(SNMMI clinical guidelines http://www.snmmi.org/ClinicalPractice/content.aspx?ItemNumber=10817&navItemNumber=10786)

Pediatric activity should follow image gently guidelines https://www.imagegently.org/Procedures/Nuclear-Medicine

If you see errors, please let me know! wendy-galbraith@ouhsc.edu

Radiopharmaceutical	Trade Name "Common name"	Clinical Use	Dosages* (mCi)
99mTc Physical Half-life (P) 6h Technetium-99m-pertechnetate (from Molybdenum-99 generator) High Specific Activity from LEU of U235 fission A9969 $10	"Tech" "TcO4" "Tc99m" "^{99m}Tc"	Lantheus (11994-0091-12) AWP $30380.54; WAC $25317.12 (11994-0091-11) AWP $24699.68; WAC $20583.07 No Curium information	Range 10 10 0.1 1 10
Tc99m pertechnetate labeled carbon sys.	Technegas aerosol, 9/2023 Cyclomedic-73814-0986-20; AWP pkg $18600 unit; WAC pkg $15500 unit $310; C9150 per study dose $372 pass through	Ventilation -HCPCS Level II code A9506 Graphite crucible for preparation of technetium Tc-99m labeled carbon aerosol, one crucible	30
Tc99m-bicisate (ECD)	Neurolite Lantheus; A9557 per study dose; up to 25 mCi CMS 2025 $683.80	Lantheus (11994-0006-02) AWP pkg $8799.18 unit $4399.59; WAC pkg $7332.65 unit $3666.33	25
Tc99m-disofenin (DISIDA)	Hepatolite (Pharma is DC Dec 2019)	Hepatobiliary Imaging Gallbladder EF	5
Tc99m-exametazine (HMPAO)	Ceretec-available from DraxImage and GE; A9521 up to 25 mCi CMS 2025 $802.34 A9569 WBC per study dose CMS 2025 $1040.32	Brain perfusion imaging-stabilized Infection WBC label-unstabilized GE (17156-025-05) no preserv AWP pkg $10798 unit $2159.60; DIR pkg $8998.33 unit $1799.66	25 Range
Tc99m-macroaggregated albumin	"MAA" Curium and DraxImage; A9540 up to 10 mCi	Pulmonary perfusion and embolism, Pre Y-90 SIR Spheres distribution test	Particle dependent 3-5
Tc99m-mebrofenin	Choletec "Mebro" Bracco, Sun Pharma; A9537 up to 15 mCi	Hepatobiliary Imaging Gallbladder EF Bracco (00270-0083-20) 10 vials per pkg; AWP pkg $6637.50 unit $663.75; DIR pkg $5650 unit $565 Sun (45567-0455-02) 30 vials per pkg AWP pkg $3403.80 unit $113.45; DIR pkg $2836.50 unit $94.55	5
Tc99m-medronate	"MDP" DraxImage MDP-25; Cardinal Health, Sun Pharma A9503	Sun (45567-0040-02) 30 vials per pkg AWP pkg $2946.60 unit $98.22; DIR pkg 2455.50 unit $81.50 Jubilant Draximage (65174-0660-30) 30 kits per pkg No AWC or WAC or DIR Cardinal Health (65857-0505-10) 10 vials per pkg No AWP no WAC or DIR	25
Tc99m-mertiatide	"MAG3" Curium, DraxImage, Sun Pharma; A9562 up to 15 mCi	Renal imaging (ERPF) Curium (69945-0096-20) no AWP or WAC (5 vials per pkg) Jubilant Draximage (65174-261-05)	10
Tc99m-oxidronate	"HDP" Curium; A9561; up to 30 mCi	Bone imaging	25
Tc99m-pentetate Pentetate Kit Jubilant-Drax (12/89) Pentetate Kit Curium (3/25) (69945-314-30, also 01 & 05)	"DTPA" DraxImage; A9539 up to 25 mCi A9567 up to 75 mCi	Renal imaging (GFR function, renal flow studies) Lung Ventilation for matching with MAA Cardiac first pass Cerebral-Peritoneal shunt	3, 10 35-75 25 1

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Tc99m-pyrophosphate Cis-Pyro Sun Pharm (6/87) Technescan PYP Kit Curium (5/74)	"Hot pyp" A9538 up to 25 mCi "Cold pyp" or "pyp"	Curium (69945-0094-20) no AWP no WAC Sun (45567-0060-02) 30 vials per pkg; AWP pkg $2305.80 unit $76.86; DIR pkg $1921.50 unit $64.05 Sun (45567-0060-02) (30 vials per pkg)	15 25 1 0
Tc99m-red blood cells	Ultratag Curium (69945-068-20) A9560; per study dose; up to 30 mCi Curium No AWP no WAC	GI bleeds Hemangioma ENVG (MUGA) RNVG (MUGA) L to R shunt Spleen (heat damaged RBC's)	30 30 30 30 30 30
Tc99m-sestamibi Cardinal Health, Curium, DraxImage, Lantheus, Sun Pharma A9500 Per study dose up to 40 mCi	"Sestamibi" or "mibi"	Lantheus (11994-0003-20) AWP pkg $2335.79 unit $116.79; WAC pkg $1946.46 unit $97.32 Lantheus (11994-0001-20) Cardiolite AWP pkg $2835.23 unit $141.76; WAC pkg $2362.69 unit $118.13 Curium (69945-0092-20) AWP pkg $3247 unit $646; WAC pkg $2706 unit $541.2 Sun (45567-0555-02) 30 vials per pkg AWP pkg $13517.28 unit $450.57; DIR pkg $11264.40 unit $375.48 Cardinal Health (65857-0500-05) 20 vials per pkg no AWP/WAC or DIR Jubilant Draximage (45548-0141-10) 10 vials pkg no AWC no WAC no DIR	10/30 25 25
Tc99m-succimer	"DMSA" Nephroscan Feb 2022 Theragnostics (71083-0020-05) Distributed by GE; A9551 up to 10 mCi;	Renal cortical imaging	5 0.1 to 0.05 ped
Tc99m-sulfur colloid AN-Sulfur Colloid Sun Pharm (4/79) Sulfur Colloid Kit Jubilant-Drax (11/23)	"Sulfur colloid" Sun (45567-0030-01) 5 vials per pkg AWP pkg $3757.02 unit $751.41; DIR pkg $3130.85 unit $626.17 Jubilant Draximage (NO NDC INFORMATION)	Liver-spleen, Bone marrow Lymphoscintigraphy Gastric emptying Gastric reflux Aspiration/Salivagram Cystography (augmented bladder) Peritoneo-venous shunt (LeVeen shunt)	5 0.4 1 0.3 0.2 1 0.5
Tc99m-tetrofosmin Myoview GE (2/96 – 0.23 mg) Myoview 30 GE (3/05 – 1.38 mg)	Myoview A9502 Per study dose GE (17156-0024-05) 10ml vial AWP pkg $4093.09 unit $818.62; DIR pkg $3410.91 unit $682.18; GE (17156-0026-30) 30ml vial AWP pkg $14619 unit $2923.80; DIR pkg $12182.50 unit $2436.50	Myocardial perfusion imaging	10/30
Tc99m-tilmanocept	Lymphoseek (Cardinal Health 2017) (65857-450-05) AWP pkg $19847.16 unit $ 3969.43; WAC pkg $16539.30 unit $ 3307.86; A9520 up to 0.5 mCi	Lymphoscintigraphy 250 mcg per vial	0.5

*ACR–SPR (American College of Radiology-Society of Pediatric Radiology) Technical Standard for Diagnostic Procedures Using Radiopharmaceuticals. Available at: https://www.acr.org/-/media/ACR/Files/Practice-Parameters/Radiopharmaceuticals.pdf. Revised 2016. American College of Radiology. ACR-AAPM practice

parameter for reference levels and achievable administered activity for nuclear medicine and molecular imaging. 2015; Available at: https://www.acr.org/-/media/ACR/Files/Practice-Parameters/RefLevels-NucMed.pdf.

Radiopharmaceutical	Trade Name "Common name"	Clinical Use	Dosages (mCi)
Carbon-11 choline (2013) (P = 20 min)	Mayo Clinic-Rochester, Minn, Zevacor ANDA A9515 up to 20 mCi CMS-2025 $2062.94/dose	Prostate cancer recurrence	10-20
Copper (Cu)-64 dotatate (8/20) (P = 12.6hr)	**DETECTNET** (Curium) Available everyday & Friday after 10:30 Pass-through until Jan 1 2024; A9592 CMS 2025 per mCi $595.10 = $2618.44	Somatostatin receptor positive neuroendocrine tumors Curium (69945-0064-01) AWP unit $4620; WAC $3850	4.4 (1mCi/mL)
Flourine-18 florbetaben (P = 109 min)	**NEURACEQ** -Now Lantheus (Life Molecular Imaging) (Primal) Contract manufacturing Q9983 up to 8.1 mCi CMS 2025 $1273.76 per dose (54828-0001-01) AWP $4080' WAC $3400; DIR $3400	Risk of Alzheimer's	8
Flourine-18 florbetapir	**AMYVID** (Lilly) (00002-1200-01) AWP $3428.88; WAC $2857.40; DIR $2857.40 CMS 2025 $2194.62; Contract manufacturing Distributed by Petnet and some Cardinal PET facilities; A9586 up to 10 mCi	Risk of Alzheimer's	10
Fluorine-18 flortaucipir (5/20)	**TAUVID™** (Avid Radiopharmaceuticals, Inc bought by **Lilly**) (00002-1220-01) AWP $4200; WAC $3500; Contract Manufacturing Distributed by Petnet and some Cardinal PET facilities; A9586 CMS 2025 dose $2194.62	Risk of Alzheimer's	10
Fluorine-18 flotufolastat (5/23)	**POSLUMA** (Blue Earth Diag.) (69932-0002-01) AWP $6078.96; WAC $5065.80; Distributed by PetNet- A9608 $614.78/mCi pass through	Prostate cancer initial or recurrence	8
Fluorine-18 fludeoxyglucose	"FDG" Various ANDA; A9552 up to 45 mCi	Lantheus (11994-0015-01) single-dose AWP pkg&unit $555.44; WAC pkg&unit $462.87	10
Fluorine-18 fluciclovine (5/16)—Replaced by Posluma	**AXUMIN** (Blue Earth Diagnostics) (69932-0001-01) AWP $6199.78; WAC $5166.48; Distributed by Petnet: A9588 per 1 mCi CMS 2025 $268.42 = $2684.20	Prostate cancer recurrence	10
Fluorine-18 fluorodopa (1/22)	Feinstein Institute, Manhasset, NY (Tom Chaly); NDA 200655 must have ANDA - GE FASTLAB 2 HPLC+). CMS has removed the NCD, PET centers could get the coverage for Fluorodopa PET studies through the local CMS contractors.A9602 CMS 2025 $458.62/mCi = $2293.10	Suspected parkinsonian syndromes-ANDA	5
Fluorine-18 fluoroestradiol (5/20)	**CERIANNA™ (GE** bought Zionexa, US) Contract manufacturing through PETNET – A9591 per 1 mCi CMS 2025 $498.67 = $2992.02 GE (72874-0001-01) AWP $5538; DIR $4615	Estrogen receptor (ER)-positive lesions as an adjunct to biopsy in patients with recurrent or metastatic breast cancer	6
Fluorine-18 flurpiridaz (10/2024)	**FLYRCADO** (GE) (00407-8787-01) up to 10 mCi; AWP $2700; WAC $2250 2025-CMS Pass-through HCPCS Level II code A9611, "Flurpiridaz F 18, diagnostic per 1 millicurie	myocardial blood flow (MBF) 2.5 to 3 mCi rest/9 to 9.5 stress (1 hr apart); if pharmalogic use 6 to 6.5 mCi for stress (0.5 hr apart)	3/9
Fourine-18 flutemetamole (10/13)	**VIZAMYL (GE)** (17156-0067-30) AWP $95070-30 mL MDV; DIR $79200; Contract manufacturing Distributed by Pharmalogic and Cardinal PET facilities Q9982 CMS 2025 $874.10 per dose	Risk of Alzheimer's	5
Fluorine-18 piflufolastat (PSMA) (5/21)	**PYLARIFY Lantheus –** (Progenics Pharmaceuticals) (71258-0022-00) A9595 AWP $ 6642.62; WAC $5535.52; Distributed by any contract manufacturer A9595 CMS 2025 $332.44/mCi = $3324.40	Prostate cancer initial and recurrence	10
Flourine-18 sodium fluoride	"NaF" Various ANDA; A9580 up to 30 mCi	Bone metastasis	5

Gallium-68 dotatoc (8/19) (P = 68 min)	Univ of Iowa Hosp & Clinics; Various ANDA C9067 CMS 2025 $4.05/0.01 mCi = $1620	Somatostatin receptor positive neuroendocrine tumors	4
Gallium-68 dotatate (6/16)	**NETSPOT** (Advanced Accelerator Applications-Novartis) (69488-0001-40) AWP $3600; WAC $3000; DIR $3000; Generator distribution various; A9587 per 0.1 mCI CMS 2025 $51.09 = $2758.86	Somatostatin receptor positive neuroendocrine tumors Pass-through ended Jan 2022	5.4
Gallium-68 PSMA – CALI-cGMP 212 (approved 12/2020) Gallium-68 PSMA (KIT) Novartis: Locametz (3/22) Telix: Illuccix (12/21) Gozellix (3/25) (6 hr exp. 500 mCi kit max; cyclotron ARTMS QUANTM system	CALI-cGMP under 212: PSMA-11 with HBED-CC chelator; A9594 (ucla) CMS 2025 $372.17 per mCi = $1860.85; A9593 (ucsf) CMS 2025 $534.91 per mCi = $2674.55 FDA approved: Telix: Feb 2022 ^{68}Ga-HBED-PSMA-11 (gozetotide- **Illuccix**-74725-0100-64); A9596 CMS 2025 $1026.05/mCi = $5130.25; AWP $6199.20; WAC $5166; Novartis/AAA: Mar 2022 ^{68}Ga-HBED-PSMA-11 (gozetotide-**Locametz** 69488-0017-61) AWP $6921.60; WAC $5768; A9800 CMS 2025 $873.44/mCi x 7 = $6114.08; pass through until July 1 2025-Novartis is trying to get a second passthrough Not approved yet: Theragnostics/GE: now AAA agreement distribution: (GalliProst) ^{68}Ga-THP-PSMA THP-	Prostate-specific membrane antigen (PSMA) positive lesions in men with prostate cancer with suspected metastasis who are candidates for initial definitive therapy or with suspected recurrence based on elevated serum prostate-specific antigen (PSA) level	3-7 PI 3-5 reg $ 6 =$$ 7 =$$$
Nitrogen-13 ammonia (P = 10m)	"Ammonia" Various ANDA; A9526 up to 40 mCi	Myocardial perfusion	10-20
Rubidium-82 Chloride (Sr-82 generator) (P = 75s)	Cardio-Gen-82 (Bracco-00270-0150-00) Ruby-Fill (DraxImage-65174-0021-10); A9555 up to 60 mCi per study dose	PET cardiac perfusion imaging	30-60
Cyclotron Products non-PET			
Gallium-67 citrate (P=78h)	"Gallium" (Lantheus DC 2022); A9556 per mCi	Soft-tissue tumor Inflammatory process imaging	7
Indium-111 chloride (P=68h)	Indiclor (Curium)	Labeling monoclonal antibodies and peptides	3 to 9
Indium-111 pentetate Indium DTPA GE (2/82)	Indium DTPA (GE) (17156-0251-08) AWP $3187.81; DIR $2656.51; A9548 per 0.5 mCi CMS 2025 $715.61	Cerebral Spinal Fluid (CSF) kinetics SDV; 1 mCi/mL	0.5
Indium-111 oxyquinoline	Indium Oxine (GE 12/85) and (BWXT 7/2018); A9547 per 0.5 mCi CMS 2025 $772.61; A9570 WBC per study dose CMS 2025 $1031.39	Labeling leukocytes and platelets GE (17156-0021-01) AWP $5051.95; DIR $4209.96	0.7
Indium-111 pentetreotide	**Octreoscan** (Covidian-); A9572 up to 6 mCi; CMS 2025 $1914.61	Imaging neuroendocrine tumors	6
Iodine-123 iobenguane(metaiodobenzylguanidine) (P=13.2h)	**Adreview**-GE (17156-0235-01) 2 mCi/mL vial AWP $6130.09 DIR $5108.41; A9582 up to 15 mCi CMS 2025 $2074.81	Neuroendocrine tumor imaging 78803 Sympathetic nerve activity in heart failure 0332T	10
Iodine-123 ioflupane	**DatScan** –GE (17156-0210-01) AWP $2961.60; DIR $2468 (2 mCi/mL); ioflupane-**Curium** (3/2022) M-F early delivery No AWP or WAC	Dopamine receptor imaging for Parkinson's disease 78803 A9584 up to 5 mCi CMS 2025 $1388.02	5
Iodine-123 sodium iodide	"123 caps" Curium, Cardinal A9509 Use for 1-4 mCi doses of I-123 for whole body imaging for less than 1 mCi and thyroid imaging see A9516 100 to 999 mcrCi	Thyroid imaging and uptake	0.3
Thallium-201 Chloride (P=73h) Thallous Chloride Curium (10/79)	"Thallium" (Lantheus DC 2022); (Curium Not Returned to market 12/2022) TRACE (Discontinued Mount Sinai Medical Center, FL. 11/2001)	Myocardial perfusion imaging Parathyroid Tumor imaging	4
Naturally Radioactive Products			
Carbon-14 Urea (P=5,730y)	Pytest Haylard Health (63584-0001-00) AWP $2947.48 (AVENT DC Dec 2023)	Detection of H. Pylori infection	0.001

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Reactor Products			
Strontium-89 (P=52.7d)	Metastron (GE DC MF FEB 2019; available BioMed through Triad-Drax 2020); A9600 $3975/mCi	Palliative treatment of bone pain of skeletal metastases	4
Iodine-125 human serum albumin (P=60d)	Jeanatope, "RISA" (IsoTex); A9532 per 5 mcrCi	Plasma volume determination	0.005 – 0.01
Iodine-125 iothalamate	Glofil (IsoTex)	Measurement of glomerular filtration	0.01-0.03
Iodine-131 human serum albumin (P=8d)	Megatope (IsoTex); A9524 per 5 mcrCi	Vascular volume studies-protein turnover studies	0.01
Iodine-131 metaiodobenzylguanidine	I-131 MIBG;	Pheochromocytomas and neuroblastomas Diagnostic	0.5
Iodine-131 sodium iodide	"Iodine" Draximage, International Isotopes; A9517 $23.73/per mCi	Whole Body Scan Thyroid therapy	2 10 - 200
Xenon-133 gas (5.2d)	"Xenon" Curium, Lantheus ; A9558 per 10 mCi	Lantheus (11994-0128-25) AWP pkg $3117.06 unit $623.41; WAC pkg $2597.55 unit $519.51	10-20
Yittrium-90 ibitumomab (P=64h)	**ZEVALIN** (Acrotech Biopharma-72893-0007-04) now Spectrum); AWP $81165.58; WAC $66804.65; A9543 $65,476.58 up to 40 mCi	Non-Hodgkin's lymphoma	32 max
Radium-223 dichloride (P=11.4d) Ac227>Th227>Ra223	**XOFIGO** (Bayer-50419-0208-01) distributed by Cardinal Health-DENVER)-A9606 $157.91/mcrCi AWP $36102.57 WAC $30085.56	CRPC with symptomatic bone metastases 4-apha decays with gamma 81 keV (15%), 84 (24%), and 154 5%	About 0.14 total x6
Lutetium Lu-177 dotatate (P=6.6d)	**LUTATHERA** (AAA-69488-0003-01) Feb 2018 (DISTRIBUTED TO HOSPITAL IN VIAL) Lu-177m (Tp1/2 160 days) contaminant [Lu-176(n,g)Lu177 & Lu177m] A9513 $/mCi AP $71770.46; WAC $59808.72; DIR $59808.72	NE Tumors with somatostatin receptors	200 q8 wks x 4 doses
Lutetium Lu-177 vipivotide tetraxetan (March 2022)	**Pluvicto** -Endocyte/Novartis/AAA-69488-0010-61;AWP $58444.48; WAC $48703.73; lutetium-177 (Lu-177) PSMA 617 [n.c.a Yb-177(n,g) Lu-177] A9607 $229.76/mCi	Metastatic Prostate Treatment -	200 q6wks x6 doses

Investigational Radiopharmaceuticals		**Indication**
F-18	126 FDA registered ongoing clinical trials FLT (AML) and FMISO (hypoxia)	18F-flurpiridaz (MBF) -NOS (inflammation in every disease state)-FMAU (uracil agent –cancer) –FEOBV (Parkinson) -FTT (PARP inhibitor breast/ovarian) –FAZA (lung) –FCH (hepatocarcinoma) –TFB (thyroid) -CETO (primary aldosteronism) –FSPG (liver) -PSS232 (amyotrophic lateral sclerosis)
Zr-89	7	-panitumumab (squamous cell head and neck) –DFO-YS5 (multiple myeloma) –Df crefmirlimab (CD8 Tcells) –AP-101 (ALS)
Ac-225	15	-FPI (neurotensin receptor tumors) –daratumumab (AML)
Lu-177	55	-dotatate (Breast, pancreatic, meningioma, CNS) –PMSA (prostate)
Brachytherapy Devices	**Trade Name "Common name"**	**Indication**
Iodine-125 iodohydroxybenzenesulfonate (LIQUID) & Cecium-131 Chloride in NS (LIQUID)	Iotrex Cesitrex	Use in GliaSite device for recurrent malignant gliomas – MFG change now IsoRay in Richland, WA (2014)
Ir-192 (P=74d)	Checkmate	Decrease in-stent restenosis
Sr-90 (P=29y)	Novoste BetaCath	Decrease in-stent restenosis
P-32 (P=14d)	Guidant Galileo	Decrease in-stent restenosis
Y-90 glass (64h)	TheraSphere	Hepatocarcinoma

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Y-90 resin-polymer	SIR-Spheres	Hepatocarcinoma/Colorectal mets 27-81 mCi
Discontinued Radiopharmaceuticals	**Trade Name "Common name"**	**FDA Indication and off label uses**
Chromium-51 sodium chromate (P=27.7d)	Chromitope	Labeling RBC's (DC MFG 2011)
Cobalt-57 cyanocobalamin (P=270d)	Rubratope	Detection of pernicious anemia (DC MFG 2006)
Cobalt -57 & -58 cyanocobalamin	Dicopac	Detection of pernicious anemia
Indium-111 capromab pendetide	ProstaScint – Ayto Bio distributed by Cardinal	Monoclonal antibody for imaging prostate cancer DC MFG 5 2018
Indium-111 Imciromab	Myoscint	MAB for diagnosis of myocardial necrosis
Indium-111 satumomab pendetide	OncoScint CR/OV	MAB Colorectal and ovarian cancer
Iodine-131 iodohippurate	Hippuran	Renal imaging and function studies (ERPF)
Iodine-131 metaiodobenzylguanidine (7/2018)	AZEDRA (Lantheus owns Progenics) A9590 per $338.06/1 mCi	TX Pheochromocytomas and neuroblastomas Diagnostic (DC MFG 3/2024) (±2.5) mL of solution with a total radioactivity of 240–413 mCi/vial
Krypton-81m gas (Rb-81 generator) (P=13s)		Pulmonary ventilation imaging
Phosphorus-32 Chromic phosphate	P-32 Phosphocol	TX intracavitary malignancies DC MFG 2009
Phosphrous-32 Sodium phosphate	"P-32"	Therapy of polycythemia vera DC MFG 2009
Samarium-153 lexidronam (EDTMP)	Quadramet (Lantheus)(Jazz)	Palliative treatment of bone pain of skeletal metastases DC MFG 10/2021
Technetium-99m-pertechnetate (from Molybdenum-99 generator) Low Specific Activity from Mo98 (Feb 2018) Northstar	Radiogenix	Same as U235 source (DC MFG Nov 2023)
Tc99m-albumin colloid	Microlite	Imaging RES (liver/spleen)
Tc99m-arcitumomab	CEA-Scan	Monoclonal antibody for colorectal cancer DC MFG 2007
Tc99m-apcitide	AcuTect	Peptide imaging of DVT DC MFG 2006
Tc99m-depreotide	Neotect	Somatostatin receptor-bearing pulmonary masses (NSCLC)
Tc99m-fanolesomab	NeutroSpec	MAB Infection-DC MFG 11/05
Tc99m-gluceptate	"Gluco"	Renal cortical imaging DC MFG 12/08
Tc99m-human serum albumin	"HSA"	Imaging of cardiac chambers
Tc99m-lidofenin	"HIDA"	Hepatobiliary imaging
Tc99m-nofetumomab merpentan	Verluma	MAB Fab fragment for imaging SCLC
Tc99m-teboroxime	Cardiotec	Myocardial perfusion imaging
Iodine-131 tositumomab	Bexxar	Treatment of Non-Hodgkin's Lymphoma DC MFG 2/2014 (112 to 168 mCi with avg 110 mCi)

*Usual dosage range of radiopharmaceutical used dosages are adjusted for patients' weight, sex, and clinical diagnosis. Pediatric doses are appropriately lowered on an age and weight bases. ACR–SPR (American College of Radiology-Society of Pediatric Radiology) Technical Standard for diagnostic Procedures Using Radiopharmaceuticals. Available at: https://www.acr.org/-/media/ACR/Files/Practice-Parameters/Radiopharmaceuticals.pdf. Revised 2016. American College of Radiology. ACR-AAPM practice parameter for reference levels and achievable administered activity for nuclear medicine and molecular imaging. 2015; Available at: https://www.acr.org/-/media/ACR/Files/Practice-Parameters/RefLevels-NucMed.pdf.

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1. What is the new packaging threshold for diagnostic radiopharmaceuticals unbundled for HOPPS in 2025?
CMS finalized a packaging threshold of $630 for determining separate payments for diagnostic radiopharmaceuticals

2. Why did CMS choose a $630 threshold for unbundling diagnostic radiopharmaceuticals and a 2.0 multiplier?
The finalized $630 threshold, which was broadly supported by the nuclear medicine community, reflects the unique status of diagnostic radiopharmaceuticals as supplies for nuclear medicine procedures that warrant a specific threshold that is distinct from the broader drug packaging threshold for therapeutic products. The diagnostic radiopharmaceutical threshold of $630 is two times the average amount CMS assumes is attributed to packaged diagnostic radiopharmaceuticals ($314). The final 2.0 multiplier CMS adopted is consistent with the two-times rule CMS uses to assign services to Ambulatory Payment Classification (APC) levels, which also uses a single 2.0 multiplier. Many commenters also supported a threshold based on a 1.75 multiplier, which is one of the multipliers used to determine whether a service qualifies for additional payments as high-cost outlier under the HOPPS. CMS declined to adopt that approach, stating it believed 1.75 was an appropriate multiplier for outlier payments because services qualifying for outlier payments also must exceed an additional fixed-dollar threshold. Since CMS intends to only have a single threshold to determine separate payment for diagnostic radiopharmaceuticals, it believes the higher 2.0 multiplier is more appropriate.

3. How will the threshold be adjusted in future years?
The threshold will be updated by the Producer Price Index (PPI) for Pharmaceuticals in future years.

4. How does CMS determine which diagnostic radiopharmaceuticals receive separate payment?
CMS finalized as proposed the methodology to identify products to be paid separately. CMS will use claims data to estimate the per day cost of each product. Products that have a per day cost at or below the $630 threshold will remain packaged.

26 products that were proposed to be paid separately also qualified for separate payment in the final rule

HCPCS	APC	Short Description	Qualifier if appliable	Prop	Final	Updated if applicable	Pt Dosage
A9515	9451	Choline C11		$2036.25	$2062.94		1 dose
A9521	0766	Tc99m exametazime		$5161.14	$5450.36	$802.34	1 dose
A9542	0769	In111 ibritumomab		$844.76	$798.02		1 dose
A9547	0770	In111 oxyquinoline		$783.61	$772.61		1 dose
A9548	0771	In111 pentetate	Per 0.5 mCi	$708.32	$715.29		0.5 mCi
A9557	0774	Tc99m bicisate		$714.49	$683.80		1 dose
A9568	0775	Tc99m arcitumomab		$812.29	$809.51		1 dose
A9569	0776	Tc99m wbc		$1029.28	$1040.32		1 dose
A9570	0777	In111 wbc		$1052.58	$1031.39		1 dose
A9572	0779	In111 pentetreotide		$1919.76	$1914.61		1 dose
A9582	0780	I123 iobenguane ADREVIEW		$2102.06	$2074.81		1 dose
A9584	0781	I123 iofluopane DatScan		$1435.64	$1388.02		1 dose
A9586	1664	F18 florbetapir TAUVID		$2148.39	$2194.62		1 dose
A9587	9056	Ga68 dotatate NETSPOT	Per 0.1 mCi	$50.82	$51.09		5 mCi
A9588	9052	F18 fluciclovine AXUMIN	Per mCi	$273.55	$268.42		10 mCi
A9591	9370	F18 fluoroestradiol CERIANNA	Per mCi	$524.15	$677.08	$498.67	6 mCi
A9592	9383	Cu64 dotatate DETECTNET	Per mCi	$1084.19	$1468.21	$595.10	4.4 mCi
A9593	9409	Ga68 psma-11 ucsf CYCLOTRON	Per mCi	$580.50	$886.70	$534.91	5 mCi
A9594	9410	Ga68 psma-11 ucla CYCLOTRON	Per mCi	$371.02	$868.23	$372.17	5 mCi
A9595	9430	F18 piflufolastat PYLARIFY	Per mCi	$337.46	$515.12	$332.44	8-10 mCi
A9596	9443	Ga68 psma ILLUCCIX	Per mCi	$975.48	$1026.05		5-7 mCi

(SNMMI clinical guidelines http://www.snmmi.org/ClinicalPractice/content.aspx?ItemNumber=10817&navItemNumber=10786)

Pediatric activity should follow image gently guidelines https://www.imagegently.org/Procedures/Nuclear-Medicine

A9602	9053	F18 fluorodopa CYCLOTRON	Per mCi	$146.88	$458.62		5 mCi
A9800	9055	Ga68 psma LOCAMETZ	Per mCi	$873.44	$873.44		5-7 mCi
C9067	9923	Ga68 dotatoc CYCLOTRON	Per 0.01 mCi	$4.07	$4.05		5.4 mCi
Q9982	9459	F18 flutemetamol VIZAMYL		$2256.50	$874.10		8 mCi
Q9983	9458	F18 florbetaben NEURACEQ		$1154.70	$1273.76		1 dose

5. How often will CMS determine separately payable diagnostic radiopharmaceuticals?

This determination will be made on an annual basis using more recent claims data.

6. What payment methodology will CMS use in 2025 for separately payable diagnostic radiopharmaceuticals?

For 2025, CMS finalized payment based on **mean unit cost (MUC), with no exceptions.**

7. Why did CMS reject the use of ASP (Average Sales Price) data for the payment methodology?

In response to comments recommending the use of ASP data, CMS acknowledged the potential value in using ASP information in the future but indicated that more consistent, validated, and universal reporting would be necessary before ASP data could be a viable payment methodology for the agency to adopt.

8. How will new diagnostic radiopharmaceuticals be paid if they lack pass-through status or claims data?

Payment for diagnostic radiopharmaceuticals with HCPCS codes that do not have pass-through status and for which there is no claims data will be paid based on ASP data. If ASP data is not available, payment rates will be based on wholesale acquisition cost (WAC), and in the absence of WAC, CMS will pay 95 percent of the product's most recent average wholesale price (AWP), e.g. HCPCS Level II code A9611, "Flurpiridaz F 18, diagnostic, 1 millicurie?
The AWP & WAC state up to 10 mCi for AWP $2700; WAC $2250.

9. Does this policy affect diagnostic radiopharmaceuticals with pass-through status?

CMS confirmed that this policy does not affect the qualifications or payment methodology for products with pass-through status.

10. How will the offset amount be applied?

CMS will continue to subtract an offset amount from the payment for services using pass-through products to avoid double payment for the radiopharmaceutical. CMS did not apply an offset to separately payable diagnostic radiopharmaceuticals without pass-through status.

11. What is the economic impact of this change in CMS policy?

The separate payment provisions for diagnostic radiopharmaceuticals will be budget neutral. CMS indicates it will monitor for any unintended consequences and may propose modifications as necessary in the future.

*Usual dosage range of radiopharmaceutical used dosages are adjusted for patients' weight, sex, and clinical diagnosis. Pediatric doses are appropriately lowered on an age and weight bases. ACR–SPR (American College of Radiology-Society of Pediatric Radiology) Technical Standard for Diagnostic Procedures Using Radiopharmaceuticals. Available at: https://www.acr.org/-/media/ACR/Files/Practice-Parameters/Radiopharmaceuticals.pdf. Revised 2016. American College of Radiology. ACR-AAPM practice parameter for reference levels and achievable administered activity for nuclear medicine and molecular imaging. 2015; Available at: https://www.acr.org/-/media/ACR/Files/Practice-Parameters/RefLevels-NucMed.pdf.