



Centers for Medicare & Medicaid Services (CMS) Healthcare Common Procedure Coding System (HCPCS) Application Summaries and Coding Recommendations

Second Quarter, 2022 HCPCS Coding Cycle

This document presents a summary of each HCPCS code application and CMS' coding decision for each application processed in CMS' Second Quarter 2022 Drug and Biological HCPCS code application review cycle. Each individual summary includes the request number; topic/issue; summary of the applicant's request as written by the applicant with occasional non-substantive editorial changes made by CMS; and CMS' final HCPCS coding decision. All new coding actions will be effective October 1, 2022, unless otherwise indicated.

The HCPCS coding decisions below will also be included in the October 2022 HCPCS Quarterly Update, pending publication by CMS in the coming weeks at:
<https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update>

For inquiries regarding coverage, please contact to the insurer(s) in whose jurisdiction(s) claim(s) would be filed. Specifically, contact the Medicaid agency in the state in which a Medicaid claim is filed, the individual private insurance entity, the Department of Veterans Affairs, or, for local Medicare coverage determinations, contact the Medicare contractor in the jurisdiction the claim would be filed. For detailed information describing CMS' national coverage determination process, refer to information published at <https://www.cms.gov/Medicare/Coverage/DeterminationProcess> and <https://www.cms.gov/Center/Special-Topic/Medicare-Coverage-Center>.

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 and support streamlined billing. This long-standing policy makes coding more robust, and facilitates accurate payment and reporting of the exact dose administered, as only 999 units can appear on a claim line for Medicare fee-for-service using the CMS-1500 form. The dose descriptors assigned to codes established in this quarterly coding cycle are in alignment with this policy.

Fluorodopa F 18 - HCP2203289TD59

Topic/Issue

Request to establish a new HCPCS Level II code to identify Fluorodopa F 18.

Applicant's suggested language: AXXXX "Fluorodopa F18, diagnostic, per millicurie"

Applicant's Summary

The Feinstein Institute for Medical Research submitted a request to establish a new HCPCS Level II code to identify Fluorodopa F 18 injection, which is a radioactive diagnostic agent used in positron emission tomography (PET) imaging. Fluorodopa F 18 was approved by the FDA on March 29, 2009. No existing HCPCS code specifically describes this drug product. A unique A code is necessary to identify use of Fluorodopa F 18 Injection and appropriately reimburse hospitals, physician offices, and diagnostic testing facilities for the product. Fluorodopa F 18 Injection is indicated for use in PET to visualize dopaminergic nerve terminals in the striatum for the evaluation of adult patients with suspected Parkinsonian syndromes (PS). Fluorodopa F 18 PET is an adjunct to other diagnostic evaluations. In dopaminergic nerve terminals in the brain, Fluorodopa F 18 Injection is decarboxylated by amino acid decarboxylase to Fluorodopamine F 18 and stored in presynaptic vesicles in the brain. The accumulation of Fluorodopamine F 18 in the striatum is visually detected in the PET scan. The recommended dose for adults is 185 megabecquerels (MBq) [5 millicuries (mCi)] administered as an intravenous injection infused over 1 minute. Fluorodopa F 18 Injection is supplied as a clear, colorless injection in a septum capped glass vial containing between 37 MBq/mL to 1,480 MBq/mL (1 mCi/mL to 40 mCi/mL), of Fluorodopa F 18 at calibration time, in 28 mL ±1 mL.

Final Decision

Establish new HCPCS Level II code A9602, "Fluorodopa f-18, diagnostic, per millicurie"

Effective: 10/1/2022

PLUVICTO™ - HCP22032948BXM

Topic/Issue

Request to establish a new HCPCS Level II code to identify PLUVICTO™.

Applicant's suggested language: AXXXX, "Lutetium Lu 177 vipivotide tetraxetan, therapeutic, 1 millicurie"

Applicant's Summary

Advanced Accelerator Applications, a Novartis company, submitted a request to establish a new HCPCS Level II code for the radiopharmaceutical PLUVICTO™. PLUVICTO™ is a radioligand therapeutic agent indicated for the treatment of adult patients with prostate-specific membrane antigen (PSMA)-positive metastatic castration-resistant prostate cancer (mCRPC) who have been treated with androgen receptor (AR) pathway inhibition and taxane-based chemotherapy. PLUVICTO™ was approved by the FDA on March 23, 2022. Current HCPCS codes do not appropriately describe PLUVICTO™. The active moiety of PLUVICTO™ is the radionuclide lutetium-177 which is linked to a targeting moiety that binds with high affinity to PSMA. Upon the binding of PLUVICTO™ to PSMA-expressing cancer cells, the beta-minus emission from lutetium-177 delivers therapeutic radiation to the targeted cell, as well as to surrounding cells, and induces DNA damage which can lead to cell death. The recommended dose is 7.4 GBq (200 mCi) every 6 weeks for up to 6 doses, or until disease progression, or unacceptable toxicity. PLUVICTO™ may be administered intravenously as an injection using a disposable syringe fitted with a syringe shield (with or without a syringe pump), as an infusion using the gravity method (with or without an infusion pump), or as an infusion using the vial (with a peristaltic infusion pump). PLUVICTO™ is supplied as a 1000 MBq/mL (27 mCi/mL) of lutetium (177Lu) vipivotide tetraxetan solution for intravenous use in a clear, colorless Type I glass 30 mL single-dose vial containing 7.4 GBq (200 mCi) ± 10% of lutetium (177Lu) vipivotide tetraxetan at the date and time of administration. The solution volume in the vial is adjusted from 7.5 mL to 12.5 mL to provide a total of 7.4 GBq (200 mCi) of radioactivity.

Final Decision

Establish new HCPCS Level II code A9607, "Lutetium lu 177 vipivotide tetraxetan, therapeutic, 1 millicurie"

Effective: 10/1/2022

ENJAYMO™ - HCP220330MWLYX

Topic/Issue

Request to establish a new HCPCS Level II code to identify ENJAYMO™.

Applicant's suggested language: JXXXX, "Injection, sutimlimab-jome, 10 mg"

Applicant's Summary

Sanofi submitted a request to establish a new HCPCS Level II code for ENJAYMO™. Sutimlimab-jome is an immunoglobulin G (IgG), subclass 4 (IgG4) monoclonal antibody (mAb) that inhibits the classical complement pathway (CP) and specifically binds to complement protein component 1, s subcomponent (C1s), a serine protease which cleaves C4. ENJAYMO™ was approved by the FDA on February 4, 2022. Sutimlimab-jome does not inhibit the lectin and alternative pathways. Inhibition of the classical complement pathway at the level of C1s prevents deposition of complement opsonins on the surface of red blood cells, resulting in inhibition of hemolysis in patients with cold agglutinin disease (CAD).

Final Decision

Establish new HCPCS Level II code J1302, "Injection, sutimlimab-jome, 10 mg"

Effective: 10/1/2022

LOCAMETZ® - HCP2203296HJ9K

Topic/Issue

Request to establish a new HCPCS Level II code to identify LOCAMETZ®.

Applicant's suggested language: AXXXX, "Gallium Ga-68 gozetotide (Locametz), 1 millicurie"

Applicant's Summary

Advanced Accelerator Applications, a Novartis company, submitted a request to establish a new HCPCS Level II code for LOCAMETZ®. LOCAMETZ®, after radiolabeling with gallium-68, is a radioactive diagnostic agent indicated for positron emission tomography (PET) of prostate-specific membrane antigen (PSMA) positive lesions in men with prostate cancer: (1) with suspected metastasis who are candidates for initial definitive therapy; (2) with suspected recurrence based on elevated serum prostate-specific antigen (PSA) level; and (3) for selection of patients with metastatic prostate cancer, for whom lutetium Lu 177 vipivotide tetraxetan PSMA-directed therapy is indicated. PSMA is overexpressed in prostate cancers and can be used to target prostate cancer for the purpose of PET imaging. After LOCAMETZ® is injected, it binds to PSMA on the surface of PSMA-expressing cells, including malignant prostate cancer cells, which overexpress PSMA. Gallium-68 is a radionuclide with an emission yield that allows PET imaging. LOCAMETZ® was approved by the FDA on March 23, 2022.

Current HCPCS codes do not appropriately describe LOCAMETZ®. The recommended dose (amount of radioactivity) is 111 MBq to 259 MBq (3 mCi to 7 mCi). After reconstitution, LOCAMETZ® is administered by slow intravenous injection. LOCAMETZ® is supplied as a kit for the preparation of gallium Ga 68 gozetotide injection in a carton of 1 vial. Each multiple-dose vial contains 25 micrograms of gozetotide as white lyophilized powder packaged in a 10 mL type I Plus glass vial closed with a rubber stopper and sealed with a flip-off cap. After radiolabeling with gallium-68, the vial contains a sterile solution of gallium Ga 68 gozetotide at a strength up to 1,369 MBq (37 mCi) in up to 10 mL at calibration date and time.

Final Decision

Establish new HCPCS Level II code A9800, "Gallium ga-68 gozetotide, diagnostic, (locametz), 1 millicurie"

Effective: 10/1/2022

KIMMTRAK - HCP220302WGK84

Topic/Issue

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

Applicant's suggested language: JXXXX, "Injection, tebentafusp-tebn, (KIMMTRAK), 1 microgram".

Applicant's Summary

Immunocore Commercial LLC submitted a request to establish a new HCPCS Level II code to identify KIMMTRAK. KIMMTRAK (tebentafusp-tebn) is a bispecific gp100 peptide-HLA-directed CD3 T cell engager indicated for the treatment of HLA-A*02:01-positive adult patients with unresectable or metastatic uveal melanoma. KIMMTRAK has an approximate molecular weight of 77 kDa. KIMMTRAK is produced by recombinant DNA technology in *Escherichia coli* cells. KIMMTRAK injection is supplied in 100 mcg / 0.5 mL solution in single-dose vials as a sterile, preservative-free, clear, colorless or slightly yellowish solution. KIMMTRAK is administered by intravenous infusion over 15-20 minutes. The NDC number on the package label and for billing is 80446 – 0401 – 01. Each single-dose vial contains tebentafusp-tebn (100 mcg), citric acid monohydrate (0.95 mg), di-sodium hydrogen phosphate (2.91 mg), mannitol (5 mg), polysorbate 20 (0.1 mg) trehalose (25 mg), and water for injection, with a pH of 6.5. The recommended dose of KIMMTRAK is 20 mcg on Day 1, 30 mcg on Day 8, and 68 mcg on Day 15, and 68 mcg once every week thereafter. Treat patients until unacceptable toxicity or disease progression occur. The TCR arm of KIMMTRAK binds to a gp100 peptide presented by human leukocyte antigen - A*02:01 (HLA-A*02:01) on the cell surface of uveal melanoma tumor cells. In vitro, KIMMTRAK bound to HLA-A*02:01-positive uveal melanoma cells and activated polyclonal T cells to release inflammatory cytokines and cytolytic proteins, which results in direct lysis of uveal melanoma tumor cells.

KIMMTRAK is a new therapeutic biological product and a single source drug. It was approved by the FDA on January 23, 2022. Based on current law, it should be paid based on its own average sales price (ASP). CMS has historically assigned a unique HCPCS code to meet this requirement.

Final Decision

1. Establish new HCPCS Level II code J9274, "Injection, tebentafusp-tebn, 1 microgram"

Effective: 10/1/2022

2. Discontinue existing HCPCS Level II code C9095, "Injection, tebentafusp-tebn, 1 microgram"

Effective: 9/30/2022

CARVYKTI™ - HCP220325DNBRP

Topic/Issue

Request to establish a new HCPCS Level II code to identify CARVYKTI™.

Applicant's suggested language: QXXXX "Ciltacabtagene autoleucel, up to 100 million car-positive viable T cells, including leukapheresis and dose preparation procedures, per therapeutic dose."

Applicant's Summary

Johnson & Johnson Healthcare Systems Inc., on behalf of Janssen Biotech, Inc., submitted a request to establish a new HCPCS Level II code to identify CARVYKTI™ (ciltacabtagene autoleucel) for intravenous infusion. CARVYKTI™ was approved by the FDA on February 28, 2022. Existing codes are inadequate to describe CARVYKTI™ because the existing codes refer to unspecified prescription drugs. Payment and average sales price (ASP) reporting is linked to HCPCS code. Establishing a separate and distinct HCPCS code for CARVYKTI™ is necessary for ASP reporting and more efficient claims processing and payments. CARVYKTI™ is a B cell maturation antigen (BCMA)-directed genetically modified autologous T cell immunotherapy indicated for the treatment of adult patients with relapsed or refractory multiple myeloma after four or more prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody. CARVYKTI™ is provided as a single-dose for infusion containing a suspension of chimeric antigen receptor (CAR)-positive viable T-cells. The dose is 0.5 1.0×10^6 CAR-positive viable T-cells per kg of body weight, up to a maximum dose of 1×10^8 CAR-positive viable T-cells in either a 30 mL or 70 mL patient-specific infusion bag. Each CARVYKTI™ infusion bag is individually packed in an aluminum cryo cassette.

Final Decision

1. Establish new HCPCS Level II code Q2056, "Ciltacabtagene autoleucel, up to 100 million autologous b-cell maturation antigen (bcma) directed car-positive t cells, including leukapheresis and dose preparation procedures, per therapeutic dose"

Effective: 10/1/2022

2. Discontinue existing HCPCS Level II code C9093, "Ciltacabtagene autoleucel, up to 100 million autologous b-cell maturation antigen (bcma) directed car-positive t cells, including leukapheresis and dose preparation procedures, per therapeutic dose"

Effective: 9/30/2022

VABYSMO™ - HCP2202076VVDU

Topic/Issue

Request to establish a new HCPCS Level II code to identify Vabysmo™.

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

Applicant's Summary

Genentech Inc. submitted a request to establish a new HCPCS Level II code to identify faricimab-svoa, brand name, VABYSMO™. VABYSMO™, a vascular endothelial growth factor (VEGF) and angiopoietin-2 (Ang-2) inhibitor indicated for the treatment of patients with Neovascular (Wet) Age-Related Macular Degeneration (nAMD) and Diabetic Macular Edema (DME). It is administered as an intravitreal injection by a qualified physician. VABYSMO™ was approved by the FDA on January 28, 2022.

For nAMD, the recommended dose for VABYSMO™ is 6 mg (0.05 mL of 120 mg/mL solution) administered by intravitreal injection every 4 weeks (approximately every 28 ± 7 days, monthly) for the first 4 doses, followed by optical coherence tomography and visual acuity evaluations 8 and 12 weeks later to inform whether to give a 6 mg dose via intravitreal injection on one of the following three regimens: 1) Weeks 28 and 44; 2) Weeks 24, 36 and 48; or 3) Weeks 20, 28, 36 and 44. For DME, VABYSMO™ is recommended to be dosed by following one of these two dose regimens: 1) 6 mg (0.05 mL of 120 mg/mL solution) administered by intravitreal injection every 4 weeks (approximately every 28 days \pm 7 days, monthly) for at least 4 doses. If after at least 4 doses, resolution of edema based on the Central Subfield Thickness (CST) of the macula as measured by optical coherence tomography is achieved, then the interval of dosing may be modified by extensions of up to 4 week interval increments or reductions of up to 8 week interval increments based on CST and visual acuity evaluations through week 52; or 2) 6 mg dose of VABYSMO™ can be administered every 4 weeks for the first 6 doses, followed by 6 mg dose via intravitreal injection at intervals of every 8 weeks (2 months) over the next 28 weeks. Although additional efficacy was not demonstrated in most patients when VABYSMO™ was dosed every 4 weeks compared to every 8 weeks, some patients may need every 4 weeks (monthly) dosing after the first 4 doses. Patients should be assessed regularly.

Final Decision

1. Establish new HCPCS Level II code J2777, "Injection, faricimab-svoa, 0.1 mg"

Effective: 10/1/2022

2. Discontinue existing HCPCS Level II code C9097, "Injection, faricimab-svoa, 0.1 mg"

Effective: 9/30/2022

Releuko™ - HCP2203233WGGX

Topic/Issue

Request to establish a new HCPCS Level II code to identify Releuko™.

Applicant's suggested language: Q512X, "Filgrastim-ayow, 1 mg/mL"

Applicant's Summary

Amneal Pharmaceutical, Inc submitted a request to establish a new HCPCS Level II code to identify Releuko™. Releuko™ (filgrastim-ayow) injection, is indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever. It reduces the time to neutrophil recovery and the duration of fever, following induction or consolidation chemotherapy treatment of patients with Acute Myeloid Leukemia (AML). It reduces the duration of neutropenia and neutropenia-related clinical sequelae, e.g., febrile neutropenia, in patients with nonmyeloid malignancies undergoing myeloablative chemotherapy followed by bone marrow transplantation (BMT). It also reduces the incidence and duration of sequelae of severe neutropenia, (e.g., fever, infections, oropharyngeal ulcers) in symptomatic patients with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia. Releuko™ was approved by the FDA on February 25, 2022.

Final Decision

1. Establish new HCPCS Level II code Q5125, "Injection, filgrastim-ayow, biosimilar, (releuko), 1 microgram"

Effective: 10/1/2022

2. Discontinue existing HCPCS Level II code C9096, "Injection, filgrastim-ayow, biosimilar, (releuko), 1 microgram"

Effective: 9/30/2022

Lanreotide - HCP220317610PU

Topic/Issue

Request to establish a new HCPCS Level II code to identify Lanreotide Acetate.

Applicant's suggested language: JXXXX, "Injection, lanreotide, depot form, 1 mg"

Applicant's Summary

Cipla USA, Inc. submitted a request to establish a new HCPCS Level II code to identify Lanreotide Injection. Lanreotide is a prolonged-release formulation for deep subcutaneous injection. It contains the drug substance lanreotide acetate, a synthetic octapeptide with a biological activity similar to naturally occurring somatostatin, water for injection and acetic acid (for pH adjustment). Lanreotide Injection is a prescription medicine that is injected subcutaneously by a healthcare professional. It is indicated for the following: 1) Long-term treatment of acromegalic patients who have had an inadequate response to surgery and/or radiotherapy, or for whom surgery and/or radiotherapy is not an option. 2) Treatment of adult patients with unresectable, well or moderately differentiated, locally advanced or metastatic gastroenteropancreatic neuroendocrine tumors (GEP-NETs) to improve progression-free survival. The goal of treatment in acromegaly is to reduce growth hormone (GH) and insulin growth factor-1 (IGF-1) levels to normal. Lanreotide Injection is thought to form a drug depot at the injection site due to the interaction of the formulation with physiological fluids.

The most likely mechanism of drug release is a passive diffusion of the precipitated drug from the depot towards the surrounding tissues, followed by the absorption to the bloodstream. In acromegaly the recommended starting dosage of Lanreotide Injection is 90 mg given by deep subcutaneous route, at 4-week intervals for 3 months. Thereafter, the dosage is adjusted based on GH and/or IGF-1 levels. In GEP-NETs, the recommended dosage of Lanreotide Injection is 120 mg administered every 4 weeks by deep subcutaneous injection. Lanreotide Injection is supplied in strengths of 60 mg/0.2 mL, 90 mg/0.3 mL, and 120 mg/0.5 mL as a white to pale yellow, semi-solid formulation in a single-dose, sterile, prefilled, ready-to-use, polypropylene syringe and a safety needle device. The safety needle device is a sterile, single use needle system consisting of a needle (1.2 mm x 20 mm, stainless steel) held in protective plastic safety housing. Existing code J1930, "Injection, lanreotide, 1 mg" is currently used for Somatuline Depot[®] and Lanreotide Injection. Lanreotide Injection does not "perform a significantly different function" than Somatuline Depot[®] and there is no "significant therapeutic distinction" between the two products. Lanreotide Injection was approved by the FDA on December 17, 2021.

Final Decision

Establish new HCPCS Level II code J1932, "Injection, lanreotide, (cipla), 1 mg"

Effective: 10/1/2022

Somatuline® Depot - HCP2203310KQ9B

Topic/Issue

Request to revise existing HCPCS Level II code J1930 “Injection, lanreotide, 1 mg” to include the brand name Somatuline® Depot.

Applicant’s suggested language: J1930, “Injection, lanreotide (Somatuline Depot), 1mg”

Applicant’s Summary

Ipsen Biopharmaceuticals submitted a request to revise the descriptor of existing HCPCS Level II code J1930, “Injection, lanreotide, 1 mg” to include the brand name Somatuline® Depot. CMS established a new HCPCS Level II code in 2009 -J1930 (Injection, lanreotide, 1 mg) to identify Somatuline® Depot, a single source drug or biological approved by FDA under the 505(b)(1) New Drug Approval pathway (NDA) #22-074. Somatuline® Depot was approved by the FDA on August 30, 2007. On December 19, 2021, Cipla Limited and its subsidiary Cipla USA, Inc., announced the FDA approval for its lanreotide injection product, with the NDA being submitted by Cipla subsidiary InvaGen Pharmaceuticals, Inc. for a lanreotide acetate product under the 505(b)(2) NDA (#215395). Cipla’s lanreotide acetate product is not rated as therapeutically equivalent to any other drug product, including Ipsen’s Somatuline® Depot, as reflected in FDA’s Orange Book. Thus, Cipla’s lanreotide acetate product is also a single source drug.

Pursuant to the requirement for separate payment for single source drugs under section 1847A of the Social Security Act, and CMS implementation policies and procedures, Somatuline® Depot and Cipla’s lanreotide acetate product should be granted unique HCPCS Level II code. Somatuline® Depot is a somatostatin analog indicated for: the long-term treatment of acromegalic patients who have had an inadequate response to or cannot be treated with surgery and/or radiotherapy; the treatment of adult patients with unresectable, well-or moderately-differentiated, locally advanced or metastatic gastroenteropancreatic neuroendocrine tumors to improve progression-free survival; the treatment of adults with carcinoid syndrome; when used, it reduces the frequency of short-acting somatostatin analog rescue therapy. Lanreotide, the active component of Somatuline® Depot is an octapeptide analog of natural somatostatin. The mechanism of action of lanreotide is believed to be similar to that of natural somatostatin. Dosage: Injection: 60mg/0.2mL, 90mg/0.3mL, and 120mg/0.5mL single-dose prefilled syringes. Administration: For deep subcutaneous injection only. Intended for administration by a healthcare provider. Somatuline® Depot is supplied in strengths of 60mg/0.2mL, 90mg/0.3mL, and 120mg/0.5mL as a white to pale yellow, semi-solid formulation in a single, sterile, prefilled, ready-to-use, polypropylene syringe fitted with an automatic safety system, a bromobutyl rubber plunger stopper and a 20 mm needle covered by a plastic cap. Each prefilled syringe is placed in a plastic tray, sealed in a laminated pouch and packed in a carton.

Final Decision

Per the final decision for application HCP220317610PU, CMS established a new HCPCS Level II code J1932, “Injection, lanreotide, (cipla), 1 mg” effective 10/1/2022 to identify Lanreotide Injection manufactured by Cipla USA, Inc.

We are aware that Ipsen’s patent exclusivity for Somatuline® Depot will expire in approximately two years. At that time, generic formulations of lanreotide acetate rated as therapeutically equivalent in the FDA Orange Book may become available. Therefore, a product specific code including the brand name would not be suitable due to the possibility that HCPCS code J1930 may describe a multiple source drug code in the near future. As a result, CMS is not revising existing HCPCS Level II code J1930, “Injection, lanreotide, 1 mg.”

OPDUALAG™ - HCP220328QDK7E

Topic/Issue

Request to establish a new HCPCS Level II code to identify OPDUALAG™.

Applicant's suggested language: JXXXX, "Injection, nivolumab, 1 mg, and relatlimab-rmbw"

Applicant's Summary

Bristol Myers Squibb submitted a request to establish a new HCPCS Level II code for OPDUALAG™ (nivolumab and relatlimab-rmbw) injection, for intravenous use). OPDUALAG™ is a combination of nivolumab, a programmed death receptor-1 (PD-1) blocking antibody, and relatlimab, a lymphocyte activation gene-3 (LAG-3) blocking antibody, indicated for the treatment of adult and pediatric patients 12 years of age or older with unresectable or metastatic melanoma. OPDUALAG™ was approved by the FDA on March 18, 2022.

No permanent or temporary HCPCS code currently exists that describes OPDUALAG™, a biological approved under a unique Biologics License Application. A unique code is needed to recognize and ensure appropriate average sales price (ASP)-based payment for OPDUALAG™ as a unique biological under section 1847A of the Social Security Act. Relatlimab is a human IgG4 monoclonal antibody that binds to the LAG-3 receptor, blocks interaction with its ligands, including MHC II, and reduces LAG-3 pathway-mediated inhibition of the immune response. Antagonism of this pathway promotes T-cell proliferation and cytokine secretion. Binding of the PD-1 ligands, PD-L1 and PD-L2, to the PD-1 receptor found on T-cells, inhibits T-cell proliferation and cytokine production. Upregulation of PD-1 ligands occurs in some tumors, and signaling through this pathway can contribute to inhibition of active T-cell immune surveillance of tumors. Nivolumab is a human IgG4 monoclonal antibody that binds to the PD-1 receptor, blocks interaction with its ligands PD-L1 and PD-L2, and reduces PD-1 pathway-mediated inhibition of the immune response, including the anti-tumor immune response. In syngeneic mouse tumor models, blocking PD-1 activity resulted in decreased tumor growth. The combination of nivolumab (anti-PD-1) and relatlimab (anti-LAG-3) results in increased T-cell activation compared to the activity of either antibody alone. In murine syngeneic tumor models, LAG-3 blockade potentiates the anti-tumor activity of PD-1 blockage, inhibiting tumor growth and promoting tumor regression.

The recommended dosage of OPDUALAG™ for adult and pediatric patients 12 years of age or older who weigh at least 40 kg is 480 mg nivolumab and 160 mg relatlimab administered intravenously every 4 weeks until disease progression or unacceptable toxicity occurs. The recommended dosage for pediatric patients 12 years of age or older who weigh less than 40 kg has not been established. OPDUALAG™ is administered by intravenous infusion over 30 minutes. OPDUALAG™ (nivolumab and relatlimab-rmbw) injection is a sterile, preservative-free, clear to opalescent, colorless to slightly yellow solution for intravenous use supplied in a single-dose vial containing 240 mg of nivolumab and 80 mg of relatlimab per 20 mL (12 mg and 4 mg per mL) per carton (NDC 0003-7125-11).

Final Decision

Establish new HCPCS Level II code J9298, “Injection, nivolumab and relatlimab-rmbw, 3 mg/1 mg”

Effective: 10/1/2022

Dual Layer PalinGen® X-Membrane - HCP220317NRCFG

Topic/Issue

Request to establish a new HCPCS Level II code to identify Dual Layer PalinGen® X-Membrane.

Applicant's suggested language: XXXXX, "Dual Layer PalinGen® X-Membranes"

Applicant's Summary

Amnio Technology submitted a request to establish a new HCPCS Level II code to identify Dual Layer PalinGen® X-Membrane. Dual Layer PalinGen® X-Membranes are dehydrated, cross-linked, human allografts derived from the placenta specifically is two layers of amniotic membrane. They contain extracellular matrix components to support wound management. They are minimally manipulated, preserving many of the natural growth factors normally present in amniotic tissue. The patient population for use of the Dual Layer PalinGen® X-Membrane products includes children and adults suffering from non-healing acute and chronic wounds (diabetic, venous, mixed venous-arterial, pressure ulcers), complex and/or open surgical wounds and burns. Dual Layer PalinGen® X-Membranes are intended for homologous use and support the repair of soft tissue injury, which include full and partial-thickness, chronic, acute, and hard to heal wounds. Dual Layer PalinGen® X-Membranes are used to cover the wounds and offer protection from the surrounding environment and serve as a selective barrier for the movement of nutrients. The size of the membrane is determined by the physician and should be large enough to completely cover the wound. After preparation of the wound site, the human amnion allograft is applied to the wound surface, extended beyond the wound margins, and secured in place using the clinician's choice of fixation. As determined by the physician, reapplication may be necessary.

Final Decision

After review of the FDA's Tissue Reference Group (TRG) letter submitted by the applicant, the Dual Layer PalinGen® X-Membrane product information submitted to CMS as part of the HCPCS Level II application appears to differ from the information that was submitted to the FDA's TRG. Based on written feedback from the TRG, Dual Layer PalinGen® X-Membrane, when intended for use "as a barrier," appears to meet the criteria for regulation solely under section 361 of the Public Health Service (PHS) Act and the regulations in 21 CFR part 1271. However, in the HCPCS Level II application for the Dual Layer PalinGen® X-Membrane, the applicant referenced additional intended uses. Specifically, the application stated that "Dual Layer PalinGen® X-Membranes are intended for homologous use and support the repair of soft tissue injury, which include full and partial-thickness, and hard to heal wounds." Based on this information, it appears that the Dual Layer PalinGen® X-Membrane may not be suitable for registration as a human cells, tissues, and cellular and tissue-based product (HCT/P) under section 361 of the PHS Act and the regulations in 21 CFR part 1271.

CMS refers the applicant back to the FDA's TRG to obtain written feedback regarding how the product, consistent with its intended uses described in the HCPCS Level II application, is appropriately regulated. The applicant is welcome to submit a complete HCPCS Level II application in a subsequent coding cycle where the information presented to CMS in the

application is consistent with written feedback obtained from the FDA's TRG. Information for submitting questions to the FDA's TRG is located at:

<https://www.fda.gov/vaccines-blood-biologics/tissue-tissue-products/tissue-reference-group>.

Cortiva® and Matrix HD® - HCP220317E4HDE

Topic/Issue

Request to establish a new HCPCS Level II code to identify Cortiva® and Matrix HD®.

Applicant's suggested language: XXXXX, "Cortiva or Matrix HD, per square centimeter"

Applicant's Summary

RTI Surgical, Inc. submitted a request to establish a new HCPCS Level II code to identify Cortiva® and Matrix HD®. Cortiva® allograft dermis and Matrix HD® allograft dermis are acellular dermis grafts sterilized using the Tutoplast® tissue sterilization process, which retains the three-dimensional intertwined multidirectional fibers, vascular channels and key components of the native tissue. The Tutoplast® tissue sterilization process is validated to inactivate and/or remove a panel of viruses, bacteria, fungi and spores, including enveloped and non-enveloped viruses as well as DNA and RNA viruses. This improves the safety profile and healing characteristics of Cortiva® and Matrix HD® compared to other minimally manipulated Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/P's) regulated under Public Health Service Act (PHS) 361, 21 CFR 1271. Cortiva® and Matrix HD® are used in the treatment of chronic, non-healing extremity wounds such as diabetic foot ulcers, venous leg ulcers and other non-healing wounds. Cortiva® and Matrix HD® are available in multiple size configurations, shipped in single-use packages and may be stored in ambient conditions for up to 5 years.

Final Decision

The applicant submitted a copy of the FDA Tissue Reference Group (TRG) letter for Matrix HD® but not for Cortiva®. After review of the TRG letter, we believe that the Matrix HD® allograft dermis information submitted to CMS appears to differ from the information that was submitted to the FDA's TRG. Based on written feedback from the TRG, Matrix HD® allograft dermis, for use as a "wound cover for various wounds including diabetic foot ulcers and burns," appears to be regulated solely under section 361 of the Public Health Service (PHS) Act and the regulations in 21 CFR part 1271. However, in the HCPCS Level II application for Matrix HD® allograft dermis, the applicant referenced additional intended uses. The application stated that "Cortiva® allograft dermis and Matrix HD® allograft dermis are acellular dermis grafts used in in the treatment of diabetic ulcers, Charcot foot ulcers, venous ulcers, trauma wounds, pressure sores/ulcers and other partial and full thickness wounds." Based on this information, it appears that Matrix HD® allograft dermis may not be suitable for registration as an HCT/P under section 361 of the PHS Act and regulations in 21 CFR part 1271.

CMS refers the applicant back to the FDA's TRG to obtain written feedback regarding how the products Cortiva® and Matrix HD® are consistent with the intended uses described in the HCPCS Level II application and are appropriately regulated. The applicant is welcome to submit a complete HCPCS Level II application in a subsequent coding cycle where the information presented to CMS in the application is consistent with written feedback obtained from the FDA's TRG. Information for submitting questions to the FDA's TRG is located at: <https://www.fda.gov/vaccines-blood-biologics/tissue-tissue-products/tissue-reference-group>.

In addition, the application stated that “Cortiva® and Matrix HD® allograft dermis are not identical to Flex HD® or AlloPatch HD®.” However, in order to make a revision to existing HCPCS Level II code Q4128, which currently reads, “Flex hd, allopatch hd, or matrix hd, per square centimeter” to remove “matrix hd” to instead read, “Flex hd, or allopatch hd, per square centimeter,” CMS would need to be provided a letter from the FDA’s TRG specifying how these products are regulated and how they relate to one another.

Vendaje AC™ - HCP2203313FABU

Topic/Issue

Request to establish a new HCPCS Level II code to identify Vendaje AC™

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

Applicant's Summary

BioStem Technologies, Inc. submitted a request to establish a new HCPCS Level II code to identify Vendaje AC™. Vendaje AC™ is a sterile, single use, dehydrated human amnion and chorion membrane allograft. Vendaje AC™ is comprised of a scaffold of extracellular matrix proteins, active growth factors and cytokines. This product is a structural tissue allograft utilized as a skin substitute under homologous use. Vendaje AC™ functions as a protective barrier for soft tissue wounds by resorbing into the wound. Vendaje AC™ is a skin substitute used as a protective covering during the repair and reconstruction of the integumentary system concerning chronic and acute pressure sores/ulcers related to disease processes, partial thickness burns to full thickness burns, draining wounds, post-surgical wounds, and trauma wounds. Vendaje AC™ creates an ideal microenvironment for the wound bed by serving as a barrier providing protection from the surrounding environment (e.g., pathogens and irritants). The amnion and chorion membrane prevent unwanted diffusion of moisture at the wound. No existing code adequately defines Vendaje AC™, a dehydrated amnion and chorion layer with a nominal average thickness of 140 micrometers. Vendaje AC™ is available in sizes of 1x1cm to 10x20cm. The 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 with or without sutures.

Final Decision

CMS received an application requesting to establish a new HCPCS Level II code to identify Vendaje AC™ in the fourth quarter (Q4) 2021 coding cycle. CMS' Q4 2021 final decision referred the applicant back to the FDA's TRG to obtain written feedback regarding how the product, consistent with the intended uses described in their Q4 2021 HCPCS Level II application, is appropriately regulated.

This Q2 2022 application requesting to establish a new HCPCS Level II code to identify Vendaje AC™ continues to have inconsistencies with the intended uses described in the TRG letter for Vendaje AC™. The Q2 2022 HCPCS application stated "This can be incredibly efficient for burn victims to offset dehydration and enable the body to repair tissue and replace lost proteins...Amniotic and chorionic membrane allografts provide a stable scaffold that are anti-inflammatory, non-immunologic and anti-microbial. By utilizing these properties, Vendaje AC™ is an effective protective covering for superficial dermal and soft tissue wound treatments."

Accordingly, our decision remains unchanged. The applicant is welcome to submit a complete HCPCS Level II application in a subsequent coding cycle where the information presented to CMS in the application is consistent with written feedback obtained from the FDA's TRG. Information for submitting questions to the TRG is located at:

<https://www.fda.gov/vaccines-blood-biologics/tissue-tissue-products/tissue-reference-group>.

Vendaje Optic™ - HCP220331B4MR4

Topic/Issue

Request to establish a new HCPCS Level II code to identify Vendaje Optic™

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

Applicant's Summary

BioStem Technologies, Inc. submitted a request to establish a new HCPCS Level II code to identify Vendaje Optic™. Vendaje Optic™ is a sterile, single use, dehydrated human amniotic membrane composed of the amnion layer. Vendaje Optic™ is comprised of a scaffold of extracellular matrix proteins, active growth factors and cytokines. Our product is a structural tissue allograft intended for homologous use as a wound covering for ocular surfaces. Vendaje Optic™ functions as a protective barrier during repairs of the surface of the ocular system and resorbs into ophthalmic wounds. Vendaje Optic™ is a skin substitute that serves as a protective covering during repair and reconstruction procedures for the surface of the eye concerning ophthalmic conditions with conjunctival tissue, abnormal epithelium development, non-healing corneal ulcers, post-surgical wounds, and trauma wounds. Vendaje Optic™ creates an ideal microenvironment by serving as a barrier offering protection from the surrounding environment (e.g., pathogens and irritants). The amniotic membrane offers a vapor barrier preventing unwanted water loss from excessive evaporation at the wound. Existing codes do not adequately describe Vendaje Optic™, a dehydrated amnion layer with a nominal average thickness of 30 microns. Vendaje Optic™ is available in sizes of 8mm, 10mm, and 12mm discs 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 with or without sutures and sterile dressings.

Final Decision

CMS received an application requesting to establish a new HCPCS Level II code to identify Vendaje Optic™ in the fourth quarter (Q4) 2021 coding cycle. The Q4 2021 final decision referred the applicant back to the FDA's TRG to obtain written feedback regarding how the product, consistent with the intended uses described in their Q4 2021 HCPCS Level II application, is appropriately regulated.

This Q2 2022 application requesting to establish a new HCPCS Level II code to identify Vendaje Optic™ continues to have inconsistencies with the intended uses described in the TRG letter for Vendaje Optic™. The Q2 2022 HCPCS application stated "Amniotic allografts provide a protective covering that is anti-inflammatory, non-immunologic and anti-microbial. By utilizing these properties, Vendaje Optic™ is a safe and effective wound cover for ocular treatments."

Accordingly, our decision remains unchanged. The applicant is welcome to submit a complete HCPCS Level II application in a subsequent coding cycle where the information presented to CMS in the application is consistent with written feedback obtained from the FDA's TRG. Information for submitting questions to the TRG is located at: <https://www.fda.gov/vaccines-blood-biologics/tissue-tissue-products/tissue-reference-group>.

Sanopellis - HCP220401W6H7E

Topic/Issue

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

Applicant suggested language: XXXXX, “Sanopellis, per square centimeter”

Applicant’s Summary

ReNu, LLC submitted a request to establish a new HCPCS Level II code to identify Sanopellis. Sanopellis is a minimally manipulated, dehydrated, human amniotic allograft membrane that contains extracellular matrix components to support cellular attachment and proliferation for tissue repair. The products are terminally sterilized to provide extended shelf life. They are indicated for full and partial-thickness, chronic, acute and hard to heal wounds. After preparation of the wound site, the human amnion allograft is surgically applied to the wound surface, extended beyond the wound margins and secured in place using the clinician’s choice of fixation. As determined by the physician, a reapplication may be necessary. Sanopellis is available in multiple sizes: 2cm x 3cm, 4cm x 4cm, and 4cm x 6cm.

Final Decision

CMS received an application requesting to establish a new HCPCS Level II code to identify Sanopellis in the first quarter (Q1) 2022 coding cycle. The Q1 2022 final decision referred the applicant back to the FDA’s TRG to obtain written feedback regarding how the product, consistent with the intended uses described in their Q1 2022 HCPCS Level II application, is appropriately regulated.

This Q2 2022 application requesting to establish a new HCPCS Level II code to identify Sanopellis continues to have inconsistencies with the intended uses described in the TRG letter for Sanopellis. The applicant stated that Sanopellis is “intended for homologous use and support the repair of soft tissue injury, which include full and partial-thickness, chronic, acute and hard to heal wounds.”

Accordingly, our decision remains unchanged. The applicant is welcome to submit a complete HCPCS Level II application in a subsequent coding cycle where the information presented to CMS in the application is consistent with written feedback obtained from the FDA’s TRG. Information for submitting questions to the TRG is located at: <https://www.fda.gov/vaccines-blood-biologics/tissue-tissue-products/tissue-reference-group>.

SurGraft XT - HCP220401A9MCL

Topic/Issue

Request to establish a new HCPCS Level II code to identify SurGraft XT.

Applicant's suggested language: XXXXX, "SurGraft XT, per sq. cm"

Applicant's Summary

Surgenex, LLC submitted a request to establish a new HCPCS Level II code to identify SurGraft XT, a dual layer amniotic tissue derived allograft for management of wounds and burn injuries. SurGraft XT is a sterile, single use, dehydrated allograft derived from donated human amniotic membrane. SurGraft XT acts as a cover and a barrier that offers protection from the surrounding environment. There is currently no HCPCS code available to describe SurGraft XT. The intended use of SurGraft XT includes the management of wounds, such as partial and full thickness wounds, pressure sores/ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds (e.g. donor site/grfts, post-laser surgery, post-Mohs surgery, podiatric wounds, wound dehiscence), trauma wounds, (e.g., abrasions, lacerations, partial thickness burns, skin tears), and draining wounds. SurGraft XT is a fully resorbable graft that acts by providing a physical barrier to the wound. SurGraft XT can be reapplied as needed. SurGraft XT is intended for external application. Following standard wound preparation, SurGraft XT is applied directly to the wound. SurGraft XT adheres to the wound bed without fixation. SurGraft XT is fully resorbable and does not have to be removed from the wound bed. SurGraft XT is supplied sterile, in a single use package in a variety of sizes.

Final Decision

After review of the Tissue Reference Group (TRG) letter submitted by the applicant, the SurGraft XT product information submitted to CMS appears to differ from the information that was submitted to the FDA's TRG. Based on written feedback from the TRG, SurGraft XT, when intended for use "as a barrier and provide protective coverage, from the surrounding environment, to acute and chronic wounds" appears to meet the criteria for regulation solely under section 361 of the Public Health Service (PHS) Act and the regulations in 21 CFR part 1271. However, in the HCPCS Level II application for SurGraft XT, the applicant referenced additional intended uses. The application stated that "SurGraft XT is a sterile, single use, dehydrated allograft skin substitute intended for use in the local treatment of wounds." Based on this information, it appears that the SurGraft XT may not be suitable for registration as a human cells, tissues, and cellular and tissue-based product (HCT/P) under section 361 of the PHS Act and the regulations on 21 CFR part 1271.

CMS refers the applicant back to the FDA's TRG to obtain written feedback regarding how the product, consistent with its intended uses described in the HCPCS Level II application, is appropriately regulated. The applicant is welcome to submit a complete HCPCS Level II application in a subsequent coding cycle where the information presented to CMS in the application is consistent with written feedback obtained from the FDA's TRG. Information for submitting questions to the FDA's TRG is located at: <https://www.fda.gov/vaccines-blood-biologics/tissue-tissue-products/tissue-reference-group>.

Plasma - HCP220308JVR7E

Topic/Issue

Request to establish a new HCPCS Level II code to identify young fresh frozen plasma (yFFP).

Applicant's suggested language: "Young fresh frozen plasma, collected and screened male/female age specific from one-three donors with increased safety analysis for specific recipient."

Applicant's Summary

Solutionology Health LLC submitted a request to establish a new HCPCS Level II code to identify yFFP. yFFP is used for the treatment of inflammatory neurodegenerative diseases (e.g., Parkinson's disease). yFFP contains higher levels of cytokines, growth factors, insulin like growth factors 1 and 2, and chemokines - including CCL11/Eotaxin and osteocalcin. yFFP's route of administration is topically injected (interstitial or subcutaneous infusions), intravenously or via therapeutic plasma exchange.

Final Decision

CMS refers the applicant to the FDA's Tissue Reference Group (TRG) to obtain written feedback regarding how the product, consistent with its intended uses described in the HCPCS Level II application, is appropriately regulated. After obtaining the FDA's written feedback, the applicant is welcome to submit a complete HCPCS Level II application in a subsequent coding cycle. Information for submitting questions to the FDA's TRG is located at:

<https://www.fda.gov/vaccines-blood-biologics/tissue-tissue-products/tissue-reference-group>