



Centers for Medicare & Medicaid Services (CMS) Healthcare Common Procedure Coding System (HCPCS) Application Summaries and Coding Decisions Second Quarter 2021 Coding Cycle for Drug and Biological Products

This document presents, in request number sequence, a summary of each HCPCS code application and CMS' coding decision for each application processed in CMS' Second Quarter 2021 Drug and Biological HCPCS code application review cycle. Each summary includes:

- Application number;
- Topic/Issue;
- Summary of the applicant's request as written by the applicant with occasional non-substantive editorial changes made by CMS;
- CMS' final or preliminary coding decision; and
- Effective date of any coding action which, for the purpose of this publication, refers to the date the code is first available to be billed on claims.

The HCPCS coding decisions below will also be included in the October 2021 HCPCS Quarterly Update, pending publication by CMS in the coming weeks at:

<https://www.cms.gov/Medicare/Coding/HCPCSRleaseCodeSets/Alpha-Numeric-HCPCS>.

Request # 20.200**Topic/Issue**

Request to establish a new HCPCS Level II code to identify Symphony, an extracellular matrix bioengineered skin substitute derived from ovine forestomach tissue and including hyaluronic acid.

Applicant's suggested language: "QXXXX — Symphony, per square centimeter"

Applicant's Summary

Symphony is a bioengineered skin substitute composed of extracellular matrix (ECM) and hyaluronic acid (HA). Symphony contains three layers of ovine-derived ECM, which contains more than 150 essential ECM proteins, including structural proteins, adhesion proteins, and signaling proteins—all of which aid the wound healing process. A single layer of HA has been included in the composite design to provide additional healing biology and ensure a moist wound environment that is critical to healing. The composite design scaffolds the patient's own cells to rebuild dermal tissues in acute and chronic wounds.

Preliminary Decision

This request is being deferred to a subsequent coding cycle because the scope of the request necessitates that additional consideration be given before CMS reaches a final decision.

Request # 21.072

Topic/Issue

Request to establish a new HCPCS Level II code to identify Kimyrsa.

Applicant's suggested language: "XXXXX- Injection, oritavancin (Kimyrsa), 30mg"

Applicant's Summary

Kimyrsa is a single-dose, antibacterial drug infused over one (1) hour for the treatment of adult patients with acute bacterial skin and skin structure infections (ABSSSI) caused by certain bacteria. It is a semi synthetic, lipoglycopeptide antibacterial drug for the treatment of adult patients with ABSSSI caused by designated pathogens. Kimyrsa is indicated for the treatment of adult patients with ABSSSI caused by susceptible isolates of designated Gram-positive microorganisms. Oritavancin has three mechanisms of action: (i) inhibition of the transglycosylation (polymerization) step of cell wall biosynthesis by binding to the stem peptide of peptidoglycan precursors; (ii) inhibition of the transpeptidation (crosslinking) step of cell wall biosynthesis by binding to the peptide bridging segments of the cell wall; and (iii) disruption of bacterial membrane integrity, leading to depolarization, permeabilization, and cell death. These multiple mechanisms contribute to the concentration dependent bactericidal activity of oritavancin. The recommended dosage of Kimyrsa is 1,200 mg administered as a single dose by intravenous infusion over 1 hour in patients 18 years and older. It is supplied as sterile, lyophilized powder containing 1,200 mg of oritavancin (as oritavancin diphosphate) in a single-dose clear glass vial, which must be reconstituted and further diluted prior to intravenous administration. No existing code adequately describes Kimyrsa because it is a unique single source drug for which a new code is needed to facilitate reimbursement based on its average sales price (ASP) data.

Final Decision

1. Establish new HCPCS Level II code J2406 "Injection, oritavancin (kimyrsa), 10 mg."

Kimyrsa is a single source drug that is not therapeutically equivalent to the other Food and Drug Administration (FDA) approved oritavancin product, and has a New Drug Application (NDA).

CMS has a long-standing convention to assign dose descriptors in the smallest amount that could be billed in multiple units to accommodate a variety of doses, making coding more robust, and facilitating accurate payment and reporting of the exact dose administered.

2. Revise existing HCPCS Level II code J2407, which currently reads "Injection, oritavancin, 10 mg" to add "orbactiv" to instead read "Injection, oritavancin (orbactiv), 10 mg."

Effective: 10/1/2021

Request # 21.073**Topic/Issue**

Request to establish a new HCPCS Level II code to identify Apis.

Applicant's suggested language: "QXXXX-Apis, a bioengineered skin and soft tissue (skin substitute) device, absorbable, per square centimeter"

Applicant's Summary

Apis is a 510(k)-cleared skin and soft tissue (skin substitute) device, classified in the Food and Drug Administration (FDA) product code FRO by the Center for Devices and Radiological Health. Apis is fully absorbable, biodegradable and manufactured through a proprietary synthesis of three materials. Gelatin, a porcine collagen derivative, is the primary material accounting for > 50% of the Apis composition. The two other materials are Manuka honey and hydroxyapatite. The FDA cleared Apis on May 31, 2019 (K182725). Apis is currently marketed and available for use in the United States. It was first marketed in the United States during the second half of 2019, and was first sold in December 2019.

Preliminary Decision

This request is being deferred to a subsequent coding cycle because the scope of the request necessitates that additional consideration be given before CMS reaches a final decision.

Request # 21.074

Topic/Issue

Request to establish a new HCPCS Level II code to identify Cosela (trilaciclib).

Applicant's suggested language: "JXXXX, Injection, trilaciclib, 240 mg/m²"

Applicant's Summary

Cosela indicated to decrease the incidence of chemotherapy-induced myelosuppression in adult patients when administered prior to a platinum/etoposide-containing regimen or topotecan-containing regimen for extensive-stage small cell lung cancer.

The recommended dosage of Cosela is 240 mg/m². Cosela is packaged in a single-use 300 mg vial. Each carton contains 300 mg of trilaciclib in a single-dose vial. Cosela is administered as a 30-minute intravenous infusion within 4 hours prior to the start of chemotherapy on each day chemotherapy is administered. The number of vials needed for a given patient to administer a single dose is calculated based on body surface area (BSA), with a recommended dosage of 240 mg/m². The number of single use (i.e., single dose) vials needed for the average adult patient is two vials. This estimate is based on the calculated dose mentioned above and the standard vial size of 300 mg. Cosela is a unique, single use drug that was FDA approved under a section 505(b)(1) new drug application (NDA) and whose active ingredients have no therapeutic equivalents as determined by the FDA's Orange Book.

Final Decision

1. Establish a new HCPCS Level II code J1448 "Injection, trilaciclib, 1mg."

Effective: 10/1/2021

2. HCPCS code C9078, which is effective 7/1/2021, will be discontinued on 9/30/2021 because it will be replaced with HCPCS code J1448.

For Medicare purposes, existing modifier JW "Drug Amount Discarded, Not Administered to Any Patient" may be used as appropriate to report any drug wastage. For example, the drug is supplied as a 300mg/m² single dose vial. Someone weighing 66 pounds would use one vial, and someone weighing 265 pounds would use two vials. For someone whose weight is between 66 and 265 pounds, a second vial would be opened with some wastage.

CMS has a long-standing convention to assign dose descriptors in the smallest amount that could be billed in multiple units to accommodate a variety of doses, making coding more robust, and facilitating accurate payment and reporting of the exact dose administered.

Request # 21.075

Topic/Issue

Request to revise the existing HCPCS code J0693.

Applicant's suggested language: "Injection, cefiderocol, 5 mg" to instead read "Injection, cefiderocol, 250 mg"

Regarding a previous request 20.121, CMS made a final decision to establish a new HCPCS Level II code J0693 "Injection, cefiderocol, 5 mg", effective 1/1/2021.

Applicant's Summary

The trade name of cefiderocol is Fetroja. Fetroja is a cephalosporin antibacterial drug indicated in patients 18 years of age or older for the treatment of the following infections caused by susceptible Gram-negative microorganisms: Complicated Urinary Tract Infections (cUTI), including Pyelonephritis and Hospital-acquired Bacterial Pneumonia and Ventilator-associated Bacterial Pneumonia (HABP/VABP).

Fetroja is administered via intravenous infusion after reconstitution. The recommended dosage of Fetroja is 2 grams every 8 hours infused over 3 hours with dosage adjustment dependent on renal function. For patients with creatinine clearance (CLcr) greater than or equal to 120 mL/min, Fetroja 2 grams administered every 6 hours by IV infusion over 3 hours is recommended. Fetroja 1 gram (cefiderocol) for injection is supplied as a white to off-white sterile lyophilized powder for reconstitution in single-dose. The recommended duration of treatment with Fetroja is 7 to 14 days.

The applicant's rationale for the request to revise the unit of measure for HCPCS code J0693 to 250 milligrams is based on the recommended dosing based on patient-specific characteristics. The current unit of measure of 5 milligrams assigned to the HCPCS code J0693 requires an extremely high number of billing units to be reported on the provider claim. A larger unit of measure based on 250 milligrams would continue to follow CMS' convention of assigning dose descriptors in the smallest amount that could be billed in multiple units that account for the variety of doses based on recommended dosages. This would also minimize the number of billing units to be included on the single claim line.

Final Decision

1. Establish a new HCPCS Level II code J0699 "Injection, cefiderocol, 10 mg."

Effective: 10/1/2021

CMS re-reviewed the clinical circumstances of Fetroja, and determined that 10 mg would be the smallest amount that could be billed in multiple units to accommodate a variety of doses. This update supports streamlined billing, as only 999 units can appear on a claim line for Medicare fee-for-service.

2. Discontinue exiting HCPCS Level II code J0693 “Injection, cefiderocol, 5 mg.”

Effective: 9/30/2021

Request # 21.076

Topic/Issue

Request to establish a new HCPCS Level II code to identify Triferic Avnu (ferric pyrophosphate citrate injection).

Applicant's suggested language: "J1XXX, (Ferric pyrophosphate citrate injection), for intravenous use, 0.1 mg of iron."

Applicant's Summary

Triferic Avnu (ferric pyrophosphate citrate injection), an iron replacement product, is a mixed ligand iron complex in which iron (III) is bound to pyrophosphate and citrate. Triferic Avnu (ferric pyrophosphate citrate) injection is a clear, slightly yellow-green color sterile solution containing 6.75 mg of elemental iron (III) per 4.5 mL (1.5 mg iron (III) per mL) filled in a 5 mL low density polyethylene (LDPE) luer-lock ampule. It contains iron in the form of ferric pyrophosphate citrate. Iron binds to transferrin for transport to erythroid precursor cells to be incorporated into hemoglobin. Triferic Avnu is a single source drug as defined by the Social Security Act and none of Rockwell's other formulations are multiple source drugs. As such, CMS is required to calculate the average sales price of only Triferic Avnu and in turn reimburse providers based upon this rate. To effectuate this statutory requirement, CMS assigns a unique HCPCS code to all single source drugs. Therefore, Triferic Avnu must be assigned its own unique HCPCS code. Triferic Avnu is an iron replacement product indicated for the replacement of iron to maintain hemoglobin in adult patients with hemodialysis-dependent chronic kidney disease (HDD-CKD). Triferic Avnu ampule is administered directly into the pre-dialyzer infusion line, post-dialyzer infusion line, or to a separate connection to the venous blood line over 3 to 4 hours. Its dosage is 6.75g iron (III) intravenously over 3 to 4 hours at each hemodialysis session via pre-dialyzer infusion line, post-dialyzer infusion line, or a separate connection to the venous blood line. Injection: 6.75 mg iron (III) per 4.5 mL solution (1.5 mg iron (III) per mL) in single-dose luer lock ampule. The injection is a clear to slightly yellow-green solution available in single-dose luer lock ampules.

Final Decision

1. Establish a new HCPCS Level II code J1445 "Injection, ferric pyrophosphate citrate solution (triferic avnu), 0.1 mg of iron."

Effective: 10/1/2021

Existing modifier "JA" "administered intravenously" is available for use to specify route of administration. Triferic Avnu is a single source drug that is not therapeutically equivalent to the other Food and Drug Administration (FDA) approved ferric pyrophosphate citrate product, and has a New Drug Application (NDA).

2. Revise existing HCPCS code J1443, which currently reads "Injection, ferric pyrophosphate citrate solution, 0.1 mg of iron" to add "Triferic" to instead read "Injection, ferric pyrophosphate citrate solution (triferic), 0.1 mg of iron."

Effective: 10/1/2021

Request # 21.077

Topic/Issue

Request to establish a new HCPCS Level II code to identify Lipiodol (Ethiodized oil).

Applicant's suggested language: "J01XX-Ethiodized oil, per mg"

Applicant's Summary

Lipiodol (Ethiodized oil) is a medicinal product classified as a non-hydrosoluble contrast agent. Lipiodol is an oily pale yellow to amber solution with opacifying properties due to its iodine content. Each mL of Lipiodol contains 480 mg of iodine combined with ethyl esters of iodized fatty acids from poppy seed oil.

Approved uses of Lipiodol:

- Lymphography in adult and pediatric patients
- Hysterosalpingography in adults
- Selective hepatic intra-arterial use for imaging tumors in adults with known hepatocellular carcinoma (HCC)

There is no distinct HCPCS Level II code, and the use of a not otherwise classified (NOC) HCPCS code does not allow for appropriate tracking of utilization. Furthermore, referencing the American Health Information Management Association (AHIMA) coding guideline, billing for drugs should not continue to code with a NOC code permanently, but to seek a distinct code, to facilitate accurate reimbursement for any drug or biological.

Final Decision

CMS does not believe that this product needs a unique HCPCS Level II code, as it would be expected to be bundled and billed by providers with the procedure itself. CMS is open to hearing from the applicant or other interested parties about whether any insurers are paying separately for this product, or have a policy to do so, from the procedure.

Request # 21.078**Topic/Issue**

Request to establish a new HCPCS Level II code to identify Amondys 45 (casimersen) injection.

Applicant's suggested language: JXXXX – Injection, casimersen, 10 mg

Applicant's Summary

Amondys 45 is an antisense oligonucleotide indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 45 skipping.

The recommended dose of Amondys 45 is 30 milligrams per kilogram administered once weekly as a 35- to 60-minute IV infusion. Amondys 45 injection is supplied in single-dose vials. Each single dose vial contains 100 mg/2 mL casimersen (50 mg/mL).

Final Decision

Establish a new HCPCS Level II code J1426 “Injection, casimersen, 10 mg.”

Effective: 10/1/2021

Request # 21.079

Topic/Issue

Request to establish a new HCPCS Level II code to identify Breyanzi (lisocabtagene maraleucel) suspension, for intravenous infusion.

Applicant's suggested language: "JXXXX – Lisocabtagene maraleucel, up to 110 million autologous anti-CD19 CAR-positive viable T cells, consisting of 1:1 CAR+ viable T cells of the CD8 and CD4 components, including dose preparation procedures, per therapeutic dose."

Applicant's Summary

Breyanzi is a CD19-directed genetically modified autologous T-cell immunotherapy. Breyanzi is administered as a defined cellular composition to reduce variability in CD8-positive and CD4-positive T cell dose. Binding of the CAR T cells to CD19 expressed on the cell surface of tumor and normal B cells induces CAR T cell activation and proliferation, with the release of pro-inflammatory cytokines, and cytotoxic killing of target cells. Breyanzi is for autologous use only. Breyanzi is used to treat adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy. Breyanzi is administered based on the dosage volume specified on the Certificate of Release for Infusion (RFI Certificate) and administers it via intravenous infusion. In accordance with the attached prescribing information, Breyanzi is indicated for the treatment of adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including DLBCL not otherwise specified (including DLBCL arising from indolent lymphoma), high-grade B-cell lymphoma, primary mediastinal large B-cell lymphoma, and follicular lymphoma grade 3B.

A single dose of Breyanzi contains 50 to 110 × 10⁶ CAR-positive viable T cells (consisting of 1:1 CAR-positive viable T cells of the CD8 and CD4 components), with each component supplied separately in one to four single-dose vials. Each vial of Breyanzi contains 5 mL with a total extractable volume of 4.6 mL of CD8 or CD4 component T cells. Each mL contains 1.5 × 10⁶ to 70 × 10⁶ CAR-positive viable T cells. Each vial of Breyanzi therefore contains between 6.9 × 10⁶ and 322 × 10⁶ CAR-positive viable T cells in 4.6 mL cell suspension (between 1.5 × 10⁶ and 70 × 10⁶ CAR-positive viable T cells/mL). The infusion volume is calculated based on the concentration of cryopreserved drug product CAR-positive viable T cells concentration.

Breyanzi is a cell suspension for infusion. It consists of genetically modified autologous T cells, supplied in vials as separate frozen suspensions of each CD8 component and CD4 component. Each CD8 or CD4 component is packed in a carton containing up to 4 vials, depending upon the concentration of the cryopreserved drug product CAR-positive viable T cells. The cartons for the CD8 component and CD4 component are packaged in an outer carton.

Final Decision

Establish a new HCPCS Level II code Q2054 "Lisocabtagene maraleucel, up to 110 million autologous anti-CD19 CAR-positive viable T cells, including leukapheresis and dose preparation procedures, per therapeutic dose."

Effective: 10/1/2021

Request # 21.080**Topic/Issue**

Request to establish two new HCPCS Level II codes to identify Cabenuva kits for injection.

Applicant's suggested language: "JXXXX Injection, cabotegravir/rilpivirine kit, 400mg/600mg, (Cabenuva)" and

"JXXXX Injection, cabotegravir/rilpivirine kit, 600mg/900mg, (Cabenuva)."

Applicant's Summary

Cabenuva is indicated as a complete regimen for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults to replace the current antiretroviral regimen in those patients who are virologically suppressed on a stable antiretroviral regimen with no history of treatment failure and with no known or suspected resistance to either cabotegravir or rilpivirine. Cabenuva contains two long-acting HIV-1 antiretroviral drugs, cabotegravir and rilpivirine.

Cabenuva must be administered by a healthcare professional. Following oral lead-in, the recommended initial injection doses of Cabenuva in adults are a single 600 mg (3-mL) injection of cabotegravir and a single 900 mg (3-mL) injection of rilpivirine. After the initiation injections, the recommended monthly continuation injection doses of Cabenuva in adults are a single 400 mg (2-mL) injection of cabotegravir and a single 600 mg (2-mL) injection of rilpivirine at each visit.

Cabenuva is supplied in two dosing kits. Each kit contains one vial of cabotegravir and one vial of rilpivirine, co-packaged as follows:

Cabenuva 400-mg/600-mg Kit (NDC 49702-253-15) containing:

One single-dose vial of cabotegravir containing 400 mg/2 mL (200 mg/mL) of cabotegravir.

One single-dose vial of rilpivirine containing 600 mg/2 mL (300 mg/mL) of rilpivirine.

Cabenuva 600-mg/900-mg Kit (NDC 49702-240-15) containing:

One single-dose vial of cabotegravir containing 600 mg/3 mL (200 mg/mL) of cabotegravir.

One single-dose vial of rilpivirine containing 900 mg/3 mL (300 mg/mL) of rilpivirine.

No currently available codes describe Cabenuva as the co-packaged product is newly approved. Cabenuva is only available as the co-packaged product.

Final Decision

Establish a new HCPCS Level II code J0741 "Injection, cabotegravir and rilpivirine, 2mg/3mg."

Effective: 10/1/2021

Request # 21.081

Topic/Issue

Request to establish a new HCPCS Level II code to identify NULIBRY (fosdenopterin).

Applicant's suggested language: "JXXXX: Injection, fosdenopterin, 0.1 mg"

Applicant's Summary

NULIBRY (fosdenopterin) is cyclic pyranopterin monophosphate (cPMP) indicated to reduce the risk of mortality in patients with molybdenum cofactor deficiency (MoCD) Type A. Patients with MoCD Type A have mutations in the MOCS1 gene leading to deficient MOCS1A/B dependent synthesis of the intermediate substrate, cPMP. Substrate replacement therapy with NULIBRY provides an exogenous source of cPMP, which is converted to molybdopterin. Molybdopterin is then converted to molybdenum cofactor, which is needed for the activation of molybdenum-dependent enzymes, including sulfite oxidase (SOX), an enzyme that reduces levels of neurotoxic sulfites. There are currently no other drugs or biologicals with the same active ingredient category/generic name as NULIBRY (fosdenopterin) and therefore, no existing HCPCS codes adequately describe this product. NULIBRY (fosdenopterin) was approved by the FDA under a New Drug Application (NDA) on February 26, 2021. The recommended dosage regimen of NULIBRY in patients (by gestational age) is based on actual body weight. NULIBRY is administered as an intravenous infusion once daily at a rate of 1.5 mL/minute with non-DEHP tubing with a 0.2 micron filter. NULIBRY is given through an infusion pump at a rate of 1.5 mL per minute. Dose volumes below 2 mL may require syringe administration through slow intravenous push. NULIBRY (fosdenopterin) for injection is a white to pale yellow lyophilized powder or cake in a single-dose clear glass vial for reconstitution. Each NULIBRY vial contains 9.5 mg of fosdenopterin. Each carton of NULIBRY contains one vial (NDC 73129-001-01).

Final Decision

CMS would welcome the applicant or other parties identifying any insurers who have a claims processing need for a HCPCS Level II code. We understand that NULIBRY is either administered in the inpatient setting where a HCPCS Level II code is not needed, or provided directly to the caregiver through a specialty pharmacy, where National Drug Codes (NDCs) are the primary code set used for claims processing for self-administered drugs and biologics. An existing NDC, as well as existing HCPCS Level II code J3490 "Unclassified drugs," are available for assignment by insurers to identify NULIBRY, if they deem appropriate. For Medicare and other interested insurers, existing code J3490 can be used. For coding guidance for non-Medicare insurers, we refer the applicant to the insurers in whose jurisdiction claims would be filed, such as the Medicaid agency in the state in which a claim would be filed, or the individual private insurance entity.

Request # 21.082**Topic/Issue**

Request to establish a new HCPCS Level II code to identify PEPAXTO (melphalan flufenamide).

Applicant's suggested language: "JXXXX, Injection, melphalan flufenamide, 1mg"

Applicant's Summary

PEPAXTO is indicated in combination with dexamethasone for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy and whose disease is refractory to at least one proteasome inhibitor, one immunomodulatory agent, and one CD38-directed monoclonal antibody.

Final Decision

Establish a new HCPCS Level II code J9247 "Injection, melphalan flufenamide, 1mg."

Effective: 10/1/2021

Request # 21.083**Topic/Issue**

Request to establish a new HCPCS Level II code to identify Evkeeza (evinacumab-dgnb) injection.

Applicant's suggested language: "JXXXX – Injection, evinacumab-dgnb 15 mg/kg"

Applicant's Summary

EVKEEZA is indicated as an adjunct to other low-density lipoprotein cholesterol (LDL-C) lowering therapies for the treatment of adult and pediatric patients, aged 12 years and older, with homozygous familial hypercholesterolemia (HoFH).

Final Decision

Establish a new HCPCS Level II code J1305 "Injection, evinacumab-dgnb, 5mg."

Effective: 10/1/2021

Request # 21.084**Topic/Issue**

Request to establish a new HCPCS Level II code to identify injection, Brilliant Blue G, 0.25 mg.

No suggested applicant language.

Applicant's Summary

TissueBlue (Brilliant Blue G Ophthalmic Solution) 0.025% is a1 sterile, stable, single dose ophthalmic solution supplied in 2.25ml syringes, pre-filled to volume of 0.5ml. It aids in retinal surgery by selectively staining the thickened internal limiting membrane (ILM) which has formed onto the inner side of the retina in vitreoretinal disorders. Existing codes do not adequately describe TissueBlue because it is the only FDA approved product for staining internal limiting membrane, only Active Pharmaceutical Ingredient (API) product, Orphan drug, pre-filled sterile syringe, 4% polyethylene glycol to increase density and improve targeting to posterior pole (other products need additive), safety advantages over current products that have: Potential medication errors, storage requirements, durability issues, requirement to mix individual doses, lack of sterility during preparation, risk of impurities in a non-API product.

TissueBlue is indicated to selectively stain the internal limiting membrane (ILM). Transparent nature of ILM makes it difficult to visualize and peel. TissueBlue Ophthalmic Injection is applied onto inner retinal surface, enabling ILM to be clearly stained and distinguished from unstained retina, thereby facilitating removal. Single-dose ophthalmic solution supplied in 2.25ml syringes pre-filled to 0.5ml volume. TissueBlue is injected into the Balanced Salt Solution (BSS)-filled vitreous cavity using a blunt cannula attached to the pre-filled syringe, without allowing the cannula to contact the retina or allowing TissueBlue to get under the retina. Sufficient staining expected within a few seconds. Following staining, all excess dye is removed from the vitreous cavity. TissueBlue is supplied in a sterile, single-dose Luer lock, 2.25ml glass syringe, with a grey rubber plunger stopper and tip cap with polypropylene plunger rod in a pre-formed polypropylene blister pouch sealed with a Tyvek® lid.

Final Decision

CMS does not believe that this product needs a unique HCPCS Level II code, as it would be expected to be bundled and billed by providers with the procedure itself.

The applicant may be interested in applying for Medicare Outpatient Prospective Payment System (OPPS) pass-through status, available at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/drugapplication.pdf>.

Request # 21.085**Topic/Issue**

Request to modify existing HCPCS Level II code Q4209 (10/2019) to identify Esano A®.

No suggested applicant language.

Applicant's Summary

Esano A is a human amniotic membrane allograft intended for treatment of non-healing wounds and burn injuries. It is indicated for use in patients with acute or chronic wounds, including but not limited to chronic, non-infected, diabetic foot ulcers, chronic, non-infected, partial or full thickness diabetic foot skin ulcers (due to venous insufficiency), pressure ulcer, surgical wounds and burns which have not adequately responded to conventional therapy.

Final Decision

Evolution Biologyx, LLC, submitted an application for Esano A®, a human amniotic membrane allograft, which is stated by the applicant to be identical to Surgenex, LLC's SurGraft®. A letter from the Food and Drug Administration's (FDA's) Tissue Reference Group (TRG) for SurGraft® was provided as part of the application for Esano A®. However, the FDA Establishment Identifier (FEI) number and FDA registration for Evolution Biologyx, LLC's Esano A® are different from the FEI and FDA registration for Surgenex, LLC's SurGraft®. CMS would like to be sure that Esano A® and SurGraft® are the same product, and are registered properly with the FDA. As a result, CMS refers the applicant to the FDA to ensure that the registration for Esano A® is in order, and to confer with the TRG to make sure the product they reviewed is the same product that is the subject of the HCPCS Level II application request. After obtaining the FDA's feedback pertaining to Esano A®, the applicant is welcome to submit a complete HCPCS code application in a subsequent coding cycle.

Request # 21.086**Topic/Issue**

Request to establish a new HCPCS Level II code to identify VIM Human Amniotic Membrane.

Applicant's suggested language: "QXXXX-VIM PER SQ CM"

Applicant's Summary

VIM human amniotic membrane is a minimally manipulated allograft sheet of human amnion that is terminally sterilized. Regulated under Public Health Service Act (PHS Act) 361, 21 CFR 1271.80, VIM human amniotic membrane allograft is derived from human tissue and is indicated for homologous use. Proprietary processing preserves the biological components and structure of the extracellular matrix (ECM) without disrupting tensile strength and elasticity. This process preserves structural and signaling proteins such as collagen, glycoproteins, proteoglycans, cytokines, and growth factors, which are crucial to the biochemical and biomechanical processes occurring at a cellular level. VIM human amniotic membrane allograft is intended for homologous use at the discretion of a physician where human amniotic membrane may be beneficial as a wound covering or barrier. The product is applied topically and held in place with normal fixation and sterile dressings. The product is provided sterile in 2x2cm and 4x4cm sizes and may be cut to size. Existing HCPCS level II codes do not adequately describe VIM per sq cm. Product-specific coding is necessary to facilitate accurate reporting and payment under CMS Part B drugs and biologics average sales price (ASP) methodology, low/high cost assignment for Outpatient Prospective Payment System (OPPS) payment and to facilitate coverage and payment from commercial insurers.

Final Decision

Based on written feedback from the Food and Drug Administration's (FDA's) Tissue Reference Group (TRG), the VIM human amniotic membrane for "use as a wound covering or barrier in surgical, orthopedic, ophthalmic and wound applications", appears to be regulated solely under section 361 of the Public Health Service Act and the regulations in 21 CFR part 1271. As a result of the TRG's feedback, CMS has decided to:

Establish a new HCPCS Level II code Q4251 "Vim, per square centimeter."

Effective: 10/1/2021

Request # 21.087

Topic/Issue

Request to establish a new HCPCS Level II code to identify Vendaje.

Applicant's suggested language: "Q4XXX, Vendaje, per square centimeter"

Applicant's Summary

Vendaje is a sterile, single use, dehydrated human amniotic membrane composed of the amnion layer. Our product is a structural tissue allograft used as a skin substitute under homologous use. Vendaje functions as a protective barrier by resorbing into the wound and repairs superficial dermal and soft tissue wounds. Vendaje provides a scaffold of extracellular matrix proteins, active growth factors and cytokines. These crucial components support healing and infection control. No existing code adequately defines Vendaje, a dehydrated amnion layer with a nominal average thickness of 30 microns. Vendaje is a skin substitute for repairing and reconstructing for the integumentary system concerning chronic and acute pressure sores/ulcers related to disease processes, partial thickness burns, draining wounds, post-surgical wounds, and trauma wounds such as abrasions and skin tears. The product acts on the patient as an effective protective covering. Vendaje creates an ideal microenvironment for the wound bed by preventing pathogens and irritants from entering. The amniotic membrane offers a vapor barrier preventing unwanted water loss from excessive evaporation at the wound thus reducing pain and inflammation. Vendaje is available in sizes of 1x1cm, 2x2cm, 2x4cm, 4x4cm, 4x6cm, 4x8cm, and 6x6cm, and dosage is based on the size of the wound. The route of administration is topical by applying the membrane over the wound or within the surgical site. It is affixed by hydrostatic tension. Vendaje is aseptically packaged and sealed in an inner poly/foil peel pouch. An irradiation indicator is fixed on the inner package and then sealed with an outer poly/foil peel pouch. The packaged allograft is terminally sterilized by electric beam, labeled, and sealed in a dust cover containing an IFU (Instruction for Use), patient labels, and a tissue tracking card.

Final Decision

Based on written feedback from Food and Drug Administration's (FDA's) Tissue Reference Group (TRG), Vendaje intended to "physically support and serve as a barrier for the integumentary system", appears to be regulated solely under section 361 of the Public Health Service Act and the regulations in 21 CFR part 1271. As a result of the TRG's feedback, CMS has decided to:

Establish a new HCPCS Level II code Q4252 "Vendaje, per square centimeter."

Effective: 10/1/2021

Request # 21.088**Topic/Issue**

Request to establish a new HCPCS Level II code to identify TAG, a Triple Layer Amniotic Graft.

Applicant's suggested language: "Q4XXX-TAG, per sq cm"

Applicant's Summary

TAG is a sterile, dehydrated, triple layer amniotic allograft composed solely from the amniotic membrane of donated human placental tissue. This triple layer amniotic allograft was reviewed and confirmed by the Food and Drug Administration's (FDA's) Tissue Reference Group (TRG), as meeting the criteria for regulation under 361 of the Public Health Service (PHS) Act as Human Cells, Tissues and Cellular and Tissue-Based Products (HCT/P) described in 21 CFR 1271.10. Following standard wound preparation, TAG is applied directly to the wound, providing coverage as a protective barrier for acute and chronic wounds. Sales/Marketing: TAG is currently marketed and available for use and purchase in the United States. TAG was first made available for market in the U.S., on February 13, 2021.

Final Decision

Flower Orthopedics, Corp., submitted an application for TAG, a triple layer amniotic graft, which is stated by the applicant to be identical to Surgenex, LLC's SurGraft® TL. A letter from the Food and Drug Administration's (FDA's) Tissue Reference Group (TRG) for SurGraft® TL was provided as part of the application for TAG. However, the FDA Establishment Identifier (FEI) number and FDA registration for Flower Orthopedics, Corp.'s TAG are different from the FEI and FDA registration for Surgenex, LLC's SurGraft® TL. CMS would like to be sure that TAG and SurGraft® TL are the same product, and are registered properly with the FDA. As a result, CMS refers the applicant to the FDA to ensure that the registration for TAG is in order, and to confer with the TRG to make sure the product they reviewed is the same product that is the subject of the HCPCS Level II application request. After obtaining the FDA's feedback pertaining to TAG, the applicant is welcome to submit a complete HCPCS code application in a subsequent coding cycle.

Request # 21.089**Topic/Issue**

Request to establish a new HCPCS Level II code to identify Zenith Amniotic Membrane.

Applicant's suggested language: "QXXXX Zenith Amniotic Membrane per sq centimeter."

Applicant's Summary

Zenith Amniotic Membrane is a dehydrated amniotic membrane allograft. Zenith Amniotic Membrane is used as a barrier and covering for acute and chronic non-healing wounds and burn injuries. Currently available HCPCS codes for synthetic and biologic wound healing technologies are product and brand specific. Therefore, no currently available permanent HCPCS code appropriately describes Zenith Amniotic Membrane. Zenith Amniotic Membrane is used for the treatment of acute and chronic non-healing wounds including but not limited to non-infected partial or full-thickness diabetic foot ulcers, venous leg ulcers, pressure ulcers, surgical wounds, and burn injuries which have not responded to conventional therapy. Zenith Amniotic Membrane acts as a biological barrier and wound cover which works to protect chronic non-healing wound and burn injuries from the surrounding environment throughout the healing process. Zenith Amniotic Membrane allograft is available in the following sizes: 1 x 1 cm, 2 cm x 2 cm, 2 cm x 3 cm, 4 cm x 4 cm, 4 cm x 6 cm, 4 cm x 8 cm, 8 x 8 cm, 10 x 10 cm, 10 x 12 cm, and 10 x 20 cm. Zenith Amniotic Membrane is applied over the wound or burn site following wound preparation in a physician office, or outpatient setting. Zenith Amniotic Membrane is provided in a sterile sealed package and is intended for single use.

Final Decision

Based on written feedback from Food and Drug Administration's (FDA's) Tissue Reference Group (TRG), the Zenith Amniotic Membrane for use as "a barrier or cover for acute and chronic wounds" and "to cover irregular and deep wounds", appears to be regulated solely under section 361 of the Public Health Service Act and the regulations in 21 CFR part 1271. As a result of the TRG's feedback, CMS has decided to:

Establish a new HCPCS Level II code Q4253 "Zenith amniotic membrane, per square centimeter."

Effective: 10/1/2021

Request # 21.090**Topic/Issue**

Request to establish a new HCPCS Level II code to identify Invitra ECM.

No suggested applicant language

Applicant's Summary

Invitra ECM is a membrane derived from placental tissue. It is beneficial as a structural matrix to facilitate wound healing for cell proliferation, differentiation, and adherence to the area of application. Applications include soft tissue injury, wound care for non-healing ulcers or burns. Patient populations include those who exhibit indications such as treatment of chronic, non-infected, partial- and full-thickness acute or chronic wounds including diabetic lower extremity ulcers or second- and third-degree burns. Also, for wounds with exposed tendon, muscle, bone or other vital structures.

Final Decision

After review of the Food and Drug Administration's (FDA's) guidance, it does not appear to CMS that Invitra ECM is suitable for registration as a Human Cells, Tissues, and Cellular and Tissue-Based Product (HCT/P). CMS refers the applicant to the FDA's Tissue Reference Group (TRG) to obtain written feedback regarding how the product is appropriately regulated. After obtaining the FDA's written feedback, the applicant is welcome to submit a complete HCPCS code application in a subsequent coding cycle. Information for submitting questions to the TRG is located at: <https://www.fda.gov/vaccines-blood-biologics/tissue-tissue-products/tissue-reference-group>.

Request # 21.091**Topic/Issue**

Request to revise the HCPCS Level II code set by discontinuing HCPCS code Q4228 for BioNextPATCH™ described below:

Q4228 “BioNextPATCH™ per sq centimeter”

Applicant's Summary

BioNextPATCH is a dehydrated amniotic membrane allograft used for the treatment of nonhealing wounds and burn injuries. BioNextPATCH amniotic membrane allograft delivers cytokines, proteins and growth factors to help regenerate soft tissue. Human amniotic membrane is a thin collagenous membrane that consists of collagen layers including the basement membrane and stromal matrix. The extracellular matrix (ECM) components of the amniotic tissue include collagens, growth factors, fibronectin, laminins, integrins and hyaluronans. Additionally, amniotic membrane allograft is immune privileged and possesses little or no risk of foreign body reaction which can lead to fibrosis and graft failure.

BioNextPATCH is no longer manufactured or used.

Final Decision

Discontinue HCPCS Level II code Q4228 “BioNextPATCH™ per sq centimeter.”

Effective: 09/30/2021

Request # 21.092**Topic/Issue**

Request to revise the HCPCS Level II code set by discontinuing HCPCS code Q4236 for carePATCH as described below:

Q4236 “carePATCH per sq centimeter.”

Applicant's Summary

carePATCH is a dehydrated amniotic membrane allograft used for the treatment of non-healing wounds and burn injuries. carePATCH amniotic membrane allograft delivers cytokines, proteins and growth factors to help regenerate soft tissue. Human amniotic membrane is a thin collagenous membrane that consists of collagen layers including the basement membrane and stromal matrix. The extracellular matrix (ECM) components of the amniotic tissue include collagens, growth factors, fibronectin, laminins, integrins and hyaluronans. Additionally, amniotic membrane allograft is immune privileged and possesses little or no risk of foreign body reaction, which can lead to fibrosis and graft failure.

carePATCH amniotic membrane allograft is available in the following sizes: 2 cm X 2 cm, 2 cm x 4 cm, 4 cm x 4 cm, 4 cm x 6 cm, 5cm x 5cm, 4 cm x 8 cm. carePATCH is applied over a wound or burn site following wound preparation in a physician office, or outpatient setting. carePATCH is provided in a sterile sealed package and is intended for single use.

carePATCH will not be manufactured by us or any other entity and there will be no claims submitted to any payers.

Final Decision

Discontinue HCPCS Level II code Q4236 “carePATCH per sq centimeter.”

Effective: 09/30/2021

Request # 21.093

Topic/Issue

Request to re-establish HCPCS Level II code J7333 to identify Visco-3.

Applicant's suggested language: J7333 "Hyaluronan or derivative, Visco-3, for intra-articular injection, per dose"

Applicant's Summary

Visco-3 is indicated for the treatment of osteoarthritis (OA) pain of the knee in patients who have failed to respond adequately to conservative non-pharmacologic therapy and simple analgesics, e.g., acetaminophen. Visco-3 is administered via intraarticular injection by a healthcare practitioner into the joint space of the affected knee. A treatment regimen of Visco-3 is 2.5mL injection administered once per week for three weeks for a total of three injections. Visco-3 supplements the naturally occurring hyaluronic acid in the synovial fluid within the joint capsule of the affected knee to provide cushioning and lubrication to the joint, which have been reduced due to the degradation of the joint caused by the osteoarthritis. In 2018, Visco-3 was assigned to HCPCS code J7321, the same HCPCS code as its predicate product, Supartz FX. Visco-3 has the same composition as Supartz FX; however, Supartz FX is approved by the FDA as a five injection regimen versus Visco-3 as a three injection treatment series. This relationship between Visco-3 and Supartz FX – same product but approved by the FDA under a different brand name for a different number of injections in a treatment regimen – is identical to the Hyalgan (five injection) and Triluron (three injection) products in the same product class manufactured by Fidia Farmaceutici S.p.A. In 2019, Triluron was assigned a new and unique HCPCS code (J7332) separate from Hyalgan (J7321). Based on that precedent, Zimmer Biomet submitted a code modification request during the Q1 2020 coding cycle requesting a new and unique HCPCS code separate from Supartz FX be assigned to VISCO-3. CMS agreed with the request and created J7333 to identify Visco-3 effective 7/1/2020. Subsequently, during the Q4 2020 coding cycle, CMS reversed the coding decision made during the Q1 2020 coding cycle, discontinuing code J7333 and categorizing Visco-3 within J7321 again. Accordingly, Zimmer Biomet requests that CMS reestablish level II HCPCS code J7333 with the description "Hyaluronan or derivative, VISCO-3, for intra-articular injection, per dose."

Final Decision

CMS maintains its decision from Quarter 4, 2020 regarding Visco-3's inclusion in existing HCPCS Level II code J7321. This decision is consistent with our policy at https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Downloads/051807_coding_announcement.pdf, which states: "Section 1847A requires single source drugs or biologicals that were within the same billing and payment code as of October 1, 2003, be treated as multiple source drugs, so the payment under Section 1847A for these drugs and biologicals is based on the volume weighted average of the pricing information for all of the products within the billing and payment code." Visco-3 was approved by the Food and Drug Administration (FDA) under a premarket approval (PMA) supplement number P980044-S027 on December 21, 2015 and not an original PMA. The original application supporting Visco-3 approval was PMA number P980044 for Supartz FX, approved on January 24, 2001. Consistent with other decisions made in accordance with this policy, and in light of the fact that the original PMA supporting the

approval for Visco-3 was included within the same billing and payment code prior to October 1, 2003, CMS maintains that Visco-3 should be included in HCPCS code J7321 with Supartz.

We understand that the applicant is engaging further with the FDA regarding Visco-3's approval pathway, and CMS welcomes new information should it become available.