tumours (SMQ) which only has narrow search terms.			

# Detail Report

CR Number: 2024180005		Implementation Date: 01-Jul-24	Related CR: 2024180005	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Neuroendocrine tumour of the thymus	Approved as Requested	Proposed PT	
To SMQ	Non-haematological malignant tumours (SMQ)		Neuroendocrine tumour of the thymus	10091079
Term scope	Narrow		To SMQ	
			Non-haematological malignant tumours (SMQ)	20000228
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	
MSSO Comment:	The proposal to add PT Neuroendocrine tumour of the thymus to Non-haematological malignant tumours (SMQ) as a narrow term is approved as requested. Thymic neuroendocrine tumors, otherwise known as thymic carcinoid tumors, are uncommon primary thymic neoplasms with neuroendocrine differentiation that generally present as a mass within the anterior mediastinum. As the intermediate and high-grade variants are considered malignant, Neuroendocrine tumour of the thymus will be added to Non-haematological malignant tumours (SMQ) which only has narrow terms.			

CR Number: 2024180006		Implementation Date: 01-Jul-24	Related CR: 2024180006	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Radioactive seed localisation	Approved as Requested	Proposed PT	
To SMQ	Malignancy related therapeutic and diagnostic procedures (SMQ)		Radioactive seed localisation	10091085
Term scope	Narrow		To SMQ	
			Malignancy related therapeutic and diagnostic procedures (SMQ)	20000093
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	
MSSO Comment:	The proposal to add PT Radioactive seed localisation to Malignancy related therapeutic and diagnostic procedures (SMQ) as a narrow term is approved as requested. The radioactive seed localization is an intraoperative localization technique used in many types of cancer surgery such as breast cancer conservative surgery. The technique uses a radioactive seed placed in the center of the target prior to removal surgery. When the removal occurs, the physician uses a radiation detector to locate and remove the seed and surrounding tissue. Radioactive seed localisation matches the inclusion criteria of Malignancy related therapeutic and diagnostic procedures (SMQ) which only has narrow search terms. The term will be placed in parallel to PT Fiducial marker placement.			

# Detail Report

CR Number: 2024180007		Implementation Date: 01-Jul-24	Related CR: 2024180007	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Scapulectomy	Approved as Requested	Proposed PT	
To SMQ	Malignancy related therapeutic and diagnostic procedures (SMQ)		Scapulectomy	10091226
Term scope	Narrow		To SMQ	
			Malignancy related therapeutic and diagnostic procedures (SMQ)	20000093
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	

**MSSO Comment:** The proposal to add PT Scapulectomy to Malignancy related therapeutic and diagnostic procedures (SMQ) as a narrow term is approved as requested. Scapulectomy and limb-salvage surgery are indicated for low and high-grade tumors of the scapula and soft-tissue sarcomas that secondarily invade the bone. Scapulectomy matches the inclusion criteria of the Malignancy related therapeutic and diagnostic procedures (SMQ) and will be added in line with other terms like e.g. Gastrectomy. This SMQ includes only narrow search terms.

CR Number: 2024180008		Implementation Date: 01-Jul-24	Related CR: 2024180008	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Dysfunctional tear syndrome	Approved as Requested	Proposed PT	
To SMQ	Corneal disorders (SMQ)		Dysfunctional tear syndrome	10091181
Term scope	Broad		To SMQ	
			Corneal disorders (SMQ)	20000156
			Term scope	
			Broad	
			Term_category	
			A	
			Term_weight	
			0	

**MSSO Comment:** The proposal to add PT Dysfunctional tear syndrome to Corneal disorders (SMQ) as a broad term is approved as requested. Dysfunctional tear syndrome represents any alteration in the quantity and/or quality of the tear film. It is a chronic condition with multiple subtypes that include dry eye disease and associated tear film disorders. The term will be added to the broad scope of the Corneal disorders (SMQ) aligned with PT Tear film instability.

# Detail Report

CR Number: 2024180009		Implementation Date: 04-Jul-24	Related CR: 2024180009	
<u>Change Requested</u>	Add term to SMQ	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Interface fluid syndrome	Approved as Requested	Proposed PT	
To SMQ	Corneal disorders (SMQ)		Interface fluid syndrome	10091276
Term scope	Broad		To SMQ	
			Corneal disorders (SMQ)	20000156
			Term scope	
			Broad	
			Term_category	
			A	
			Term_weight	
			0	

**MSSO Comment:** The proposal to add PT Interface fluid syndrome to Corneal disorders (SMQ) as a broad term is approved as requested. Interface fluid syndrome is a complication associated with laser in situ keratomileusis surgery where a fluid pocket in the corneal stroma decreases visual acuity. Interface fluid syndrome will be added to the broad scope of Corneal disorders (SMQ) in line with other PTs like PT Ocular procedural complication and PT Thermal burns of eye.

CR Number: 2024180010		Implementation Date: 04-Jul-24	Related CR: 2024180010	
<u>Change Requested</u>	Add term to SMQ	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Eyeball cerclage	Approved as Requested	Proposed PT	
To SMQ	Retinal disorders (SMQ)		Eyeball cerclage	10091262
Term scope	Narrow		To SMQ	
			Retinal disorders (SMQ)	20000158
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	

**MSSO Comment:** The proposal to add PT Eyeball cerclage to Retinal disorders (SMQ) as a narrow term is approved as requested. Eyeball cerclage is a surgical procedure performed both for preventing retinal detachment in pathological conditions of the retina at particular risk of developing a detachment, and for the treatment of retinal detachment, when this has already occurred. It is performed by applying a solid band of silicone, around the eyeball, in order to bring the part closer to the detached retina, occlude any holes or breaks, and then repair the retinal detachment by restoring the retina back to its normal state of adhesion. Eyeball cerclage will be added to the narrow scope of the Retinal disorders (SMQ) aligned with PT Retinal laser coagulation.

# Detail Report

CR Number: 2024180011		Implementation Date: 04-Jul-24	Related CR: 2024180011	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Macular pigmentary changes	Approved as Requested	Proposed PT	
To SMQ	Retinal disorders (SMQ)		Macular pigmentary changes	10091257
Term scope	Narrow		To SMQ	
			Retinal disorders (SMQ)	20000158
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	

**MSSO Comment:** The proposal to add PT Macular pigmentary changes to Retinal disorders (SMQ) as a narrow term is approved as requested. Macular pigmentary changes refer to alterations in the macula's pigmentation. These changes can be indicative of various retinal conditions and are often observed through retinal imaging techniques such as fundus photography, optical coherence tomography, or autofluorescence imaging. The term matches the inclusion criterion: Terms relating to the macula and will be added to the narrow scope of the Retinal disorders (SMQ).

CR Number: 2024180012		Implementation Date: 04-Jul-24	Related CR: 2024180012	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Retinectomy	Approved as Requested	Proposed PT	
To SMQ	Retinal disorders (SMQ)		Retinectomy	10091084
Term scope	Narrow		To SMQ	
			Retinal disorders (SMQ)	20000158
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	

**MSSO Comment:** The proposal to add PT Retinectomy to Retinal disorders (SMQ) as a narrow term is approved as requested. Retinectomy refers to the excision of the retina. During retinectomy, the complete peripheral retina may be excised, leaving the central retina untouched. Excising only the peripheral retina also prevents postoperative proliferation and traction. Retinectomy will be added to the narrow scope of Retinal disorders (SMQ) aligned with e.g. PT Vitrectomy.

# Detail Report

CR Number: 2024180013		Implementation Date: 04-Jul-24	Related CR: 2024180013	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Lupus retinopathy</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Retinal disorders (SMQ)</i>		<i>Lupus retinopathy</i>	10091210
Term scope	<i>Narrow</i>		To SMQ	
			<i>Retinal disorders (SMQ)</i>	20000158
			Term scope	
			<i>Narrow</i>	
			Term_category	
			A	
			Term_weight	
			0	

**MSSO Comment:** The proposal to add PT Lupus retinopathy to Retinal disorders (SMQ) as a narrow term is approved as requested. Retinal vasculitis is an under-recognized manifestation of systemic lupus erythematosus (SLE). Mild and visually nonthreatening manifestations are common, consisting of cotton-wool spots with or without hemorrhages. They are observed in 3 to 30 percent of ambulatory and hospitalized patients with SLE, respectively. Lupus retinopathy meets the inclusion criteria and will be added to the narrow scope of Retinal disorders (SMQ).

CR Number: 2024180014		Implementation Date: 04-Jul-24	Related CR: 2024180014	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Nikolsky's sign positive</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Hypersensitivity (SMQ)</i>		<i>Nikolsky's sign positive</i>	10091102
Term scope	<i>Narrow</i>		To SMQ	
			<i>Hypersensitivity (SMQ)</i>	20000214
			Term scope	
			<i>Narrow</i>	
			Term_category	
			A	
			Term_weight	
			0	

**MSSO Comment:** The proposal to add PT Nikolsky's sign positive to Hypersensitivity (SMQ) as a narrow term is approved as requested. Nikolsky's sign is a clinical dermatological examination technique used to diagnose certain skin conditions, particularly pemphigus vulgaris and other blistering disorders. When Nikolsky's sign is positive, gentle lateral pressure on apparently normal-looking skin causes separation of the epidermis from the dermis. The demoted non-current PT Nikolsky's sign was part of the narrow scope of the Hypersensitivity (SMQ).

# Detail Report

CR Number: 2024180015		Implementation Date: 04-Jul-24	Related CR: 2024180015	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Sepsis associated acute kidney injury</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Toxic-septic shock conditions (SMQ)</i>		<i>Sepsis associated acute kidney injury</i>	10091260
Term scope	<i>Broad</i>		To SMQ	
			<i>Toxic-septic shock conditions (SMQ)</i>	20000070
			Term scope	
			<i>Broad</i>	
			Term_category	
			A	
			Term_weight	
			0	

**MSSO Comment:** The proposal to add PT Sepsis associated acute kidney injury to Toxic-septic shock conditions (SMQ) as a broad term is approved as requested. Sepsis-associated acute kidney injury is common in critically ill patients and is strongly associated with adverse outcomes, including an increased risk of chronic kidney disease, cardiovascular events and death. PT Sepsis associated acute kidney injury will be added as a broad scope term representing organ damage to Toxic-septic shock conditions (SMQ) aligned with PT Acute kidney injury.

CR Number: 2024180016		Implementation Date: 04-Jul-24	Related CR: 2024180016	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Superior mediastinal syndrome</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Malignancy related conditions (SMQ)</i>		<i>Superior mediastinal syndrome</i>	10091155
Term scope	<i>Narrow</i>		To SMQ	
			<i>Malignancy related conditions (SMQ)</i>	20000092
			Term scope	
			<i>Narrow</i>	
			Term_category	
			A	
			Term_weight	
			0	

**MSSO Comment:** The proposal to add PT Superior mediastinal syndrome to Malignancy related conditions (SMQ) as a narrow term is approved as requested. Superior Vena Cava Syndrome (SVCS) refers to signs and symptoms caused by obstruction of the superior vena cava. Superior mediastinal syndrome (SMS) is the term used when SVCS coexists with an obstruction of the trachea. Although the terms are often used interchangeably in children, because a mediastinal pathology causing SVCS generally results in SMS as well, due to the limited chest volume, these are distinct medical concepts. PT Superior mediastinal syndrome will be added to Malignancy related conditions (SMQ) aligned with PT Superior vena cava syndrome.

# Detail Report

CR Number: 2024180017		Implementation Date: 04-Jul-24	Related CR: 2024180017	
<u>Change Requested</u>	Add term to SMQ	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Catamenial epilepsy	Approved as Requested	Proposed PT	
To SMQ	Convulsions (SMQ)		Catamenial epilepsy	10091246
Term scope	Narrow		To SMQ	
			Convulsions (SMQ)	20000079
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Catamenial epilepsy to Convulsions (SMQ) as a narrow term is approved as requested. Catamenial epilepsy describes a worsening of seizures in relation to the menstrual cycle and may affect around 40% of women with epilepsy. This term, which describes a specific type of epilepsy, meets criteria for inclusion in the narrow search terms of Convulsions (SMQ).

CR Number: 2024180018		Implementation Date: 04-Jul-24	Related CR: 2024180018	
<u>Change Requested</u>	Add term to SMQ	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Pericardiolysis	Approved as Requested	Proposed PT	
To SMQ	Noninfectious myocarditis/pericarditis (SMQ)		Pericardiolysis	10091159
Term scope	Broad		To SMQ	
			Noninfectious myocarditis/pericarditis (SMQ)	20000239
			Term scope	
			Broad	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Pericardiolysis to Noninfectious myocarditis/pericarditis (SMQ) as a broad term is approved as requested. Pericardiolysis is a surgical procedure to free adhesions between the visceral and parietal pericardium or between the pericardium and surrounding tissues or organs. This procedure, which treats a possible complication of pericarditis, will be added to the broad search terms of this SMQ.



# Detail Report

CR Number: 2024180019		Implementation Date: 04-Jul-24	Related CR: 2024180019	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Endoscopic ultrasound-guided hepaticogastrostomy	Approved as Requested	Proposed PT	
To SMQ	Biliary tract disorders (SMQ)		Endoscopic ultrasound-guided hepaticogastrostomy	10091263
Term scope	Narrow		To SMQ	
			Biliary tract disorders (SMQ)	20000125
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	
MSSO Comment:	The proposal to add PT Endoscopic ultrasound-guided hepaticogastrostomy to Biliary tract disorders (SMQ) as a narrow term is approved as requested. This procedure is an hepaticogastrostomy performed under endoscopic ultrasound guidance and used mostly in cases of hepatic biliary obstruction as an alternative method of drainage of the biliary tree when an endoscopic retrograde cholangiopancreatography is not possible.			

CR Number: 2024180020		Implementation Date: 04-Jul-24	Related CR: 2024180020	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Myoepithelial carcinoma of salivary gland	Approved as Requested	Proposed PT	
To SMQ	Oropharyngeal neoplasms (SMQ)		Myoepithelial carcinoma of salivary gland	10091222
Term scope	Narrow		To SMQ	
			Oropharyngeal neoplasms (SMQ)	20000110
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	
MSSO Comment:	The proposal to add PT Myoepithelial carcinoma of salivary gland to Oropharyngeal neoplasms (SMQ) as a narrow term is approved as requested. PT Myoepithelial carcinoma of salivary gland was added in version 27.1 and represents an invasive malignant salivary gland neoplasm that is almost exclusively composed of myoepithelial cells. Myoepithelial carcinoma may arise de novo or within a pre-existing pleomorphic adenoma and is the second most common histological subtype of carcinoma excluding pleomorphic adenoma. PT Myoepithelial carcinoma of salivary gland fits the inclusion criterion "Oropharyngeal neoplasms, cysts, and pre-neoplastic lesions" and its addition is in line with already included PTs like PT Acinic cell carcinoma of salivary gland, PT Metastatic salivary gland cancer, PT Salivary gland adenoma, PT Salivary gland neoplasm etc. All PTs in Oropharyngeal neoplasms (SMQ) are narrow in scope.			

# Detail Report

CR Number: 2024180021		Implementation Date: 04-Jul-24	Related CR: 2024180021	
<u>Change Requested</u>	Add term to SMQ	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Parotid calcification	Approved as Requested	Proposed PT	
To SMQ	Oropharyngeal conditions (excl neoplasms, infections and allergies) (SMQ)		Parotid calcification	10091256
Term scope	Narrow		To SMQ	
			Oropharyngeal conditions (excl neoplasms, infections and allergies) (SMQ)	20000114
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	

**MSSO** The proposal to add PT Parotid calcification to Oropharyngeal conditions (excl neoplasms, infections and allergies) (SMQ) as a narrow term is approved as requested. PT  
**Comment:** Parotid calcification was added in version 27.1. Parotid calcifications can be an incidental finding on computed tomography and have been reported to be associated with chronic inflammatory conditions. Addition of PT Parotid calcification is in line with already included PT Salivary gland calculus. All PTs of this SMQ are narrow in scope.

# Detail Report

CR Number: 2024180022		Implementation Date: 04-Jul-24	Related CR: 2024180022	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Endoscopic ultrasound-guided hepaticogastrostomy	Approved as Requested	Proposed PT	
To SMQ	Malignancy related therapeutic and diagnostic procedures (SMQ)		Endoscopic ultrasound-guided hepaticogastrostomy	10091263
Term scope	Narrow		To SMQ	
			Malignancy related therapeutic and diagnostic procedures (SMQ)	20000093
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	

**MSSO Comment:** The proposal to add PT Endoscopic ultrasound-guided hepaticogastrostomy to Malignancy related therapeutic and diagnostic procedures (SMQ) as a narrow term is approved as requested. Hepaticogastrostomy is the surgical creation of a communication between the hepatic duct and the stomach. Endoscopic Ultrasound (EUS)-guided hepaticogastrostomy is an option to treat obstructive jaundice when Endoscopic retrograde cholangiopancreatography (ERCP) drainage fails. These procedures represent alternatives to surgery and percutaneous transhepatic biliary drainage and have been made possible through the continuous development and improvement of EUS scopes and accessories. Although this procedure can be used for benign biliary obstructions, the majority of EUS-HGS procedures are performed for neoplastic reasons due to the higher prevalence of malignant obstructions and the frequent need for palliative care in cancer patients. Endoscopic ultrasound-guided hepaticogastrostomy will be added to Malignancy related therapeutic and diagnostic procedures (SMQ) which only has narrow search terms.

# Detail Report

CR Number: 2024180023		Implementation Date: 04-Jul-24	Related CR: 2024180023	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Atypical parkinsonism</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Neuroleptic malignant syndrome (SMQ)</i>		<i>Atypical parkinsonism</i>	10091145
Term scope	<i>Broad</i>		To SMQ	
			<i>Neuroleptic malignant syndrome (SMQ)</i>	20000044
			Term scope	
			<i>Broad</i>	
			Term_category	
			<i>D</i>	
			Term_weight	
			<i>0</i>	
MSSO Comment:	The proposal to add PT Atypical parkinsonism to Neuroleptic malignant syndrome (SMQ) as a broad term is approved as requested. PT Atypical parkinsonism was added in version 27.1. Parkinson terms are part of broad scope category D of the SMQ. The clinical features of secondary and atypical parkinsonism are similar to those of Parkinson disease (eg, resting tremor, rigidity, bradykinesia, postural instability). Also, patients with atypical parkinsonism might be treated with dopamin agonists (although response to levodopa is not as efficient) and NMS is also seen in patients treated for parkinsonism in the setting of withdrawal of L-Dopa or dopamine agonist therapy, as well as with dose reductions and a switch from one agent to another.			

CR Number: 2024180024		Implementation Date: 04-Jul-24	Related CR: 2024180024	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>BASDAI score decreased</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Arthritis (SMQ)</i>		<i>BASDAI score decreased</i>	10091234
Term scope	<i>Broad</i>		To SMQ	
			<i>Arthritis (SMQ)</i>	20000216
			Term scope	
			<i>Broad</i>	
			Term_category	
			<i>A</i>	
			Term_weight	
			<i>0</i>	
MSSO Comment:	The proposal to add PT BASDAI score decreased to Arthritis (SMQ) as a broad term is approved as requested. PT BASDAI score decreased was added in version 27.1. The Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) Score Calculator is a tool used to assess disease activity in Ankylosing Spondylitis (AS) patients. The numeric score reflects the severity of disease activity in AS patients and aids healthcare professionals in making treatment decisions and monitoring the progression of the condition. Addition of this PT is in line with the already included PT Ankylosing spondylitis.			

# Detail Report

CR Number: 2024180025		Implementation Date: 04-Jul-24	Related CR: 2024180025	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	BASDAI score increased	Approved as Requested	Proposed PT	
To SMQ	Arthritis (SMQ)		BASDAI score increased	10091236
Term scope	Broad		To SMQ	
			Arthritis (SMQ)	20000216
			Term scope	
			Broad	
			Term_category	
			A	
			Term_weight	
			0	

**MSSO** The proposal to add PT BASDAI score increased to Arthritis (SMQ) as a broad term is approved as requested. PT BASDAI score increased was added in version 27.1.  
**Comment:** The Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) Score Calculator is a tool used to assess disease activity in Ankylosing Spondylitis (AS) patients. The numeric score reflects the severity of disease activity in AS patients and aids healthcare professionals in making treatment decisions and monitoring the progression of the condition. Addition of this PT is in line with the already included PT Ankylosing spondylitis.

CR Number: 2024180026		Implementation Date: 04-Jul-24	Related CR: 2024180026	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Osteoplasty	Approved as Requested	Proposed PT	
To SMQ	Arthritis (SMQ)		Osteoplasty	10091271
Term scope	Broad		To SMQ	
			Arthritis (SMQ)	20000216
			Term scope	
			Broad	
			Term_category	
			A	
			Term_weight	
			0	

**MSSO** The proposal to add PT Osteoplasty to Arthritis (SMQ) as a broad term is approved as requested. PT Osteoplasty was added in version 27.1 and relates to a plastic surgery on the bone, in particular the replacement of lost bone tissue or reconstruction of defective bone parts. It is also used for therapy of osteoarthritis, e.g. in the arthroscopic treatment of primary glenohumeral osteoarthritis by humeral osteoplasty with excision of the goat's beard osteophyte in young, active patients. And in early stages of hip osteoarthritis, osteoplasty is performed for the purpose of altering the rim of the socket or the femoral head to improve the function of the joint and allow a greater range of movement. PT Osteoplasty will be added with broad scope, in line with the inclusion criterion "Terms for relevant investigations and procedures that help to identify and treat arthritis and common complications" and already included PTs like PT Joint arthroplasty and PT Joint debridement.

# Detail Report

CR Number: 2024180027		Implementation Date: 04-Jul-24	Related CR: 2024180027	
<u>Change Requested</u>	Add term to SMQ	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Spinal prosthesis user	Approved as Requested	Proposed PT	
To SMQ	Arthritis (SMQ)		Spinal prosthesis user	10091190
Term scope	Broad		To SMQ	
			Arthritis (SMQ)	20000216
			Term scope	
			Broad	
			Term_category	
			A	
			Term_weight	
			0	

**MSSO Comment:** The proposal to add PT Spinal prosthesis user to Arthritis (SMQ) as a broad term is approved as requested. PT Spinal prosthesis user was added in version 27.1. Spinal "nucleus prosthesis" is used for the treatment of less advanced degeneration, wherein only the core of the disc is replaced, resulting in an anatomic reconstruction. For the more serious degeneration requiring complete or total disc prosthesis, in addition to the core, the fibrous ring is also removed, and new joint components are implanted. PT Spinal prosthesis user will be added with broad scope, in line with the already included PT Spondyloarthropathy, PT Intervertebral discitis and PT Destructive spondyloarthropathy.

CR Number: 2024180028		Implementation Date: 04-Jul-24	Related CR: 2024180028	
<u>Change Requested</u>	Add term to SMQ	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Bicameral gallbladder</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Gallbladder related disorders (SMQ)</i>		<i>Bicameral gallbladder</i>	10091223
Term scope	<i>Narrow</i>		To SMQ	
			<i>Gallbladder related disorders (SMQ)</i>	20000124
			Term scope	
			<i>Narrow</i>	
			Term_category	
			<i>A</i>	
			Term_weight	
			<i>0</i>	

**MSSO Comment:** The proposal to add PT Bicameral gallbladder to Gallbladder related disorders (SMQ) as a narrow term is approved as requested. Bicameral gallbladder, often due - though not only - to the presence of segmental adenomyomatosis, is an anomaly in which the gallbladder lumen is partitioned, often nearly completely, into two chambers. When oral cholecystography is performed for bicameral gallbladders, the contrast medium tends to concentrate only in the ductal chamber.

# Detail Report

CR Number: 2024180029		Implementation Date: 05-Jul-24	Related CR: 2024180029	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Arrhythmia induced cardiomyopathy	Approved as Requested	Proposed PT	
To SMQ	Tachyarrhythmia terms, nonspecific (SMQ)		Arrhythmia induced cardiomyopathy	10091289
Term scope	Narrow		To SMQ	
			Tachyarrhythmia terms, nonspecific (SMQ)	20000164
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	

**MSSO Comment:** The proposal to add PT Arrhythmia induced cardiomyopathy to Tachyarrhythmia terms, nonspecific (SMQ) as a narrow term is approved as requested. Arrhythmias frequently accompany heart failure and left ventricular dysfunction. Tachycardias, atrial fibrillation, and premature ventricular contractions can induce a reversible form of dilated cardiomyopathy known as arrhythmia-induced (AiCM). Arrhythmia-induced cardiomyopathy has been reported with nearly all types of tachyarrhythmias and frequent ectopy, both supraventricular and ventricular. Arrhythmia induced cardiomyopathy will be added to the Tachyarrhythmia terms, nonspecific (SMQ), which only has narrow search terms.

CR Number: 2024180030		Implementation Date: 05-Jul-24	Related CR: 2024180030	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Joint prosthesis user	Approved as Requested	Proposed PT	
To SMQ	Arthritis (SMQ)		Joint prosthesis user	10050850
Term scope	Broad		To SMQ	
			Arthritis (SMQ)	20000216
			Term scope	
			Broad	
			Term_category	
			A	
			Term_weight	
			0	

**MSSO Comment:** The proposal to add PT Joint prosthesis user to Arthritis (SMQ) as a broad term is approved as requested. PT Joint prosthesis user matches the SMQ in- and exclusion criteria and its addition with broad scope is in line with the inclusion of PT Spinal prosthesis user.

# Detail Report

CR Number: 2024180031		Implementation Date: 05-Jul-24	Related CR: 2024180031	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Adrenal-renal fusion anomaly	Approved as Requested	Proposed PT	
To SMQ	Congenital, familial and genetic disorders (SMQ)		Adrenal-renal fusion anomaly	10091285
Term scope	Narrow		To SMQ	
			Congenital, familial and genetic disorders (SMQ)	20000077
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	
MSSO Comment:	The proposal to add PT Adrenal-renal fusion anomaly to Congenital, familial and genetic disorders (SMQ) as a narrow term is approved as requested. Adrenal-renal fusion anomaly fits the inclusion criteria for Congenital, familial and genetic disorders (SMQ) which includes all PTs in SOC Congenital, familial and genetic disorders. All terms in Congenital, familial and genetic disorders (SMQ) are narrow in scope.			

CR Number: 2024180032		Implementation Date: 05-Jul-24	Related CR: 2024180032	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Agnathia	Approved as Requested	Proposed PT	
To SMQ	Congenital, familial and genetic disorders (SMQ)		Agnathia	10091259
Term scope	Narrow		To SMQ	
			Congenital, familial and genetic disorders (SMQ)	20000077
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	
MSSO Comment:	The proposal to add PT Agnathia to Congenital, familial and genetic disorders (SMQ) as a narrow term is approved as requested. Agnathia fits the inclusion criteria for Congenital, familial and genetic disorders (SMQ) which includes all PTs in SOC Congenital, familial and genetic disorders. All terms in Congenital, familial and genetic disorders (SMQ) are narrow in scope.			



# Detail Report

CR Number: 2024180033		Implementation Date: 08-Jul-24	Related CR: 2024180033	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Carotid hypoplasia	Approved as Requested	Proposed PT	
To SMQ	Congenital, familial and genetic disorders (SMQ)		Carotid hypoplasia	10091136
Term scope	Narrow		To SMQ	
			Congenital, familial and genetic disorders (SMQ)	20000077
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	

**MSSO Comment:** The proposal to add PT Carotid hypoplasia to Congenital, familial and genetic disorders (SMQ) as a narrow term is approved as requested. Carotid hypoplasia fits the inclusion criteria for Congenital, familial and genetic disorders (SMQ) which includes all PTs in SOC Congenital, familial and genetic disorders. All terms in Congenital, familial and genetic disorders (SMQ) are narrow in scope.

CR Number: 2024180034		Implementation Date: 08-Jul-24	Related CR: 2024180034	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Congenital thrombotic thrombocytopenic purpura	Approved as Requested	Proposed PT	
To SMQ	Congenital, familial and genetic disorders (SMQ)		Congenital thrombotic thrombocytopenic purpura	10091107
Term scope	Narrow		To SMQ	
			Congenital, familial and genetic disorders (SMQ)	20000077
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	

**MSSO Comment:** The proposal to add PT Congenital thrombotic thrombocytopenic purpura to Congenital, familial and genetic disorders (SMQ) as a narrow term is approved as requested. Congenital thrombotic thrombocytopenic purpura fits the inclusion criteria for Congenital, familial and genetic disorders (SMQ) which includes all PTs in SOC Congenital, familial and genetic disorders. All terms in Congenital, familial and genetic disorders (SMQ) are narrow in scope.

# Detail Report

CR Number: 2024180035		Implementation Date: 08-Jul-24	Related CR: 2024180035	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Embryo-foetal toxicity</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Congenital, familial and genetic disorders (SMQ)</i>		<i>Embryo-foetal toxicity</i>	10091119
Term scope	<i>Narrow</i>		To SMQ	
			<i>Congenital, familial and genetic disorders (SMQ)</i>	20000077
			Term scope	
			<i>Narrow</i>	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Embryo-foetal toxicity to Congenital, familial and genetic disorders (SMQ) as a narrow term is approved as requested. Embryo-foetal toxicity fits the inclusion criteria for Congenital, familial and genetic disorders (SMQ) which includes all PTs in SOC Congenital, familial and genetic disorders. All terms in Congenital, familial and genetic disorders (SMQ) are narrow in scope.

CR Number: 2024180036		Implementation Date: 08-Jul-24	Related CR: 2024180036	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Hereditary sensory and autonomic neuropathy</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Congenital, familial and genetic disorders (SMQ)</i>		<i>Hereditary sensory and autonomic neuropathy</i>	10091083
Term scope	<i>Narrow</i>		To SMQ	
			<i>Congenital, familial and genetic disorders (SMQ)</i>	20000077
			Term scope	
			<i>Narrow</i>	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Hereditary sensory and autonomic neuropathy to Congenital, familial and genetic disorders (SMQ) as a narrow term is approved as requested. Hereditary sensory and autonomic neuropathy fits the inclusion criteria for Congenital, familial and genetic disorders (SMQ) which includes all PTs in SOC Congenital, familial and genetic disorders. All terms in Congenital, familial and genetic disorders (SMQ) are narrow in scope.

# Detail Report

<b>CR Number:</b> 2024180037		<b>Implementation Date:</b> 08-Jul-24	<b>Related CR:</b> 2024180037	
<u>Change Requested</u>	Add term to SMQ	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Koolen-de Vries syndrome</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Congenital, familial and genetic disorders (SMQ)</i>		<i>Koolen-de Vries syndrome</i>	10091195
Term scope	<i>Narrow</i>		To SMQ	
			<i>Congenital, familial and genetic disorders (SMQ)</i>	20000077
			Term scope	
			<i>Narrow</i>	
			Term_category	
			A	
			Term_weight	
			0	
<b>MSSO Comment:</b> The proposal to add PT Koolen-de Vries syndrome to Congenital, familial and genetic disorders (SMQ) as a narrow term is approved as requested. Koolen-de Vries syndrome fits the inclusion criteria for Congenital, familial and genetic disorders (SMQ) which includes all PTs in SOC Congenital, familial and genetic disorders. All terms in Congenital, familial and genetic disorders (SMQ) are narrow in scope.				

<b>CR Number:</b> 2024180038		<b>Implementation Date:</b> 08-Jul-24	<b>Related CR:</b> 2024180038	
<u>Change Requested</u>	Add term to SMQ	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Mullerian duct cyst</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Congenital, familial and genetic disorders (SMQ)</i>		<i>Mullerian duct cyst</i>	10091270
Term scope	<i>Narrow</i>		To SMQ	
			<i>Congenital, familial and genetic disorders (SMQ)</i>	20000077
			Term scope	
			<i>Narrow</i>	
			Term_category	
			A	
			Term_weight	
			0	
<b>MSSO Comment:</b> The proposal to add PT Mullerian duct cyst to Congenital, familial and genetic disorders (SMQ) as a narrow term is approved as requested. Mullerian duct cyst fits the inclusion criteria for Congenital, familial and genetic disorders (SMQ) which includes all PTs in SOC Congenital, familial and genetic disorders. All terms in Congenital, familial and genetic disorders (SMQ) are narrow in scope.				

# Detail Report

CR Number: 2024180039		Implementation Date: 08-Jul-24	Related CR: 2024180039		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed PT	Cardiac ventricular diverticulum	Approved as Requested	Proposed PT		
To SMQ	Congenital, familial and genetic disorders (SMQ)		Cardiac ventricular diverticulum		10091212
Term scope	Narrow		To SMQ		
			Congenital, familial and genetic disorders (SMQ)		20000077
			Term scope		
			Narrow		
			Term_category		
			A		
			Term_weight		
			0		

MSSO Comment: The proposal to add PT Cardiac ventricular diverticulum to Congenital, familial and genetic disorders (SMQ) as a narrow term is approved as requested. Cardiac ventricular diverticulum fits the inclusion criteria for Congenital, familial and genetic disorders (SMQ) which includes all PTs in SOC Congenital, familial and genetic disorders. All terms in Congenital, familial and genetic disorders (SMQ) are narrow in scope.

CR Number: 2024180040		Implementation Date: 08-Jul-24	Related CR: 2024180040		<a href="#">MedDRA Code #</a>
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>		
Proposed PT	Dysfunctional tear syndrome	Approved as Requested	Proposed PT		
To SMQ	Lacrimonal disorders (SMQ)		Dysfunctional tear syndrome		10091181
Term scope	Narrow		To SMQ		
			Lacrimonal disorders (SMQ)		20000176
			Term scope		
			Narrow		
			Term_category		
			A		
			Term_weight		
			0		

MSSO Comment: The proposal to add PT Dysfunctional tear syndrome to Lacrimonal disorders (SMQ) as a narrow term is approved as requested. Dysfunctional tear syndrome fits the inclusion criteria for Lacrimonal disorders (SMQ). Similar terms such as PT Dry eye and PT Tear film instability are already included as narrow scope terms. All terms in this SMQ are narrow in scope.

# Detail Report

CR Number: 2024180041		Implementation Date: 08-Jul-24	Related CR: 2024180041	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Lacrimonal apparatus syringing	Approved as Requested	Proposed PT	
To SMQ	Lacrimonal disorders (SMQ)		Lacrimonal apparatus syringing	10091204
Term scope	Narrow		To SMQ	
			Lacrimonal disorders (SMQ)	20000176
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	

**MSSO** The proposal to add PT Lacrimonal apparatus syringing to Lacrimonal disorders (SMQ) as a narrow term is approved as requested. Lacrimonal apparatus syringing fits the  
**Comment:** inclusion criteria for Lacrimonal disorders (SMQ). Similar terms such as PT Lacrimonal gland operation and PT Punctal plug removal are already included as narrow scope terms. The procedure is mainly used as a diagnostic test to assess the patency of the lacrimonal apparatus, to assess the degree and site of lacrimonal pathway obstruction and occasionally also to flush debris from the lacrimonal pathway. All terms in this SMQ are narrow in scope.

CR Number: 2024180042		Implementation Date: 08-Jul-24	Related CR: 2024180042	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Auditory tube catheterisation	Approved as Requested	Proposed PT	
To SMQ	Hearing impairment (SMQ)		Auditory tube catheterisation	10091258
Term scope	Broad		To SMQ	
			Hearing impairment (SMQ)	20000171
			Term scope	
			Broad	
			Term_category	
			A	
			Term_weight	
			0	

**MSSO** The proposal to add PT Auditory tube catheterisation to Hearing impairment (SMQ) as a broad term is approved as requested. Auditory tube catheterisation fits the  
**Comment:** inclusion criteria for Hearing impairment (SMQ). Similar terms such as PT Middle ear irrigation and PT Ear operation are already included as broad scope terms.

# Detail Report

CR Number: 2024180043		Implementation Date: 08-Jul-24	Related CR: 2024180043	
<u>Change Requested</u>	Add term to SMQ	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Auditory tube catheterisation	Approved as Requested	Proposed PT	
To SMQ	Vestibular disorders (SMQ)		Auditory tube catheterisation	10091258
Term scope	Broad		To SMQ	
			Vestibular disorders (SMQ)	20000172
			Term scope	
			Broad	
			Term_category	
			A	
			Term_weight	
			0	

MSSO      The proposal to add PT Auditory tube catheterisation to Vestibular disorders (SMQ) as a broad term is approved as requested. Auditory tube catheterisation fits the  
Comment: inclusion criteria for Vestibular disorders (SMQ). Similar terms such as PT Middle ear irrigation and PT Ear operation are already included as broad scope terms.

CR Number: 2024180044		Implementation Date: 08-Jul-24	Related CR: 2024180044	
<u>Change Requested</u>	Add term to SMQ	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Sepsis associated acute kidney injury	Approved as Requested	Proposed PT	
To SMQ	Sepsis (SMQ)		Sepsis associated acute kidney injury	10091260
Term scope	Narrow		To SMQ	
			Sepsis (SMQ)	20000234
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	

MSSO      The proposal to add PT Sepsis associated acute kidney injury to Sepsis (SMQ) as a narrow term is approved as requested. This term fits the inclusion criteria for this  
Comment: SMQ. Similar terms such as PT Septic device loosening and PT Septic rash are already included as narrow scope terms. In this SMQ there are terms referring to sepsis, septic conditions, septicemia, bacteremia, fungemia, and viremia.

# Detail Report

CR Number: 2024180045		Implementation Date: 08-Jul-24	Related CR: 2024180045	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Embryo-foetal toxicity	Approved as Requested	Proposed PT	
To SMQ	Foetal disorders (SMQ)		Embryo-foetal toxicity	10091119
Term scope	Narrow		To SMQ	
			Foetal disorders (SMQ)	20000190
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	

MSSO      The proposal to add PT Embryo-foetal toxicity to Foetal disorders (SMQ) as a narrow term is approved as requested. Embryo-foetal toxicity fits the inclusion criteria for  
Comment:      Foetal disorders (SMQ). Similar terms such as PT Foetal damage and PT Foetal malformation are already included as narrow scope terms.

CR Number: 2024180046		Implementation Date: 08-Jul-24	Related CR: 2024180046	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Foetal urinary tract dilatation	Approved as Requested	Proposed PT	
To SMQ	Foetal disorders (SMQ)		Foetal urinary tract dilatation	10091292
Term scope	Narrow		To SMQ	
			Foetal disorders (SMQ)	20000190
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	

MSSO      The proposal to add PT Foetal urinary tract dilatation to Foetal disorders (SMQ) as a narrow term is approved as requested. Foetal urinary tract dilatation fits the inclusion  
Comment:      criteria for Foetal disorders (SMQ). Similar terms such as PT Foetal cerebrovascular disorder and PT Foetal cardiac disorder are already included as narrow scope terms.

# Detail Report

CR Number: 2024180047		Implementation Date: 08-Jul-24	Related CR: 2024180047	
<u>Change Requested</u>	Add term to SMQ	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Neonatal metabolic bone disease	Approved as Requested	Proposed PT	
To SMQ	Neonatal disorders (SMQ)		Neonatal metabolic bone disease	10091290
Term scope	Narrow		To SMQ	
			Neonatal disorders (SMQ)	20000191
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	

MSSO The proposal to add PT Neonatal metabolic bone disease to Neonatal disorders (SMQ) as a narrow term is approved as requested. Neonatal metabolic bone disease fits the inclusion criteria for Neonatal disorders (SMQ). Similar terms such as PT Neonatal hypoparathyroidism and PT Neonatal hypocalcaemia are already included as narrow scope terms.

CR Number: 2024180048		Implementation Date: 08-Jul-24	Related CR: 2024180048	
<u>Change Requested</u>	Add term to SMQ	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Human papillomavirus reactivation	Approved as Requested	Proposed PT	
To SMQ	Drug reaction with eosinophilia and systemic symptoms syndrome (SMQ)		Human papillomavirus reactivation	10091281
Term scope	Broad		To SMQ	
			Drug reaction with eosinophilia and systemic symptoms syndrome (SMQ)	20000225
			Term scope	
			Broad	
			Term_category	
			B	
			Term_weight	
			0	

MSSO The proposal to add PT Human papillomavirus reactivation to Drug reaction with eosinophilia and systemic symptoms syndrome (SMQ) as a broad term is approved as requested. Human papillomavirus reactivation fits the inclusion criteria for Drug reaction with eosinophilia and systemic symptoms syndrome (SMQ). Similar terms such as PT Cytomegalovirus infection reactivation and PT Epstein-Barr virus infection reactivation are already included as broad scope terms. As well, inclusion criteria include terms related to viral reactivation.



# Detail Report

CR Number: 2024180049		Implementation Date: 08-Jul-24	Related CR: 2024180049	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Nikolsky's sign positive</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Drug reaction with eosinophilia and systemic symptoms syndrome (SMQ)</i>		<i>Nikolsky's sign positive</i>	10091102
Term scope	<i>Broad</i>		To SMQ	
			<i>Drug reaction with eosinophilia and systemic symptoms syndrome (SMQ)</i>	20000225
			Term scope	
			<i>Broad</i>	
			Term_category	
			<i>B</i>	
			Term_weight	
			<i>0</i>	

**MSSO Comment:** The proposal to add PT Nikolsky's sign positive to Drug reaction with eosinophilia and systemic symptoms syndrome (SMQ) as a broad term is approved as requested. Nikolsky's sign positive fits the inclusion criteria for Drug reaction with eosinophilia and systemic symptoms syndrome (SMQ). Nikolsky's sign is a clinical dermatological examination technique used to diagnose certain skin conditions, particularly pemphigus vulgaris and other blistering disorders. PT Nikolsky's sign was recently demoted and was in Drug reaction with eosinophilia and systemic symptoms syndrome (SMQ) and is now under this new PT Nikolsky's sign positive.

CR Number: 2024180050		Implementation Date: 08-Jul-24	Related CR: 2024180050	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Nikolsky's sign positive</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Severe cutaneous adverse reactions (SMQ)</i>		<i>Nikolsky's sign positive</i>	10091102
Term scope	<i>Broad</i>		To SMQ	
			<i>Severe cutaneous adverse reactions (SMQ)</i>	20000020
			Term scope	
			<i>Broad</i>	
			Term_category	
			<i>A</i>	
			Term_weight	
			<i>0</i>	

**MSSO Comment:** The proposal to add PT Nikolsky's sign positive to Severe cutaneous adverse reactions (SMQ) as a broad term is approved as requested. Nikolsky's sign positive fits the inclusion criteria for Severe cutaneous adverse reactions (SMQ). Nikolsky's sign is a clinical dermatological examination technique used to diagnose certain skin conditions, particularly pemphigus vulgaris and other blistering disorders. PT Nikolsky's sign was recently demoted and was in Severe cutaneous adverse reactions (SMQ) and is now under this new PT Nikolsky's sign positive.

# Detail Report

CR Number: 2024180051		Implementation Date: 08-Jul-24	Related CR: 2024180051	
<u>Change Requested</u>	Add term to SMQ	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Lupus retinopathy</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Systemic lupus erythematosus (SMQ)</i>		<i>Lupus retinopathy</i>	10091210
Term scope	<i>Narrow</i>		To SMQ	
			<i>Systemic lupus erythematosus (SMQ)</i>	20000045
			Term scope	
			<i>Narrow</i>	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Lupus retinopathy to Systemic lupus erythematosus (SMQ) as a narrow term is approved as requested. PT Lupus retinopathy was added to MedDRA 27.1. Retinal vasculitis is an under-recognized manifestation of systemic lupus erythematosus (SLE). PT Lupus retinopathy meets the criteria for inclusion in Systemic lupus erythematosus (SMQ) per the SMQ Introductory Guide and will be added as a Narrow scope term similar to PT Lupus vasculitis.

CR Number: 2024180052		Implementation Date: 08-Jul-24	Related CR: 2024180052	
<u>Change Requested</u>	Add term to SMQ	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Osteoplasty</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Osteonecrosis (SMQ)</i>		<i>Osteoplasty</i>	10091271
Term scope	<i>Broad</i>		To SMQ	
			<i>Osteonecrosis (SMQ)</i>	20000180
			Term scope	
			<i>Broad</i>	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Osteoplasty to Osteonecrosis (SMQ) as a broad term is approved as requested. PT Osteoplasty was added in v27.1. Osteoplasty is a surgical procedure for bone reshaping, either for removing protruding bony surfaces or by injecting bone cement or bone graft into a painful bone lesion, such as in painful bone metastasis which are refractory to conventional therapy. PT Osteoplasty meets the inclusion criteria for Osteonecrosis (SMQ) and will be added as a Broad scope term similar to PT Bone graft.

# Detail Report

CR Number: 2024180053		Implementation Date: 08-Jul-24	Related CR: 2024180053	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Osteoplasty</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Osteoporosis/osteopenia (SMQ)</i>		<i>Osteoplasty</i>	10091271
Term scope	<i>Broad</i>		To SMQ	
			<i>Osteoporosis/osteopenia (SMQ)</i>	20000178
			Term scope	
			<i>Broad</i>	
			Term_category	
			A	
			Term_weight	
			0	

**MSSO Comment:** The proposal to add PT Osteoplasty to Osteoporosis/osteopenia (SMQ) as a broad term is approved as requested. PT Osteoplasty was added in v27.1. Osteoplasty is a surgical procedure for bone reshaping, either for removing protruding bony surfaces or by injecting bone cement or bone graft into a painful bone lesion, such as in painful bone metastasis which are refractory to conventional therapy. Percutaneous-reinforced osteoplasty is currently being investigated as a possible therapeutic procedure for fracture stabilization in high-risk patients, primarily in patients with bone metastases or osteoporosis. PT Osteoplasty meets the inclusion criteria for Osteoporosis/osteopenia (SMQ) and will be added as a Broad scope term similar to PT Vertebroplasty.

CR Number: 2024180054		Implementation Date: 08-Jul-24	Related CR: 2024180054	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Kidney rupture</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Retroperitoneal fibrosis (SMQ)</i>		<i>Kidney rupture</i>	10023434
Term scope	<i>Broad</i>		To SMQ	
			<i>Retroperitoneal fibrosis (SMQ)</i>	20000065
			Term scope	
			<i>Broad</i>	
			Term_category	
			A	
			Term_weight	
			0	

**MSSO Comment:** The proposal to add PT Kidney rupture to Retroperitoneal fibrosis (SMQ) as a broad term is approved as requested. Renal forniceal rupture was demoted under PT Kidney rupture. Renal forniceal rupture was originally added in v27.0. Renal forniceal rupture is a common finding in patients with ureteral obstruction. It is thought to be due to increased renal pelvis pressure from backup of urine, causing one or more renal fornices to leak urine. PT Renal forniceal rupture was included in Retroperitoneal fibrosis (SMQ) as broad scope term representing associated conditions that develop as a consequence. Since it has been subsumed under PT Kidney rupture, the PT Kidney rupture will be added to Retroperitoneal fibrosis (SMQ) as a Broad concept.

# Detail Report

CR Number: 2024180055		Implementation Date: 08-Jul-24	Related CR: 2024180055	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Arrhythmia induced cardiomyopathy</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Cardiomyopathy (SMQ)</i>		<i>Arrhythmia induced cardiomyopathy</i>	10091289
Term scope	<i>Narrow</i>		To SMQ	
			<i>Cardiomyopathy (SMQ)</i>	20000150
			Term scope	
			<i>Narrow</i>	
			Term_category	
			A	
			Term_weight	
			0	

**MSSO Comment:** The proposal to add PT Arrhythmia induced cardiomyopathy to Cardiomyopathy (SMQ) as a narrow term is approved as requested. PT Arrhythmia induced cardiomyopathy was added to MedDRA v27.1. Tachycardias, atrial fibrillation, and premature ventricular contractions can induce a reversible form of dilated cardiomyopathy known as arrhythmia-induced (AiCM). Arrhythmia induced cardiomyopathy meets the criteria of inclusion for Cardiomyopathy (SMQ) and will be added as a Narrow scope term, similar to the now demoted PT Tachycardia induced cardiomyopathy which will be demoted under the new PT Arrhythmia induced cardiomyopathy.

CR Number: 2024180056		Implementation Date: 08-Jul-24	Related CR: 2024180056	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Ileocaecal valve lipoma</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Lipodystrophy (SMQ)</i>		<i>Ileocaecal valve lipoma</i>	10091131
Term scope	<i>Broad</i>		To SMQ	
			<i>Lipodystrophy (SMQ)</i>	20000177
			Term scope	
			<i>Broad</i>	
			Term_category	
			A	
			Term_weight	
			0	

**MSSO Comment:** The proposal to add PT Ileocaecal valve lipoma to Lipodystrophy (SMQ) as a broad term is approved as requested. The PT Ileocecal valve lipoma with the American English spelling was added in v27.1 and agreed to be included as Broad term in Lipodystrophy (SMQ). Ileocecal valve lipoma has now been demoted to LLT under the newly added PT with the British English spelling Ileocaecal valve lipoma. The PT Ileocaecal valve lipoma was added in v27.1 and is characterized by a diffuse infiltration of fatty tissue, most often in the submucous layer. The PT Ileocaecal valve lipoma will be added under broad scope in alignment with existing PTs such as Lipoma, Pleural lipoma and Lipoma of breast. The demoted LLT will be subsumed under the new PT in the same SMQ.

# Detail Report

CR Number: 2024180057		Implementation Date: 08-Jul-24	Related CR: 2024180057	
<u>Change Requested</u>	Add term to SMQ	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Cystatin C increased</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Acute renal failure (SMQ)</i>		<i>Cystatin C increased</i>	10058037
Term scope	<i>Broad</i>		To SMQ	
			<i>Acute renal failure (SMQ)</i>	20000003
			Term scope	
			<i>Broad</i>	
			Term_category	
			<i>A</i>	
			Term_weight	
			<i>0</i>	

MSSO The proposal to add PT Cystatin C increased to Acute renal failure (SMQ) as a broad term is approved as requested. PT Cystatin C increased fits the inclusion criteria for  
Comment: Acute renal failure (SMQ). Similar terms such as PT Blood creatinine increased and PT Blood urea nitrogen/creatinine ratio increased are already included as broad scope terms.

CR Number: 2024180058		Implementation Date: 08-Jul-24	Related CR: 2024180058	
<u>Change Requested</u>	Add term to SMQ	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Cystatin C increased</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Chronic kidney disease (SMQ)</i>		<i>Cystatin C increased</i>	10058037
Term scope	<i>Broad</i>		To SMQ	
			<i>Chronic kidney disease (SMQ)</i>	20000213
			Term scope	
			<i>Broad</i>	
			Term_category	
			<i>A</i>	
			Term_weight	
			<i>0</i>	

MSSO The proposal to add PT Cystatin C increased to Chronic kidney disease (SMQ) as a broad term is approved as requested. Cystatin C increased fits the inclusion criteria  
Comment: for Chronic kidney disease (SMQ). Similar terms such as PT Blood creatinine increased and PT Blood urea nitrogen/creatinine ratio increased are already included as broad scope terms.

# Detail Report

CR Number: 2024180059		Implementation Date: 08-Jul-24	Related CR: 2024180059	
<u>Change Requested</u>	Add term to SMQ	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Cystatin C increased	Approved as Requested	Proposed PT	
To SMQ	Rhabdomyolysis/myopathy (SMQ)		Cystatin C increased	10058037
Term scope	Broad		To SMQ	
			Rhabdomyolysis/myopathy (SMQ)	20000002
			Term scope	
			Broad	
			Term_category	
			A	
			Term_weight	
			0	

MSSO The proposal to add PT Cystatin C increased to Rhabdomyolysis/myopathy (SMQ) as a broad term is approved as requested. Cystatin C increased fits the inclusion  
Comment: criteria for Rhabdomyolysis/myopathy (SMQ). Similar terms such as PT Blood creatinine increased and PT Blood creatine phosphokinase increased are already included as broad scope terms.

CR Number: 2024180060		Implementation Date: 08-Jul-24	Related CR: 2024180060	
<u>Change Requested</u>	Add term to SMQ	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Spinal prosthesis user	Approved as Requested	Proposed PT	
To SMQ	Osteonecrosis (SMQ)		Spinal prosthesis user	10091190
Term scope	Broad		To SMQ	
			Osteonecrosis (SMQ)	20000180
			Term scope	
			Broad	
			Term_category	
			A	
			Term_weight	
			0	

MSSO The proposal to add PT Spinal prosthesis user to Osteonecrosis (SMQ) as a broad term is approved as requested. PT Spinal prosthesis user was added in v27.1  
Comment: representing the social circumstance of spinal prostheses use which are referenced in treatments for spinal degenerative conditions. PT Spinal prosthesis user meets the inclusion criteria for Osteonecrosis (SMQ) and will be added as a Broad scope term similar to PT Joint prosthesis user.

# Detail Report

<b>CR Number:</b> 2024180061		<b>Implementation Date:</b> 08-Jul-24	<b>Related CR:</b> 2024180061	
<u>Change Requested</u>	Add term to SMQ	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Spinal prosthesis user	Approved as Requested	Proposed PT	
To SMQ	Osteoporosis/osteopenia (SMQ)		Spinal prosthesis user	10091190
Term scope	Broad		To SMQ	
			Osteoporosis/osteopenia (SMQ)	20000178
			Term scope	
		Broad		
		Term_category		
		A		
		Term_weight		
		0		
MSSO Comment:	The proposal to add PT Spinal prosthesis user to Osteoporosis/osteopenia (SMQ) as a broad term is approved as requested. PT Spinal prosthesis user was added in v27.1 representing the social circumstance of spinal prostheses use which are referenced in treatments for spinal degenerative conditions. PT Spinal prosthesis user meets the inclusion criteria for Osteoporosis/osteopenia (SMQ) and will be added as a Broad scope term.			

CR Number: 2024180062		Implementation Date: 08-Jul-24	Related CR: 2024180062	
<u>Change Requested</u>	Add term to SMQ	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Spinal rod adjustment</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Osteonecrosis (SMQ)</i>		<i>Spinal rod adjustment</i>	10091228
Term scope	<i>Broad</i>		To SMQ	
			<i>Osteonecrosis (SMQ)</i>	20000180
			Term scope	
		<i>Broad</i>		
		Term_category		
		<i>A</i>		
		Term_weight		
		<i>0</i>		
MSSO Comment:	The proposal to add PT Spinal rod adjustment to Osteonecrosis (SMQ) as a broad term is approved as requested. PT Spinal rod adjustment was added in v27.1 referring to the process of modifying the position, tension, or configuration of spinal rods that have been surgically implanted to correct spinal deformities or stabilize the spine and are used in various spinal surgeries, including scoliosis correction, spinal fusion, and treatment of fractures or degenerative spine conditions. PT Spinal rod adjustment meets the inclusion criteria for Osteonecrosis (SMQ) and will be added as a Broad scope term.			

# Detail Report

<b>CR Number: 2024180063</b>		<b>Implementation Date:</b> 08-Jul-24	<b>Related CR:</b> 2024180063	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Spinal rod adjustment</i>	Approved as Requested	Proposed PT	
To SMQ	<i>Osteoporosis/osteopenia (SMQ)</i>		<i>Spinal rod adjustment</i>	10091228
Term scope	<i>Broad</i>		To SMQ	
			<i>Osteoporosis/osteopenia (SMQ)</i>	20000178
			Term scope	
			<i>Broad</i>	
		Term_category		
		A		
		Term_weight		
		0		
MSSO Comment:	The proposal to add PT Spinal rod adjustment to Osteoporosis/osteopenia (SMQ) as a broad term is approved as requested. PT Spinal rod adjustment was added in v27.1 referring to the process of modifying the position, tension, or configuration of spinal rods that have been surgically implanted to correct spinal deformities or stabilize the spine and are used in various spinal surgeries, including scoliosis correction, spinal fusion, and treatment of fractures or degenerative spine conditions. PT Spinal rod adjustment meets the inclusion criteria for Osteoporosis/osteopenia (SMQ) and will be added as a Broad scope term.			

CR Number: 2024180064		Implementation Date: 08-Jul-24	Related CR: 2024180064	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Spinal rod insertion	Approved as Requested	Proposed PT	
To SMQ	Osteoporosis/osteopenia (SMQ)		Spinal rod insertion	10053002
Term scope	Broad		To SMQ	
			Osteoporosis/osteopenia (SMQ)	20000178
			Term scope	
			Broad	
		Term_category		
		A		
		Term_weight		
		0		
MSSO Comment:	The proposal to add PT Spinal rod insertion to Osteoporosis/osteopenia (SMQ) as a broad term is approved as requested. PT Spinal rod insertion was re-promoted to PT level in v27.1 referring to surgically implanted rods that correct spinal deformities or stabilize the spine and are used in various spinal surgeries, including scoliosis correction, spinal fusion, and treatment of fractures or degenerative spine conditions. PT Spinal rod insertion meets the inclusion criteria for Osteoporosis/osteopenia (SMQ) and will be added as a Broad scope term.			



# Detail Report

CR Number: 2024180065		Implementation Date: 08-Jul-24	Related CR: 2024180065	
<u>Change Requested</u>	Add term to SMQ	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Spinal rod insertion	Approved as Requested	Proposed PT	
To SMQ	Osteonecrosis (SMQ)		Spinal rod insertion	10053002
Term scope	Broad		To SMQ	
			Osteonecrosis (SMQ)	20000180
			Term scope	
		Broad		
		Term_category		
		A		
		Term_weight		
		0		

**MSSO Comment:** The proposal to add PT Spinal rod insertion to Osteonecrosis (SMQ) as a broad term is approved as requested. PT Spinal rod insertion was re-promoted to PT level in v27.1 referring to surgically implanted rods that correct spinal deformities or stabilize the spine and are used in various spinal surgeries, including scoliosis correction, spinal fusion, and treatment of fractures or degenerative spine conditions. PT Spinal rod insertion meets the inclusion criteria for Osteonecrosis (SMQ) and will be added as a Broad scope term.

CR Number: 2024180066		Implementation Date: 08-Jul-24		Related CR: 2024180066	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>	
Proposed PT	Superior mediastinal syndrome	Approved as Requested	Proposed PT		
To SMQ	Embolic and thrombotic events, venous (SMQ)		Superior mediastinal syndrome	10091155	
Term scope	Narrow		To SMQ		
			Embolic and thrombotic events, venous (SMQ)	20000084	
			Term scope		
		Narrow			
		Term_category			
		A			
		Term_weight			
		0			

**MSSO Comment:** The proposal to add PT Superior mediastinal syndrome to Embolic and thrombotic events, venous (SMQ) as a narrow term is approved as requested. Superior mediastinal syndrome fits the inclusion criteria of Embolic and thrombotic events, venous (SMQ) for terms related to occlusion of arteries and veins associated with embolism and/or thrombosis. Superior mediastinal syndrome is superior vena cava syndrome with associated tracheal compression. Similar terms, such as PT Superior vena cava syndrome is already included in Embolic and thrombotic events, venous (SMQ). All terms are narrow scope.

# Detail Report

CR Number: 2024180067		Implementation Date: 08-Jul-24	Related CR: 2024180067	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Failure of additional condition for nonprescription use	Approved as Requested	Proposed PT	
To SMQ	Medication errors (SMQ)		Failure of additional condition for nonprescription use	10091169
Term scope	Broad		To SMQ	
			Medication errors (SMQ)	20000224
			Term scope	
			Broad	
			Term_category	
			A	
			Term_weight	
			0	
MSSO Comment: The proposal to add PT Failure of additional condition for nonprescription use to Medication errors (SMQ) as a broad term is approved as requested. PT Failure of additional condition for nonprescription use fits the inclusion criteria of Medication errors (SMQ) for terms which do not specifically represent a medication error, but have a significant potential to identify medication errors, for a broad scope term.				

CR Number: 2024180068		Implementation Date: 08-Jul-24	Related CR: 2024180068	
<a href="#">Change Requested</a>	Add term to SMQ	<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	Issue with additional condition for nonprescription use	Approved as Requested	Proposed PT	
To SMQ	Medication errors (SMQ)		Issue with additional condition for nonprescription use	10091170
Term scope	Broad		To SMQ	
			Medication errors (SMQ)	20000224
			Term scope	
			Broad	
			Term_category	
			A	
			Term_weight	
			0	
MSSO Comment: The proposal to add PT Issue with additional condition for nonprescription use to Medication errors (SMQ) as a broad term is approved as requested. PT Issue with additional condition for nonprescription use fits the inclusion criteria of Medication errors (SMQ) for terms which do not specifically represent a medication error, but have a significant potential to identify medication errors, for a broad scope term.				