DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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Baltimore, Maryland 21244-1850

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

Third Quarter, 2023 HCPCS Coding Cycle

This document presents a summary of each HCPCS code application and CMS' coding decision for each application processed in CMS' Third Quarter 2023 Drug and Biological HCPCS code application review cycle. Each individual summary includes the request number; topic/issue; summary of the applicant's submission 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 January 1, 2024, unless otherwise indicated.

The HCPCS coding decisions below will also be included in the January 2024 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 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. In addition, CMS will use the generic or chemical name if there are no other similar chemical products on the market. If there are multiple products on the market with the same generic or chemical name, and a unique code is warranted based on the statutory definition of "single source drug" in section 1847A(c)(6) of the Social Security Act, CMS will further distinguish a new code by using the brand name or manufacturer name. CMS generally creates codes for products themselves, without specifying a route of administration in the code descriptor, as there might be multiple routes of administration for the same product. Drugs that fall under this category should be billed with either JA modifier for the intravenous infusion of the drug or billed with JB modifier for subcutaneous injection of the drug. The dose descriptors assigned to codes established in this quarterly coding cycle are in alignment with these policies.

Final Determinations for the Third Quarter 2023 Drug and Biological HCPCS Applications.

ELFABRIO® - HCP230623YLQ7V

Topic/Issue

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

Applicant's suggested language: JXXXX, "Injection, pegunigalsidase alfa-iwxj, 1 mg"

Summary of Applicant's Submission

Chiesi USA, Inc. submitted a request to establish a new HCPCS Level II code to identify ELFABRIO® (pegunigalsidase alfa-iwxj) injection. ELFABRIO® was approved by the Food and Drug Administration (FDA) under the Biologics License Application (BLA) pathway on May 9, 2023. ELFABRIO® is a provider-administered biological hydrolytic lysosomal neutral glycosphingolipid-specific enzyme indicated for the treatment of adults with confirmed Fabry disease. Fabry disease is caused by deficiency of the lysosomal enzyme alpha-galactosidase A. ELFABRIO® provides an exogenous source of alpha-galactosidase A. ELFABRIO® is internalized and transported into lysosomes where it is thought to exert enzymatic activity and reduce accumulated globotriaosylceramide (Gb3). The recommended dosage of ELFABRIO®, based on actual body weight, is 1 mg/kg administered by intravenous infusion every 2 weeks. ELFABRIO® is a sterile, preservative-free, clear and colorless solution supplied in a single-dose vial. Each vial contains 20 mg/10 mL (2 mg/mL) of pegunigalsidase alfa-iwxj.

CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code J2508, "Injection, pegunigalsidase alfa-iwxj, 1 mg"

IGALMI™ - HCP230630T3DF3

Topic/Issue

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

Applicant's suggested language: XXXXX, "Dexmedetomidine sublingual film, for sublingual or buccal use, up to 180 micrograms"

Summary of Applicant's Submission

Bioxcel Therapeutics submitted a request to establish a new HCPCS Level II code for IGALMI™ (dexmedetomidine) sublingual film. IGALMI™ was approved by the Food and Drug Administration (FDA) under a 505(b)(2) New Drug Application (NDA) on April 4, 2022. IGALMI™ is used in the hospital setting for adults for acute treatment of agitation associated with schizophrenia or bipolar I or II disorder. The mechanism of action of IGALMI™ is thought to be due to activation of presynaptic alpha-2 adrenergic receptors. Each IGALMI™ sublingual film contains 120 mcg or 180 mcg of dexmedetomidine equivalent to 141.8 mcg and 212.7 mcg of dexmedetomidine hydrochloride, respectively, and doses maybe reduced as appropriate for the patient. IGALMI™ can be self-administered under the supervision of a healthcare provider, who should monitor vital signs and alertness after IGALMI™ administration to prevent falls and syncope, but there are times when a patient will not take the drug and the attending physician must place the drug in the patient's mouth. IGALMI™ offers an advantage for those patients where non-invasive treatment that avoids the need for injections is preferred, for elderly patients as there is no black box warning for dementia-related psychosis that other drugs have, and for patients for whom anti-psychotics or benzodiazepines are not preferred treatments. IGALMI™ sublingual film is supplied as a blue rectangular sublingual film, containing on its surface two darker blue spots in dose strengths of 120 mcg and 180 mcg and is packaged as individual films in heat-sealed foil pouches in 10-count and 30-count films per carton.

CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code J1105, "Dexmedetomidine, oral, 1 mcg"

Docetaxel Injection - HCP230703730CA

Topic/Issue

Request to establish a new HCPCS Level II code to identify Docetaxel injection.

Applicant's suggested language: JXXXX, "Injection, docetaxel (Ingenus) not therapeutically equivalent to J9171, 1 mg"

Summary of Applicant's Submission

Ingenus submitted a request to establish a new HCPCS Level II code to identify Docetaxel injection. Docetaxel injection was approved by the Food and Drug Administration (FDA) under a 505(b)(2) New Drug Application (NDA) on November 22, 2022. Docetaxel injection is a microtubule inhibitor indicated for: breast cancer (BC): single agent for locally advanced or metastatic BC after chemotherapy failure; and with doxorubicin and cyclophosphamide as adjuvant treatment of operable node-positive BC with recommended dosing for BC locally advanced or metastatic: 60 mg/m^2 to 100 mg/m^2 single agent and BC adjuvant: 75 mg/m^2 administered 1 hour after doxorubicin 50 mg/m^2 and cyclophosphamide 500 mg/m^2 every 3 weeks for 6 cycles; non-small cell lung cancer (NSCLC): single agent for locally advanced or metastatic NSCLC after platinum therapy failure; and with cisplatin for unresectable, locally advanced or metastatic untreated NSCLC with recommended dosing after platinum therapy failure: 75 mg/m^2 single agent and for NSCLC chemotherapy naive: 75 mg/m^2 followed by cisplatin 75 mg/m^2 ; castration-resistant prostate cancer (CRPC): with prednisone in metastatic castration-resistant prostate cancer with recommended dosing of 75 mg/m^2 with 5 mg prednisone twice a day continuously; gastric adenocarcinoma (GC): with cisplatin and fluorouracil for untreated, advanced GC, including the gastroesophageal junction with recommended dosing of 75 mg/m^2 followed by cisplatin 75 mg/m^2 (both on day 1 only) followed by fluorouracil 750 mg/m^2 per day as a 24-hour IV (days 1–5), starting at end of cisplatin infusion; squamous cell carcinoma of the head and neck (SCCHN): with cisplatin and fluorouracil for induction treatment of locally advanced SCCHN with recommended dosing of 75 mg/m^2 followed by cisplatin 75 mg/m^2 IV (day 1), followed by fluorouracil 750 mg/m^2 per day as a 24-hr IV (days 1–5), starting at end of cisplatin infusion; for 4 cycles and 75 mg/m^2 followed by cisplatin 100 mg/m^2 IV (day 1), followed by fluorouracil 1000 mg/ m^2 per day as a 24-hr IV (days 1–4); for 3 cycles. Docetaxel injection is administered intravenously (IV) over 1 hour every 3 weeks. Docetaxel injection is a sterile, non-pyrogenic, pale-yellow to brownish-yellow solution at 10 mg/mL concentration. Docetaxel injection is available in single-dose vials containing 20 mg (2 mL), 80 mg (8 mL) or 160 mg (16 mL) docetaxel (anhydrous).

CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code J9172, "Injection, docetaxel (ingenus) not therapeutically equivalent to j9171, 1 mg"

Methotrexate Injection - HCP2307036G03T

Topic/Issue

Request to establish a new HCPCS Level II code to identify Methotrexate injection.

Applicant's suggested language: JXXXX, "Methotrexate high dose injection, Accord"

Summary of Applicant's Submission

Accord Healthcare Inc. submitted a request to the establish a new HCPCS Level II code for methotrexate injection for intravenous use. Methotrexate injection was approved by the Food and Drug Administration (FDA) under a New Drug Application (NDA) on August 24, 2020. Accord's methotrexate injection is indicated for the treatment of adult patients and pediatric patients with acute lymphoblastic leukemia as part of a combination chemotherapy regimen, the treatment of adult and pediatric patients with non-hodgkins lymphoma, and the treatment of adult and pediatric patients with osteosarcoma as a part of a combination chemotherapy regimen. Methotrexate injection is not indicated for non-oncology diseases. Methotrexate injection, (100 mg/mL) is a folate analog metabolic inhibitor. Methotrexate injection inhibits dihydrofolic acid reductase. Dihydrofolates must be reduced to tetrahydrofolates by this enzyme before they can be utilized as carries of one-carbon groups in the synthesis of purine nucleotides and thymidylate. Therefore, methotrexate interferes with DNA synthesis, repair, and cellular replication. Actively proliferating tissues such as malignant cells, bone marrow, fetal cells, buccal and intestinal mucosa, and cells of the urinary bladder are in general more sensitive to the effect of methotrexate. Methotrexate injection is supplied as 5 grams/50 mL (100 mg/mL, clear orange-yellow, isotonic, sterile, preservative-free solutions in single-dose vial for intravenous use only.

CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code J9255, "Injection, methotrexate (accord) not therapeutically equivalent to j9250 or j9260, 50 mg"

Lantidra - HCP230703EKJ5T

Topic/Issue

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

Applicant's suggested language: XXXXX, "Lantidra (donislecel-jujn) Allogeneic Pancreatic Islet Cellular Suspension for Hepatic Portal Vein Infusion"

Summary of Applicant's Submission

CellTrans Inc. submitted a request to establish a new HCPCS Level II code to identify Lantidra (donislecel-jujn) infusion. Lantidra was approved by the Food and Drug Administration (FDA) under the Biologics License Application (BLA) pathway on June 28, 2023. Lantidra is an allogeneic pancreatic islet cellular therapy indicated for the treatment of adults with type 1 diabetes who are unable to approach target hemoglobin A1c (HbA1c) because of current repeated episodes of severe hypoglycemia despite intensive diabetes management and education. Lantidra is to be used in conjunction with concomitant immunosuppression. The primary mechanism of action of Lantidra is the secretion of insulin by the infused allogeneic islet beta cells. Lantidra is for infusion into the hepatic portal vein only. Interventional radiologists and surgeons with expertise in islet cell infusion may administer Lantidra in an interventional radiology suite or operating suite under controlled aseptic conditions. The recommended minimum dose is 5,000 EIN/kg for initial infusion and 4,500 EIN/kg for subsequent infusion in the same recipient. The maximum dose per infusion is dictated by the estimated tissue volume, which should not exceed 10 cc per infusion, and the total EIN present in the infusion bag (up to a maximum of 1 x 106 EIN per bag). A second infusion may be performed if the patient does not achieve independence from exogenous insulin within one year of infusion or within one year after losing independence from exogenous insulin after a previous infusion. A third infusion may be performed using the same criteria as for the second infusion. Lantidra is a cellular suspension (light yellow liquid with the presence of visible cellular aggregates) of allogeneic pancreatic islets (islets of Langerhans) in buffered transplant media containing sodium chloride, dextrose, minerals, amino acids, vitamins, and other compounds supplemented with HEPES (2-[4-(2-hydroxyethyl) piperazin-1-yl] ethanesulfonic acid; 10 mM final concentration) and human serum albumin (0.5% final concentration). Each infusion uses one lot of Lantidra which consists of islets manufactured from the pancreas of a single deceased donor. Each dose of Lantidra is provided as two (2) infusion bags connected to each other via sterile connector. One bag contains Lantidra up to a maximum of 1 x 10^6 EIN in 400 mL of transplant media and the second bag (rinse bag) contains transplant media (light yellow liquid only with no cellular aggregates present) used to rinse the Lantidra bag and the infusion line. The dosage strength is represented by the total EIN in a single preparation and varies between product batches. Dosage strength information for an individual batch is provided on the container label and in accompanying documentation (Final Islet Product Certificate of Analysis).

CMS Final HCPCS Coding Decision

CMS is denying the applicant's request to establish a new HCPCS Level II code for Lantidra. Lantidra is only utilized in the inpatient setting; therefore, there is no claims processing need to establish a HCPCS Level II code.

Pemetrexed Disodium - HCP221228RL52Y

Topic/Issue

Request to establish a new HCPCS Level II code to identify pemetrexed disodium.

Applicant's suggested language: JXXXX, "Injection, pemetrexed disodium (Hospira) not therapeutically equivalent to J9305, 10 mg"

Summary of Applicant's Submission

Pfizer, Inc. submitted a request to establish a new HCPCS Level II code to identify pemetrexed disodium injection by Hospira. Pemetrexed disodium injection was approved by the Food and Drug Administration (FDA) under a 505(b)(2) New Drug Application (NDA) on July 26, 2022. Pemetrexed injection is a folate analog metabolic inhibitor indicated for patients with locally advanced or metastatic, non-squamous non-small cell lung cancer (NSCLC) who have a creatinine clearance (calculated by Cockcroft-Gault equation) of 45 mL/min or greater. It is dosed on day 1 of each 21-day cycle at 500 mg/m^2 as an intravenous (IV) infusion over 10 minutes by a healthcare professional for treatment in the following indications: prior to and in combination with cisplatin for the initial treatment of NSCLC in patients and for up to 6 cycles in the absence of disease progression or unacceptable toxicity, as a single agent for the maintenance treatment of NSCLC in patients and until disease progression or unacceptable toxicity after 4 cycles of platinum-based first-line chemotherapy, as a single agent for the treatment of NSCLC in patients with recurrent, metastatic, non-squamous NSCLC after prior chemotherapy and until disease progression or unacceptable toxicity, and/or as initial treatment, in combination with cisplatin, of patients with malignant pleural mesothelioma whose disease is unresectable or who are otherwise not candidates for curative surgery until disease progression or unacceptable toxicity. Pemetrexed injection is not indicated for the treatment of patients with squamous cell NSCLC. It is supplied as a sterile, preservative-free, clear, colorless to pale yellow ready-to-dilute solution in a single-dose vial for IV infusion. It is supplied in strengths of 100 mg/4 mL, 500 mg/20 mL, and 1 g/40 mL. Each mL contains 25 mg pemetrexed (equivalent to 27.57 mg pemetrexed disodium), 1.2 mg monothioglycerol, and water for injection and may contain sodium hydroxide for pH adjustment.

CMS Final HCPCS Coding Decision

Existing HCPCS Level II code J9294, "Injection, pemetrexed (hospira) not therapeutically equivalent to j9305, 10 mg" adequately describes this product.

Pemrydi RTU®, Pemetrexed - HCP230622EHC7E

Topic/Issue

Request to establish a new HCPCS Level II code to identify Pemrydi RTU® (pemetrexed).

Applicant's suggested language: JXXXX, "Injection pemetrexed (Pemrydi RTU), 10mg."

Summary of Applicant's Submission

Amneal Pharmaceuticals submitted a request to establish a new HCPCS Level II code to identify Pemrydi RTU® (pemetrexed). Pemrydi RTU® was approved by the Food and Drug Administration (FDA) under a 505(b)(2) New Drug Application (NDA) on May 21, 2023. Pemrydi RTU® has been developed against lyophilized powder formulation of reference Alimta®.

CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code J9324, "Injection, pemetrexed (pemrydi rtu), 10 mg"

BARHEMSYS® - HCP230601QBMWR

Topic/Issue

Request to establish a new HCPCS Level II code to identify BARHEMSYS® (amisulpride).

Applicant's suggested language: JXXXX, “Injection, amisulpride, per 1 mg"

Summary of Applicant's Submission

Eagle Pharmaceuticals, Inc. submitted a request to establish a new HCPCS Level II code to identify BARHEMSYS® (amisulpride) injection. BARHEMSYS® was approved by the Food and Drug Administration (FDA) under a 505(b)(2) New Drug Application (NDA) on February 26, 2020. BARHEMSYS® is a dopamine-2 (D2) antagonist indicated in adults for prevention of postoperative nausea and vomiting (PONV), either alone or in combination with an antiemetic of a different class, and for treatment of PONV in patients who have received antiemetic prophylaxis with an agent of a different class or have not received prophylaxis. BARHEMSYS® is the first and only FDA-approved rescue treatment for PONV. BARHEMSYS® is supplied as a clear, colorless, nonpyrogenic, sterile solution in a single-dose vial. Each 2 mL glass vial contains 5 mg of amisulpride (2.5 mg/mL). Each 4 mL glass vial contains 10 mg amisulpride (2.5 mg/mL). When used for the treatment of PONV, one 4 mL vial of BARHEMSYS® is administered as a single intravenous dose infused over 1 to 2 minutes in the event of nausea and/or vomiting after a surgical procedure. When used for the prevention of PONV, one 2 mL vial of BARHEMSYS® is administered as a single intravenous dose infused over 1 to 2 minutes at the time of induction of anesthesia.

CMS Final HCPCS Coding Decision

1. Establish a new HCPCS Level II code J0184, “Injection, amisulpride, 1 mg”

   Effective 1/1/2024

2. Discontinue C9153, “Injection, amisulpride, 1 mg”

   Effective 12/31/2023

ABILIFY ASIMTUFII® - HCP23063051MG7

Topic/Issue

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

Applicant's suggested language: JXXXX, "Injection, aripiprazole, extended release (abilify asimtufii), 1 mg"

Summary of Applicant's Submission

Otsuka America Pharmaceutical, Inc. submitted a request to establish a new HCPCS Level II code to identify ABILIFY ASIMTUFII® (aripiprazole) extended-release injectable suspension, for intramuscular use. ABILIFY ASIMTUFII® (aripiprazole) was approved by the Food and Drug Administration (FDA) under a New Drug Application (NDA) on April 27, 2023. ABILIFY ASIMTUFII® is the first FDA-approved once-every-two months long-acting injectable indicated for the treatment of schizophrenia in adults, or as maintenance monotherapy treatment of bipolar I disorder in adults. ABILIFY ASIMTUFII® provides safe and effective treatment of schizophrenia and bipolar I disorder in adult patients by providing appropriate levels of aripiprazole in the body after injection to ensure that the minimum aripiprazole concentration known to be effective in treatment of these conditions remains in the patient's body for the two-month interval (56 days). The recommended dosage of ABILIFY ASIMTUFII® is 960 mg, administered once every 2 months via intramuscular injection. The dose can be reduced to 720 mg in patients with adverse reactions. For a minority of patients that are known cytochrome P450 2D6 poor metabolizers, the recommended dosage is 720 mg administered once every 2 months. ABILIFY ASIMTUFII® is packaged in a single-use kit that contains 1 pre-filled syringe in 960 mg/3.2 mL or 720 mg/2.4 mL strengths and 2 safety needles (a 1.5-inch, 22-gauge needle and a 2-inch, 21-gauge needle).

CMS Final HCPCS Coding Decision

1. Establish a new HCPCS Level II code J0402, "Injection, aripiprazole (abilify asimtufii), 1 mg"

   Effective 1/1/2024

2. Discontinue C9152, "Injection, aripiprazole, (abilify asimtufii), 1 mg"

   Effective 12/31/2023

ABRILADA™ - HCP230630CG02Y

Topic/Issue

Request to a establish new HCPCS Level II code to identify ABRILADA™ (adalimumab-afzb).

Applicant's suggested language: QXXXX “Injection, adalimumab-afzb (Abrilada), biosimilar, 20 mg”

Summary of Applicant's Submission

Pfizer, Inc. submitted a request to establish a new HCPCS Level II code to identify ABRILADA™ (adalimumab-afzb). ABRILADA™ was approved by the Food and Drug Administration (FDA) under the Biologics License Application (BLA) pathway on November 14, 2019. It is FDA approved as a biosimilar to Humira® (adalimumab). ABRILADA™ is a tumor necrosis factor (TNF) blocker that is prescribed and administered via subcutaneous injection under the guidance and supervision of a physician. ABRILADA™ is indicated for reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in adult patients with moderately to severely active rheumatoid arthritis (RA); for reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis (JIA) in patients 2 years of age and older; for reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with active psoriatic arthritis (PsA); for reducing signs and symptoms in adult patients with active ankylosing spondylitis; for treatment of moderately to severely active crohn’s disease (CD) in adults and pediatric patients 6 years of age and older; and for treatment of moderately to severely active ulcerative colitis (UC) in adult patients. ABRILADA™ dosage and frequency vary by indication, patient age, and weight. ABRILADA™ is a dosed at 40-80-160 mg for adults with RA, PsA, AS, adult CD, UC, PsA, and HS. ABRILADA™ is dosed at 10-20-40-80-160 mg based on weight for JIA and pediatric patients over 6 years of age with CD. ABRILADA™ injection is supplied as a sterile, preservative-free solution for subcutaneous administration. It is supplied in cartons containing either two 40 mg single-dose prefilled pens, one and two 40 mg single-dose 1 mL prefilled glass syringes, two 20 mg single-dose 1 mL prefilled glass syringes, two 10 mg single-dose 1 mL prefilled glass syringes, or as a 40 mg single-dose institutional use vial. The solution of ABRILADA™ is clear and colorless to very light brown.

CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code Q5132, “Injection, adalimumab-afzb (abrilada), biosimilar, 10 mg”

POSLUMA®, flotufolastat F18 - HCP230622R7D25

Topic/Issue

Request to a establish new HCPCS Level II code to identify POSLUMA®, flotufolastat F18.

Applicant's suggested language: AXXXX, “flotufolastat F18, diagnostic, 1 mCi”

Summary of Applicant’s Submission

Blue Earth Diagnostics, Inc. submitted a request to establish a new HCPCS Level II code to identify POSLUMA® (flotufolastat F18). POSLUMA® was approved by the Food and Drug Administration (FDA) under a New Drug Application (NDA) on May 25, 2023. POSLUMA® is a diagnostic, micro-dose radiopharmaceutical designed to bind to the extracellular epitope of the prostate-specific membrane antigen (PSMA) extracellular protein, which is overexpressed in prostate cancer. POSLUMA® injection is indicated for positron emission tomography (PET) imaging of PSMA positive lesions in individuals with prostate cancer with suspected metastasis who are candidates for initial definitive therapy, with suspected recurrence based on elevated serum prostate-specific antigen (PSA) level. The significant over expression of PSMA in nearly all prostate cancer cells makes it an excellent target for imaging in prostate cancer. POSLUMA® is supplied as a clear, colorless solution in a 50 mL multiple-dose vial containing 296 MBq/mL to 5846 MBq/mL (8 mCi/mL to 158 mCi/mL) flotufolastat F18 at calibration time and date. The typical patient dose is 8 mCi.

CMS Final HCPCS Coding Decision

1. Establish a new HCPCS Level II code A9608, “Flotufolastat f18, diagnostic, 1 millicurie”

   Effective 1/1/2024

2. Discontinue C9156, “Flotufolastat f 18, diagnostic, 1 millicurie”

   Effective 12/31/2023

Fludeoxyglucose F18 - HCP230306TDF6K

Topic/Issue

Request to establish a new HCPCS Level II code to identify fludeoxyglucose F18.

Applicant's suggested language: AXXXX, “Injection, fluorodeoxyglucose F18 FDG, therapeutic, up to 15 millicuries”

Summary of Applicant’s Submission

RefleXion Medical Inc. submitted a request to establish a new HCPCS Level II code to identify fludeoxyglucose F18 (FDG)-guided treatment. The RefleXion Medical Radiotherapy System (RMRS), now recently being marketed as SCINTIX™ that uses the fludeoxyglucose F18 (FDG)-guided treatment was authorized for marketing as a Class II device by the Food and Drug Administration (FDA) under section 513(a)(1) of the Food, Drug, and Cosmetics Act on February 1, 2023. Fludeoxyglucose F18 (FDG)-guided treatment includes modeling and precise delivery of FDG-guided external-beam radiation therapy (EBRT), a type of biology-guided radiotherapy (BgRT). BgRT delivery is distinct from conventional forms of EBRT as it requires an injected radiopharmaceutical to enable ongoing acquisition of emissions data during radiotherapy delivery and these emissions data are used to control where and how much radiation is delivered, through real-time, sub-second latency beam adjustments during treatment. BgRT with the RMRS is currently indicated for adults with tumor volumes in lung and bone subject to potential motion and positional uncertainty, and is delivered in five or fewer fractions. The RMRS employs proprietary algorithms that continuously translate radiopharmaceutical emissions data generated by FDG into real-time control mechanisms governing where and how much radiation is delivered.

CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code A9609, “Fludeoxyglucose f18 up to 15 millicuries”

VYJUVEK™ - HCP23062812W6K

Topic/Issue

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

Applicant's suggested language: JXXXX, "Beremagene geperpavec-svdt for topical administration, 5 x 10^9 PFU/mL, single unit dosage form, 2.5mL"

Summary of Applicant's Submission

Krystal Biotech submitted a request to establish a new HCPCS Level II code to identify VYJUVEK™. VYJUVEK™ was approved by the Food and Drug Administration (FDA) under the Biologics License Application (BLA) pathway on May 19, 2023. The recommended language for the new code is: Beremagene geperpavec-svdt for topical administration, 5 x 10^9 PFU/mL, single unit dosage form, 2.5mL. VYJUVEK™ (beremagene geperpavec-svdt) is a vector-based gene therapy indicated for the treatment of wounds associated with herpes-simplex virus type 1 (HSV-1) in patients 6 months of age and older with dystrophic epidermolysis bullosa with mutations in the collagen type VII alpha 1 chain (COL7A1) gene. The drug is a biological suspension mixed with excipient gel for topical application. The recommended dosage is based on the age of the patient and applied topically to wounds once a week. The maximum weekly dose by age is 1.6 x 10^9 PFU and 0.8 mL for patients 6 months to < 3 years of age and 3.2 x 10^9 PFU and 1.6 mL for patients ≥3 years of age. VYJUVEK™ is an opalescent yellow to colorless biological suspension, mixed into excipient gel, for topical application. VYJUVEK™ biological suspension is supplied as a 1.0 mL extractable volume in a single-use vial with a green cap, at a nominal concentration of 5×10^9 PFU/mL. The excipient gel is a clear viscous solution supplied as a 1.5 mL fill volume in a separate single-use vial with a blue cap. VYJUVEK™ biological suspension (1.0 mL) is mixed into the excipient gel vial prior to administration.

CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code J3401, "Beremagene geperpavec-svdt for topical administration, containing nominal 5 x 10^9 pfu/ml vector genomes, per 0.1 ml"

BRIXADI™ - HCP230524M0HG0

Topic/Issue

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

Applicant's suggested language:

1. JXXXX, "Buprenorphine extended-release, weekly, less than or equal to 32mg [BRIXADI 8mg, 16mg, 24mg, and 32mg], each"

2. JXXXX, "Buprenorphine extended-release, monthly, 64mg or greater [BRIXADI 64mg, 96mg, and 128mg], each"

Summary of Applicant's Submission

Braeburn Inc. submitted a request to establish two new HCPCS Level II codes to identify BRIXADI™. BRIXADI™ was approved by the Food and Drug Administration (FDA) under a 505(b)(2) New Drug Application (NDA) on May 23, 2023. BRIXADI™ contains buprenorphine, a partial opioid agonist. BRIXADI™ is indicated for the treatment of individuals with moderate to severe opioid use disorder who have initiated treatment with a single dose of a transmucosal buprenorphine product or who are already being treated with buprenorphine. BRIXADI™ should be used as part of a complete treatment plan that includes counseling and psychosocial support. Again, BRIXADI™ contains buprenorphine, a partial agonist at the mu-opioid receptor and an antagonist at the kappa-opioid receptor. The opioid blockade study assessed the blockade of subjective opioid drug-liking effects and pharmacokinetics (PK) of BRIXADI™ (weekly) in 47 patients with moderate or severe opioid dependence. The primary endpoint was the maximum rating (Emax) on the visual analogue scale (VAS) for drug-liking. After stabilization on immediate-release morphine, all patients completed a 3-day qualification/baseline hydromorphone challenge session consisting of 3 intramuscular doses of hydromorphone (0 mg, [placebo], 6 mg, and 18 mg) once daily for 3 consecutive days in a randomized, double-blind, crossover manner. Following the qualification phase, eligible patients received 2 injections of BRIXADI™ (weekly) for two weeks at either the 24 mg or 32 mg level. Two hydromorphone challenge sessions (3 consecutive days each) were conducted throughout the week after each weekly injection of BRIXADI™ (weekly). Both weekly BRIXADI™ doses produced immediate and sustained blockade of hydromorphone effects, including both drug-liking effects and suppression of withdrawal. BRIXADI™ (weekly) and BRIXADI™ (monthly) are different formulations. Doses of BRIXADI™ (weekly) cannot be combined to yield an equivalent BRIXADI™ (monthly) dose. BRIXADI™ should be injected slowly, into the subcutaneous tissue of the buttock, thigh, abdomen, or upper arm. Clinicians should strongly consider prescribing naloxone at the time BRIXADI™ is initiated or renewed because patients being treated for opioid use disorder have the potential for relapse, putting them at risk for opioid overdose. Furthermore, injection sites for BRIXADI™ (weekly) should be alternated/rotated for each injection. In patients who are not currently receiving buprenorphine treatment, for BRIXADI™ (weekly), the upper arm site should only be used after steady-state has been achieved (4 consecutive doses). Injection in the arm site was associated with approximately 10% lower plasma levels than other sites. BRIXADI™ is packaged as a single-use pre-filled syringe.

CMS Final HCPCS Coding Decision

1. Establish a new HCPCS Level II code J0576, “Injection, buprenorphine extended-release (brixadi), 1 mg"

   Effective 1/1/2024

2. Discontinue C9154, “Injection, buprenorphine extended-release (brixadi), 1 mg”

   Effective 12/31/2023

Though the applicant requested to establish two new HCPCS Level II codes, our coding determination results in establishing only one unique code since the FDA only approved a single New Drug Application (NDA), and any New Drug Code numbers under that same NDA are cross-walked to one new unique HCPCS Level II code.

Paclitaxel Protein-Bound Particles for Injectable Suspension (albumin-bound) - HCP23063064CCB

Topic/Issue

Request to establish a new HCPCS Level II code to identify Paclitaxel Protein-Bound Particles for Injectable Suspension (albumin-bound).

Applicant's suggested language: JXXXX, "Paclitaxel Protein-Bound Particles for Injectable Suspension (Albumin-Bound), for intravenous use, 1 mg"

Summary of Applicant's Submission

Teva Pharmaceuticals Industries Ltd. (Teva) submitted a request to establish a new HCPCS Level II code to identify Paclitaxel Protein-Bound Particles for Injectable Suspension (albumin-bound). Paclitaxel Protein-Bound Particles for Injectable Suspension (albumin-bound) was approved by the Food and Drug Administration (FDA) under a 505(b)(2) New Drug Application (NDA) on September 30, 2021. Paclitaxel Protein-Bound Particles for Injectable Suspension (albumin-bound) is a physician-administered single source drug that is a microtubule inhibitor indicated for the treatment of metastatic breast cancer, after failure of combination chemotherapy for metastatic disease or relapse within 6 months of adjuvant chemotherapy; for the treatment of locally advanced or metastatic non-small cell lung cancer (NSCLC), as first-line treatment in combination with carboplatin, in patients who are not candidates for curative surgery or radiation therapy. It is also indicated for metastatic adenocarcinoma of the pancreas as first-line treatment, in combination with gemcitabine. Paclitaxel Protein-Bound Particles for Injectable Suspension (albumin-bound) is administered by intravenous infusion, and is supplied in an injectable white to yellow suspension, lyophilized powder containing 100 mg of paclitaxel formulated as albumin-bound particles in single-dose vial for reconstitution. Dosage and administration instructions vary by indication and by patient body mass. Paclitaxel Protein-Bound Particles for Injectable Suspension (albumin-bound) should not be substituted for other paclitaxel products.

CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code J9258, "Injection, paclitaxel protein-bound particles (teva) not therapeutically equivalent to j9264, 1 mg"

UZEDY™ - HCP230629QABDC

Topic/Issue

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

Applicant's suggested language: J2000, "Injection, risperidone, (uzedy), 0.5 mg"

Summary of Applicant's Submission

Teva Pharmaceuticals Industries Ltd. (Teva) submitted a request to establish a new HCPCS Level II code to identify UZEDY™. UZEDY™ was approved by the Food and Drug Administration (FDA) under a 505(b)(2) New Drug Application (NDA) on April 28, 2023. UZEDY™ is an atypical antipsychotic indicated for the treatment of adults with schizophrenia. The mechanism of action of risperidone in schizophrenia is unclear. The drug's therapeutic activity in schizophrenia could be mediated through a combination of dopamine Type 2 (D2) and serotonin Type 2 (5HT2) receptor antagonism. The clinical effect from risperidone results from the combined concentrations of risperidone and its major metabolite, 9-hydroxyrisperidone (paliperidone). Antagonism at receptors other than D2 and 5HT2 may explain some of the other effects of risperidone. UZEDY™ (risperidone) extended-release injectable suspension is supplied in doses of 50 mg/0.14 mL, 75 mg/0.21 mL, 100 mg/0.28 mL, 125 mg/0.35 mL, 150 mg/0.42 mL, 200 mg/0.56 mL, and 250 mg/0.7 mL in single-dose prefilled syringes. UZEDY™ is administered as a subcutaneous injection and only by a qualified healthcare provider. UZEDY™ is packaged in a carton with one single-dose prefilled syringe.

CMS Final HCPCS Coding Decision

1. Establish a new HCPCS Level II code J2799, "Injection, risperidone (uzedy), 1 mg"

   Effective 1/1/2024

2. Discontinue C9158, "Injection, risperidone, (uzedy), 1 mg"

   Effective 12/31/2023

ONTAK® - HCP230702AUMJK

Topic/Issue

Request to delete an existing HCPCS Level II code J9160, “Injection, denileukin diftitox, 300 micrograms”.

Summary of Applicant's Submission

Citius Pharmaceuticals, Inc. submitted a request to delete an existing HCPCS Level II code J9160 (“Injection, denileukin diftitox, 300 micrograms”), which identifies ONTAK® (denileukin diftitox). ONTAK® was approved by the Food and Drug Administration (FDA) under the Biologics License Application (BLA) pathway on October 15, 2008. This application requests the deletion of an existing HCPCS Level II code that is no longer used. J9160 is no longer used because the item that it previously described was withdrawn from the U.S. market in 2014, and has not been marketed or available in the United States for nearly ten years.

CMS Final HCPCS Coding Decision

Discontinue existing HCPCS Level II code J9160, “Injection, denileukin diftitox, 300 micrograms”

We will also address this application at an upcoming HCPCS Public Meeting, consistent with our usual practice for public requests to discontinue a code.

RYSTIGGO® - HCP230630WK428

Topic/Issue

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

Applicant's suggested language: JXXXX, “Injection, rozanolixizumab-noli, for subcutaneous infusion, 140mg/mL”

Summary of Applicant's Submission

UCB, Inc. submitted a request to establish a new HCPCS Level II code to identify RYSTIGGO® (rozanolixizumab-noli). RYSTIGGO® was approved by the Food and Drug Administration (FDA) under the Biologics License Application (BLA) pathway on June 26, 2023. RYSTIGGO® is a neonatal fragment crystallizable (Fc) receptor blocker indicated for the treatment of adult patients with generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) antibody positive. Rozanolixizumab-noli is a humanized Immunoglobulin G4 (IgG4) monoclonal antibody that binds to the neonatal Fc receptor (FcRn), resulting in the reduction of circulating IgG. RYSTIGGO® is for subcutaneous administration only using an infusion pump. RYSTIGGO® should only be prepared and infused by a healthcare provider. RYSTIGGO® is packaged as a single dose vial with 280 mg/2 mL. The recommended dosage of RYSTIGGO® is based on body weight: for patients with a body weight less than 50 kg, the dosage is 420 mg, and volume to be infused is 3 mL; for patients 50 kg to less than 100 kg, the dosage is 560 mg, and the volume to be infused is 4 mL; for patients 100 kg and above, the dosage is 840 mg, and the volume to be infused is 6 mL.

CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code J9333, “Injection, rozanolixizumab-noli, 1 mg”

VYVGART® Hytrulo - HCP230630MCREK

Topic/Issue

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

Applicant's suggested language: XXXXX, “Injection, efgartigimod alfa 2 mg and hyaluronidase-qvfc”

Summary of Applicant's Submission

Argenx submitted a request to establish a new HCPCS Level II code to identify VYVGART® Hytrulo (efgartigimod alfa and hyaluronidase-qvfc). VYVGART® Hytrulo was approved by the Food and Drug Administration (FDA) under the Biologics License Application (BLA) pathway on June 20, 2023. VYVGART® Hytrulo is indicated for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive. The recommended dose is 1,008 mg /11,200 units (1,008 mg efgartigimod alfa and 11,200 units hyaluronidase) administered subcutaneously over approximately 30 to 90 seconds, once weekly for 4 weeks. VYVGART® Hytrulo contains an additional active ingredient known as hyaluronidase (human recombinant). The hyaluronidase increases permeability of the subcutaneous tissue by depolymerizing hyaluronan. The hyaluronidase degrades the natural occurring hyaluronan at the subcutaneous injection site, which allows efgartigimod alfa to be dispersed and absorbed for optimal administration.

CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code J9334, “Injection, efgartigimod alfa, 2 mg and hyaluronidase-qvfc”

Cyclophosphamide - HCP2306305GNU2

Topic/Issue

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

Applicant's suggested language: XXXXX, “Cyclophosphamide Injection 500 mg/mL (Dr. Reddys)”

Summary of Applicant's Submission

Dr. Reddy’s Laboratories, Inc. submitted a request to establish a new HCPCS Level II code to identify Cyclophosphamide. Cyclophosphamide injection was approved by the Food and Drug Administration (FDA) under a 505(b)(2) New Drug Application (NDA) on June 7, 2023. Cyclophosphamide is indicated for the treatment of adult and pediatric patients with malignant diseases; malignant lymphomas, Hodgkin’s disease, lymphocytic lymphoma, mixed-cell type lymphoma, histiocytic lymphoma, Burkitt’s lymphoma, multiple myeloma, leukemias, mycosis fungoides, neuroblastoma, adenocarcinoma of ovary, retinoblastoma, and breast carcinoma. Cyclophosphamide is an alkylating drug. The active alkylating metabolites of cyclophosphamide interfere with the growth of susceptible rapidly proliferating malignant cells. Cyclophosphamide injection is for intravenous administration only. Cyclophosphamide injection is available in single dose vials in three strengths: 500 mg/mL, 1 g/2 mL and 2 g/4 mL. The recommended dosage of initial course for patients with no hematologic deficiency is 40 mg/kg to 50 mg/ kg in divided doses over 2 to 5 days. Other dosage regimens include 10 mg/kg to 15 mg/kg given every 7 to 10 days or 3 mg/kg to 5 mg/kg twice weekly.

CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code J9072, “Injection, cyclophosphamide, (dr. reddy’s), 5 mg”

EPKINLY™ - HCP230626HPYFX

Topic/Issue

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

Applicant's suggested language: JXXXX, “Injection, epcoritamab-bysp (EPKINLY), 1 mg”

Summary of Applicant's Submission

Genmab and AbbVie submitted a request to establish a new HCPCS Level II code to identify EPKINLY™ (epcoritamab-bysp) injection. EPKINLY™ was approved by the Food and Drug Administration (FDA) under the Biologics License Application (BLA) pathway on May 19, 2023. EPKINLY™ is indicated for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified, including DLBCL arising from indolent lymphoma, and high-grade B-cell lymphoma after two or more lines of systemic therapy. EPKINLY™ is prepared and administered by a healthcare provider as a subcutaneous injection. EPKINLY™ should be administered in 28-day cycles until disease progression or unacceptable toxicity. Cycle 1: 0.16 mg on day 1 (step-up dose 1), 0.8 mg on day 8 (step-up dose 2), 48 mg on day 15 (first full dose), and 48 mg on day 22; cycles 2-3: 48 mg on days 1, 8, 15, and 22; cycles 4-9: 48 mg on days 1 and 15; cycles 10 and beyond: 48 mg on day 1. EPKINLY™ is supplied as one 4 mg/0.8 mL single-dose glass vial, and as one 48 mg/0.8 mL single-dose glass vial.

CMS Final HCPCS Coding Decision

1. Establish a new HCPCS Level II code J9321, “Injection, epcoritamab-bysp, 0.16 mg”

   Effective 1/1/2024

2. Discontinue C9155, “Injection, epcoritamab-bysp, 0.16 mg”

   Effective 12/31/2023

LAMZEDE® - HCP230623B143Y

Topic/Issue

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

Applicant's suggested language: JXXXX, “Injection, velmanase alfa-tycv, 1 mg”

Summary of Applicant's Submission

Chiesi USA, Inc. submitted a request to establish a new HCPCS Level II code to identify LAMZEDE® (velmanase alfa-tycv) injection. LAMZEDE® was approved by the Food and Drug Administration (FDA) under the Biologics License Application (BLA) pathway on February 16, 2023. LAMZEDE® is recombinant human lysosomal alpha-mannosidase indicated for the treatment of adult and pediatric patients with non-central nervous system manifestations of alpha-mannosidosis. LAMZEDE® is the first and only FDA-approved enzyme replacement therapy for alpha-mannosidosis, an ultra-rare progressive lysosomal storage disorder caused by deficiency in the enzyme alpha-mannosidase. The recommended dosage of LAMZEDE® is 1 mg/kg administered once every week as an intravenous infusion. LAMZEDE® is supplied as a lyophilized powder in a single-dose vial for reconstitution. Each vial contains 10 mg of velmanase alfa-tycv.

CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code J0217, “Injection, velmanase alfa-tycv, 1 mg”

QALSODY™ - HCP230629N8BRM

Topic/Issue

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

Applicant's suggested language: JXXXX, “QALSODY™ (tofersen) injection, for intrathecal use, 1 mg”

Summary of Applicant's Submission

Biogen, Inc. submitted a request to establish a new HCPCS Level II code to identify QALSODY™ (tofersen) injection for intrathecal use. QALSODY™ was approved by the Food and Drug Administration (FDA) under a New Drug Application (NDA) under the accelerated approval pathway on April 25, 2023. QALSODY™ is the first antisense oligonucleotide approved by the FDA to treat this rare superoxide dismutase 1 (SOD1) genetic mutation in patients with amyotrophic lateral sclerosis (ALS). QALSODY™ is an antisense oligonucleotide indicated for the treatment of adults with ALS associated with a mutation in the SOD1 gene. SOD1-ALS is a devastating, uniformly fatal, and ultra-rare genetic form of ALS with approximately 330 people in the U.S. living with the disease. QALSODY™ is supplied as a sterile, preservative-free, clear, and colorless to slightly yellow solution in a glass vial to be administered by intrathecal route. Each vial of drug product contains a single dose of 100 mg tofersen at a concentration of 6.7 mg/mL. The recommended dose is 100 mg (15 mL) per administration.

CMS Final HCPCS Coding Decision

1. Establish a new HCPCS Level II code J1304, “Injection, tofersen, 1 mg”

   Effective 1/1/2024

2. Discontinue C9157, “Injection, tofersen, 1 mg”

   Effective 12/31/2023

ROCTAVIAN™ - HCP230629RNQN9

Topic/Issue

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

Applicant's suggested language: JXXXX, “Injection, valoctocogene roxaparvovec-rvox, 1 mL”

Summary of Applicant's Submission

BioMarin submitted a request to establish a new HCPCS Level II code to identify ROCTAVIAN™ (valoctocogene roxaparvovec-rvox). ROCTAVIAN™ was approved by the Food and Drug Administration (FDA) under the Biologics License Application (BLA) pathway on June 29, 2023. ROCTAVIAN™ is an adeno-associated virus serotype 5 (AAV5) gene therapy for patients with hemophilia A, a rare, congenital X-linked bleeding disorder which results in prolonged bleeding and/or the inability of blood to clot normally. Hemophilia A is a rare blood disease caused by a deficiency of clotting factor VIII (FVIII), frequently manifesting as uncontrolled bleeding events. ROCTAVIAN™ is an in vivo gene therapy in which a functional copy of the human factor VIII gene is delivered intravenously, addressing the underlying etiology of the disease. ROCTAVIAN™ prevents bleeding by increasing the amount of clotting factor VIII available in the body for coagulation. ROCTAVIAN™ is an adeno-associated virus vector-based gene therapy indicated for the treatment of adults with severe hemophilia A (congenital factor VIII deficiency with factor VIII activity < 1 IU/dL) without pre-existing antibodies to adeno-associated virus serotype 5 detected by an FDA approved test. The recommended dose of ROCTAVIAN™ is 6 x 10^13 vector genomes per kilogram (vg/kg) of body weight, administered as a single intravenous infusion. ROCTAVIAN™ contains 2 × 10^13 vg/mL. The patient dose is calculated in mL. ROCTAVIAN™ is supplied frozen at ≤ -60ºC (-76°F) as suspension for intravenous infusion containing 2 x 10^13 vg/mL, in vials containing an extractable volume of not less than 8 mL.

CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code J1412, “Injection, valoctocogene roxaparvovec-rvox, per mL, containing nominal 2 × 10^13 vector genomes”

Columvi™ - HCP230628M4V5A

Topic/Issue

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

Applicant's suggested language: “Injection, glofitimab-gxbm, 2.5 mg/mL”

Summary of Applicant's Submission

Genentech submitted a request to establish a new HCPCS Level II code to identify Columvi™. Columvi™ was approved by the Food and Drug Administration (FDA) under the Biologics License Application (BLA) pathway on June 15, 2023. Columvi™ is a T-cell bispecific (TCB) antibody targeting CD20 expressed on B-cells and CD3 epsilon chain (CD3e) present on T-cells. Columvi™ is administered by a healthcare professional as an intravenous infusion through a dedicated infusion line. Columvi™ is supplied as a 2.5 mg/mL solution in a single-dose vial and as 10 mg/10 mL (1 mg/mL) solution in a single-dose vial.

CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code J9286, “Injection, glofitamab-gxbm, 2.5 mg”

Elevidys - HCP230630YE1PK

Topic/Issue

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

Applicant's suggested language: JXXXX, “Injection, delandistrogene moxeparvovec-rokl, per treatment, up to 9.31x10^15 vector genomes”

Summary of Applicant's Submission

Sarepta Therapeutics, Inc. submitted a request to establish a new HCPCS Level II code for Elevidys (delandistrogene moxeparvovec-rokl) suspension. Elevidys was approved by the Food and Drug Administration (FDA) under the Biologics License Application (BLA) pathway on June 22, 2023. Elevidys is an adeno-associated virus vector-based gene therapy indicated for the treatment of ambulatory pediatric patients aged 4 through 5 years with Duchenne muscular dystrophy (DMD) with a confirmed mutation in the DMD gene. This indication is approved under accelerated approval based on expression of Elevidys micro-dystrophin observed in patients treated with Elevidys. Elevidys addresses the root genetic cause of DMD mutations in the dystrophin gene that result in the lack of dystrophin protein by delivering a gene that codes for a shortened form of dystrophin to muscle cells known as Elevidys micro-dystrophin. Elevidys is provided in a customized kit containing ten to seventy 10 mL single-dose vials, with each kit constituting a dosage unit based on the patient’s body weight.

CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code J1413, “Injection, delandistrogene moxeparvovec-rokl, per therapeutic dose”

VENDAJE AC™ - HCP230630W40Y3

Topic/Issue

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

Applicant's suggested language: XXXXX, “VENDAJE AC, per square centimeter”

Summary of Applicant's Submission

BioStem Technologies, Inc. submitted a request to establish a new HCPCS Level II code to identify VENDAJE AC™. VENDAJE AC™ is a decellularized human amniotic and chorionic allograft product derived from placental tissues are sterilized by e-beam irradiation. VENDAJE AC™ is intended for use as a protective covering for soft tissue wounds. VENDAJE AC™ is dehydrated, packaged in different size sheets, and terminally sterilized by e-beam irradiation. VENDAJE AC™ is packaged as a sterile product in sealed, single-use pouches and is available in multiple sizes ranging from 8 mm disk to 10 cm x 12 cm sheets.

CMS Final HCPCS Coding Decision

After review of the Food and Drug Administration’s (FDA’s) Tissue Reference Group (TRG) letter submitted by the applicant, “VENDAJE™ AC, when intended for use as a protective covering for soft tissue 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.” As a result of our review of the TRG’s feedback, CMS has decided to:

Establish a new HCPCS Level II code Q4279, “Vendaje ac, per square centimeter”

Complete™ ACA - HCP230425G5HX4

Topic/Issue

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

Applicant's suggested language: QXXXX, “Complete™ ACA, per square Centimeter”

Summary of Applicant's Submission

Samaritan Biologics LLC submitted a request to establish a new Level II HCPCS code to identify Complete™ ACA, a three-layer amnion-chorion-amnion derived allograft to serve as a barrier and provide protective coverage from the surrounding environment to acute and chronic wounds. Complete™ ACA is a sterile, single use, dehydrated allograft derived from donated human amnion chorion membrane. Complete™ ACA dosage is per sq. cm, depending on the size of the wound. Complete™ ACA graft can be reapplied as needed, and is intended for external application. Following standard wound preparation, Complete™ ACA is applied directly to the wound. Complete™ ACA adheres to the wound bed without fixation. Complete™ ACA is supplied sterile, in a single use package in a variety of sizes.

CMS Final HCPCS Coding Decision

After review of the Food and Drug Administration’s (FDA’s) Tissue Reference Group (TRG) letter submitted by the applicant, “Complete™ ACA when intended for use as a barrier or cover for 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.” As a result of our review of the TRG’s feedback, CMS has decided to:

Establish a new HCPCS Level II code Q4302, “Complete aca, per square centimeter”

Complete™ AA - HCP230425N8KD7

Topic/Issue

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

Applicant's suggested language: QXXXX, “Complete™ AA, per square centimeter”

Summary of Applicant's Submission

Samaritan Biologics LLC submitted a request to establish a new Level II HCPCS code to identify Complete™ AA, a dual layer amnion derived allograft to serve as a barrier and provide protective coverage from the surrounding environment to acute and chronic wounds. Complete™ AA is a sterile, single use, dehydrated allograft derived from donated human amnion membrane. Complete™ AA dosage is per sq. cm, depending on the size of the wound, and can be reapplied as needed. Complete™ AA is intended for external application. Following standard wound preparation, Complete™ AA is applied directly to the wound. Complete™ AA adheres to the wound bed without fixation. Complete™ AA is supplied sterile, in a single use package in a variety of sizes.

CMS Final HCPCS Coding Decision

After review of the Food and Drug Administration’s (FDA’s) Tissue Reference Group (TRG) letter submitted by the applicant, “Complete™ AA, when intended for use as a barrier or cover for 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.” As a result of our review of the TRG’s feedback, CMS has decided to:

Establish a new HCPCS Level II code Q4303, “Complete aa, per square centimeter”

DermaBind DL™ - HCP230426NNTMW

Topic/Issue

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

The applicant did not submit any suggested language.

Summary of Applicant's Submission

Health Tec Wound Care submitted a request to establish a new HCPCS Level II code to identify DermaBind DL™. DermaBind DL™ is designed for application directly to acute and chronic wounds, is flexible, and is a conforming cover that adheres to complex anatomies. DermaBind DL™ membrane is intended for use as a wound covering, providing protection for the wound from the external environment and maintaining a moist environment. DermaBind DL™ is packaged in a double peel-pouch packaging configuration. The outer pouch is not sterile.

CMS Final HCPCS Coding Decision

After review of the Food and Drug Administration's (FDA's) Tissue Reference Group (TRG) letter submitted by the applicant, "Dermabind DL, when intended as a "wound covering or barrier" for "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." As a result of our review of the TRG's feedback, CMS has decided to:

Establish a new HCPCS Level II code Q4287, "Dermabind dl, per square centimeter"

DermaBind CH™ - HCP230502HP175

Topic/Issue

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

Applicant's suggested language: QXXXX, “DermaBind CH per sq cm”

Summary of Applicant's Submission

Health Tec Wound Care submitted a request to establish a new HCPCS Level II code to identify DermaBind CH™. DermaBind CH™ is a dehydrated human chorion-derived membrane allograft comprised of an extracellular matrix (ECM) that is rich in collagen, fibrin, and elastin fibers native to the tissue. It is designed for application directly to acute and chronic wounds, is flexible, and is a conforming cover that adheres to complex anatomies. DermaBind CH™ is packaged in Tyvek pouches and terminally sterilized. DermaBind CH™ membrane is intended for use as a wound covering, providing protection for the wound from the external environment and maintaining a moist environment.

CMS Final HCPCS Coding Decision

After review of the Food and Drug Administration’s (FDA’s) Tissue Reference Group (TRG) letter submitted by the applicant, “Dermabind CH™, when intended as a “wound covering” for “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.” As a result of our review of the TRG’s feedback, CMS has decided to:

Establish a new HCPCS Level II code Q4288, “Dermabind ch, per square centimeter”

DermaBind TL™ - HCP230502KNQ6X

Topic/Issue

Request to revise existing HCPCS Level II code Q4225, “Amniobind, per square centimeter” to identify DermaBind TL™.

Applicant’s suggested language: Q4225, “AmnioBind or DermaBind TL per sq cm”

Summary of Applicant’s Submission

Health Tech Wound Care submitted a request to revise existing HCPCS Level II code Q4225, "AmnioBind, per square cm" to include the brand name DermaBind TL, for example, "DermaBind TL, per square cm." CMS established a new HCPCS Level II code Q4225, effective April 1, 2022, to identify a placental membrane product AmnioBind. Another product exists that has a similar name, properties, and function, necessitating a product name change to avoid confusion of the products. DermaBind TL™ is a terminally sterilized, dehydrated, full thickness placental membrane (PM) allograft consisting of amnion, chorion, and the associated intermediate (spongy) layer (IL). Typically, following debridement, PM allografts are applied to the wound surface to provide a barrier to the environment. DermaBind TL™ should always be maintained within closed packaging until just prior to administration. At the time of administration, the product can be removed (using proper sterile technique) by pulling the membrane out of the packaging. The allograft is intended to remain on the site for five to seven days. It is designed for application directly to acute and chronic wounds, is flexible, and is a conforming cover that adheres to complex anatomies. DermaBind TL™ membrane is intended for use as a wound covering at the discretion of a physician. Additionally, Q4225 identifies AmnioBind, per square cm. DermaBind TL™ is identical in every aspect to AmnioBind, except for the product name and manufacturer name. The name of the manufacturer has changed from Predictive Biotech to HealthTech Wound Care. DermaBind TL™ is manufactured in the same laboratory using the same equipment by the same technicians.

CMS Final HCPCS Coding Decision

After review of the Food and Drug Administration’s (FDA’s) Tissue Reference Group (TRG) letter submitted by the applicant, “Dermabind TL, when intended as a “wound covering” for “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.” As a result of our review of the TRG’s feedback, and in consideration of the applicant’s explanation that both products are manufactured in the same place, using the same equipment and staff, and are identical in every aspect with the exception of the product name and manufacturer name, CMS has decided to:

Revise existing HCPCS Level II code Q4225, “Amniobind, per square centimeter” to instead read “Amniobind or dermabind tl, per square centimeter”.

PalinGen® Dual Layer Membrane - HCP230612TH25U

Topic/Issue

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

Applicant's suggested language: QXXXX, “PalinGen® Dual-layer Membranes are intended for use as a wound cover or barrier, available per square centimeter”

Summary of Applicant's Submission

Amnio Technology submitted a request to establish a new HCPCS Level II code to identify PalinGen® Dual-Layer Membranes. PalinGen® Dual-Layer Membranes are dehydrated, cross-linked, human allografts derived from the placenta specifically, a dual-layer of amniotic membrane. These membranes are minimally manipulated, preserving many of the natural growth factors normally present in amniotic tissue. The patient population for use of the PalinGen® Dual-Layer Membrane products include children and adults with non-healing acute and chronic wounds (diabetic, venous, mixed venous-arterial, pressure ulcers), complex and/or open surgical wounds, and burns. PalinGen® Dual-Layer Membranes are intended to serve as a wound covering and barrier. PalinGen® Dual-Layer Membranes are used to cover 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. PalinGen® Dual-Layer Membranes are supplied in sizes from 2 cm x 3 cm to 10 cm x 20 cm.

CMS Final HCPCS Coding Decision

After review of the Food and Drug Administration’s (FDA’s) Tissue Reference Group (TRG) letter submitted by the applicant, PalinGen® Dual-Layer Membranes product information appears to differ from the information that was submitted to the FDA’s TRG. Based on the TRG letter, “the PalinGen® Membrane Product Family, when intended for use as a “wound cover" or “barrier,” appear 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, regarding the intended use of the products as a skin substitute or that the “PalinGen® Membrane Product Family mimics the function of natural skin,” these appear to be non-homologous uses of amniotic membrane and the TRG recommends that the products would not be eligible for regulation solely under section 361 of the PHS Act and the regulations in 21 CFR part 1271. When an HCT/P is intended for non-homologous use, and none of the exceptions in 21 CFR 1271.15 apply, the HCT/P would be regulated by FDA as a drug, device, and/or biological product under the Federal Food, Drug, and Cosmetic Act and/or section 351 of the PHS Act (42 U.S.C. 262) and applicable regulations, and is subject to premarket review and approval requirements.” Based on this information, it appears that the PalinGen® Dual-Layer Membranes 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.

PalinGen® Dual Layer X-Membranes - HCP230509C9MHU

Topic/Issue

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

Applicant's suggested language: XXXXX, "Dual Layer PalinGen® X-Membranes are intended for homologous use as a wound cover or barrier, available per square centimeter"

Summary of Applicant's Submission

Amnio Technology submitted a request to establish a new HCPCS Level II code to identify Dual Layer PalinGen® X-Membranes. According to the applicant, Dual Layer PalinGen® X-Membranes are dehydrated, cross-linked, human allografts derived from the placenta specifically is two layers of amniotic membrane. 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-Membranes products includes children and adults with 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 serve as a wound covering and barrier. Dual Layer PalinGen® X-Membranes are used to cover 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. Dual Layer PalinGen® X-Membrane is supplied in sizes from 2 cm x 3 cm to 4 cm x 8 cm.

CMS Final HCPCS Coding Decision

After review of the Food and Drug Administration's (FDA's) Tissue Reference Group (TRG) letter submitted by the applicant, "Dual Layer PalinGen® X-Membranes product information appears to differ from the information that was submitted to CMS as part of the HCPCS Level II" application. Based on the TRG letter, "PalinGen® X-Membranes when intended for use as a wound cover or barrier", appear 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, regarding the intended use of the products as a "skin substitute" or that the "PalinGen® Membrane Product Family mimics the function of natural skin," these appear to be non-homologous uses of amniotic membrane and the TRG recommends that the products would not be eligible for regulation solely under section 361 of the PHS Act and the regulations in 21 CFR part 1271. When an HCT/P is intended for non-homologous use, and none of the exceptions in 21 CFR 1271.15 apply, the HCT/P would be regulated by FDA as a drug, device, and/or biological product under the Federal Food, Drug, and Cosmetic Act and/or section 351 of the PHS Act (42 U.S.C. 262) and applicable regulations, and is subject to premarket review and approval requirements." Based on this information, it appears that the PalinGen ™ XPlus 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.

RevoShield + Amniotic Barrier - HCP230626E39KK

Topic/Issue

Request to establish a new HCPCS Level II code to identify RevoShield + Amniotic Barrier.

Applicant's suggested language: QXXXX, “RevoShield + Amniotic Barrier, per sq cm”

Summary of Applicant's Submission

4Front Strategic Partners, Surgenex, LLC, submitted a request to establish a new HCPCS Level II code to identify RevoShield + Amniotic Barrier. RevoShield + Amniotic Barrier is a minimally manipulated dual layer tissue-based product derived from the amniotic membrane of the human placenta. Following preparation of the wound (e.g., excision and debridement), the RevoShield + Amniotic Barrier is applied over the wound. The intended use of the RevoShield + Amniotic Barrier is to serve as a barrier or to provide protective coverage from the surrounding environment for acute and chronic wounds. Amniotic membrane grafts contain cytokines and growth factors which have been demonstrated to enhance chronic wound healing. The RevoShield + Amniotic Barrier is available in the following sizes: 2 x 2 cm, 2 x 3 cm, 3 x 4 cm, 4 x 4 cm, 4 x 6 cm, 4 x 8 cm, 10 x 15 cm, and 10 x 20 cm.

CMS Final HCPCS Coding Decision

After review of the Food and Drug Administration’s (FDA’s) Tissue Reference Group (TRG) letter submitted by the applicant, “RevoShield + Amniotic Barrier, when intended for use “over the wound” and “as a barrier” or “protective coverage…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.” As a result of our review of the TRG’s feedback, CMS has decided to:

Establish a new HCPCS Level II code Q4289, "Revoshield + amniotic barrier, per square centimeter”

Membrane Wrap-Hydro™ - HCP230608RBXJK

Topic/Issue

Request to establish a new HCPCS Level II code to identify Membrane Wrap-Hydro™.

The applicant did not submit any suggested language.

Summary of Applicant's Submission

BioLab Sciences submitted a request to establish a new HCPCS Level II code to identify Membrane Wrap-Hydro™. Dosage is per square centimeter. Membrane Wrap-Hydro™ is indicated for chronic and acute wounds. The product serves as protective covering from the surrounding environment for acute and chronic wounds. Membrane Wrap-Hydro™ is available in various sizes. The Membrane Wrap-Hydro™ comes in a double pouch for aseptic presentation of the packaged product to a sterile field. The inner pouch is both a sterile and moisture barrier pouch that prevents the loss of moisture vapor from the product. The outer pouch is a peel pouch for aseptic presentation to the sterile field and transparent on one side to allow for visualization of the contents. The inner pouch contains the hydrated membrane, saline solution and protective mesh and uses welded seals. The pouch is transparent and designed with a tear notch for easy opening. When removed from its packaging it is easily applied allowing more of the wound base to be covered by the product.

CMS Final HCPCS Coding Decision

After review of the Food and Drug Administration's (FDA's) Tissue Reference Group (TRG) letter submitted by the applicant, "Membrane Wrap – Hydro™, when intended for use as a barrier and protective cover for wounds, appears to meet all the criteria for regulation solely under section 361 of the Public Health Service (PHS) Act and the regulations in 21 CFR part 1271." As a result of our review of the TRG's feedback, CMS has decided to:

Establish a new HCPCS Level II code Q4290, "Membrane wrap-hydro, per square centimeter"

Lamellas - HCP230609U6M3B

Topic/Issue

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

The applicant did not submit any suggested language.

Summary of Applicant's Submission

Keyport Management submitted a request to establish a new HCPCS Level II code to identify Lamellas. Lamellas Membrane is intended for use as a protective wound covering and barrier in acute and chronic wounds. Lamellas Membrane is a sterile, single use, dehydrated resorbable allograft derived from donated human placental birth tissue.

CMS Final HCPCS Coding Decision

After review of the Food and Drug Administration's (FDA's) Tissue Reference Group (TRG) letter submitted by the applicant, "Lamellas, when intended for use "over the wound" and "as a barrier" or "protective coverage…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." As a result of our review of the TRG's feedback, CMS has decided to:

Establish a new HCPCS Level II code Q4292, "Lamellas, per square centimeter"

Lamellas XT – HCP2306096YTBG

Topic/Issue

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

The applicant did not submit any suggested language.

Summary of Applicant's Submission

Keyport Management submitted a request to establish a new HCPCS Level II code to identify Lamellas XT. Lamellas XT Membrane is intended for use as a protective wound covering and barrier in acute and chronic wounds. Lamellas XT Membrane is a sterile, single use, dehydrated resorbable allograft derived from donated human placental birth tissue.

CMS Final HCPCS Coding Decision

After review of the FDA's Tissue Reference Group (TRG) letter submitted by the applicant, "Lamellas XT, when intended for use "over the wound" and "as a barrier" or "protective coverage…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." As a result of our review of the TRG's feedback, CMS has decided to:

Establish a new HCPCS Level II code Q4291, "Lamellas xt, per square centimeter"

Acesso SL - HCP230616E6YWJ

Topic/Issue

Request to establish a new HCPCS Level II code to identify Acesso SL.

Applicant's suggested language: The applicant did not submit any suggested language.

Summary of Applicant's Submission

Dynamic Medical Services LLC, Surgenex, submitted a request to establish a new Level II HCPCS code to identify Acesso SL. Acesso SL Membrane is a sterile dehydrated single layered human amniotic membrane allograft. Acesso SL Membrane is intended to serve as a barrier or cover for acute and chronic wounds and for use as a barrier to protect wounds from the surrounding environment. Following standard wound preparation, Acesso SL Membrane may be applied directly to the wound and should only be used in one patient, on a single occasion. Acesso SL is packaged in a primary foil pouch and a secondary Tyvek® pouch and sterilized by e- beam to meet a sterility assurance level of 10-6. Acesso SL is available in multiple sizes.

CMS Final HCPCS Coding Decision

After review of the Food and Drug Administration's (FDA's) Tissue Reference Group (TRG) letter submitted by the applicant, the Acesso SL product information appears to differ from the information that was submitted to the FDA's TRG. Based on the TRG letter, "Acesso, when intended for use 'over the wound' and 'as a barrier' or 'protective coverage…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, it is indicated that "Acesso SL Membrane provides a protective wound covering and barrier in acute and chronic wounds." Due to the discrepancy in the product name identified in the application (Acesso SL) and the product name identified in the TRG letter (Acesso), we are unable to determine if Acesso SL is 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 (Acesso SL), 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.

Amnio Tri-Core™ - HCP230628F6RY7

Topic/Issue

Request to establish a new HCPCS Level II code to identify Amnio Tri-Core™.

Applicant's suggested language: XXXXX, “Amnio Tri-Core™, per sq cm”

Summary of Applicant's Submission

Stability Biologics, submitted a request to establish a new Level II HCPCS code to identify Amnio Tri-Core™. Amnio Tri-Core™ is a three-layer allogeneic amniotic membrane allograft for use as a barrier and applied as a covering. Amnio Tri-Core™ allografts are desiccated and supplied sterile as single use. Sizing comes in 3 sizes from a 2x3, 4x4, and 4x8 cm sizing (see marketing materials).

CMS Final HCPCS Coding Decision

After review of the Food and Drug Administration’s (FDA’s) Tissue Reference Group (TRG) letter submitted by the applicant, “Amnio Tri-Core™ Amniotic Membrane Sheets and Amnio Core Amniotic Membrane Sheets, when intended for use as a barrier and as a covering, appear to meet all the criteria for regulation solely under section 361 of the Public Health Service (PHS) Act and the regulations in 21 CFR part 1271.” As a result of our review of the TRG’s feedback, CMS has decided to:

Establish a new HCPCS Level II code Q4295, "Amnio tri-core amniotic, per square centimeter"

Acesso DL - HCP2306168186L

Topic/Issue

Request to establish a new HCPCS Level II code to identify Acesso DL.

Applicant's suggested language: The applicant did not submit any suggested language.

Summary of Applicant's Submission

Dynamic Medical Services LLC, Surgenex, submitted a request to establish a new Level II HCPCS code to identify Acesso DL. Acesso DL Membrane is a sterile dehydrated dual layered human amniotic membrane allograft. Acesso DL Membrane is intended to serve as a barrier or cover for acute and chronic wounds and for use as a barrier to protect wounds from the surrounding environment. Following standard wound preparation, Acesso DL Membrane may be applied directly to the wound and should only be used in one patient, on a single occasion. Acesso DL is packaged in a primary foil pouch and a secondary Tyvek® pouch and sterilized by e-beam to meet a sterility assurance level of 10-6. Acesso DL is available in multiple sizes.

CMS Final HCPCS Coding Decision

After review of the Food and Drug Administration’s (FDA’s) Tissue Reference Group (TRG) letter submitted by the applicant, “Acesso DL, when intended for use “over the wound” and “as a barrier” or “protective coverage…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.” As a result of our review of the TRG’s feedback, CMS has decided to:

Establish a new HCPCS Level II code Q4293, "Acesso dl, per square centimeter"

Acesso TL - HCP230703YVDR9

Topic/Issue

Request to establish a new HCPCS Level II code to identify Acesso TL.

Applicant's suggested language: QXXXX, “ATL, per sq cm”

Summary of Applicant's Submission

Dynamic Medical Services LLC DBA Acesso Biologics, Surgenex, submitted a request to establish a new Level II HCPCS code to identify Acesso TL. Acesso TL Membrane is a sterile, single use, dehydrated allograft derived from donated human placental birth tissue. Acesso TL Membrane is a triple layer amniotic membrane. The allograft is processed using aseptic techniques and terminally sterilized by Electron Beam to achieve Sterility Assurance Level (SAL) of 10-6. Each allograft is packaged in a primary foil pouch and secondary Tyvek pouch and sterilized by e-beam to a SAL of 10-6. A single sterile, double pouched membrane is provided in a SBS paperboard shelf box. Acesso TL Membrane must be stored in ambient temperature at 15-30 °C (59-86 °F) prior to patient application. May be stored up to 5 years.

CMS Final HCPCS Coding Decision

After review of the Food and Drug Administration’s (FDA’s) Tissue Reference Group (TRG) letter submitted by the applicant, “Acesso TL, when intended for use “over the wound” and “as a barrier” or “protective coverage…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.” As a result of our review of the TRG’s feedback, CMS has decided to:

Establish a new HCPCS Level II code Q4300, “Acesso tl, per square centimeter”

Rebound™ Matrix - HCP230629TXTGU

Topic/Issue

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

Applicant's suggested language: QXXXX, “Rebound™ Matrix, per square centimeter”

Summary of Applicant's Submission

Sequence LifeScience, Inc., submitted a request to establish a new Level II HCPCS code to identify Rebound™ Matrix. Rebound™ Matrix is a full thickness minimally manipulated human placental membrane product derived from donated placental tissues that retain the structural and functional characteristics of the tissues. The final product is dehydrated, packaged in different size sheets, and terminally sterilized by irradiation. Rebound™ Matrix is composed of extracellular matrix proteins and serves as a natural, biological barrier or wound cover. The typical patient population includes those with chronic full thickness ulcers and other skin defects where a biological barrier or cover is required. Rebound™ Matrix is used by or on order for a licensed physician for single patient use. The dosage is per centimeter square (cm^2), depending on the size of the injury or site of application. Rebound™ Matrix is supplied in various size and configuration sheets (1x2, 2x2, 2x3, 2x4, 4x4, 4x6, 4x8, 7x7, 8x12 and 9x20 cm) and are stored at ambient room temperature (15-30 °C or 59-86 °F).

CMS Final HCPCS Coding Decision

After review of the Food and Drug Administration’s (FDA’s) Tissue Reference Group (TRG) letter submitted by the applicant, “the Rebound™ Matrix product when intended to serve as a ·'barrier or wound cover." appears to meet all the criteria for regulation solely under section 361 of the Public Health Service (PHS) Act and the regulations in 21 CFR part 1271.” As a result of our review of the TRG’s feedback, CMS has decided to:

Establish a new HCPCS Level II code Q4296, “Rebound matrix, per square centimeter”

Emerge™ Matrix - HCP230629NGHCW

Topic/Issue

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

Applicant's suggested language: QXXXX, “Emerge™ Matrix, per square centimeter”

Summary of Applicant's Submission

Sequence LifeScience, Inc. submitted a request to establish a new Level II HCPCS code to identify Emerge™ Matrix. Emerge™ Matrix is a dual membrane, minimally manipulated, human amniotic and chorionic membrane product derived from placental tissue that retain the structural and functional characteristics of the tissue. The final product is dehydrated, packaged in different size sheets, and terminally sterilized by irradiation. Emerge™ Matrix consist primarily of extracellular matrix proteins and serves as a natural, biologic barrier or wound cover. The typical patient population includes those with full thickness acute and chronic wounds where a biologic barrier or wound cover is required. Use of Emerge™ Matrix by qualified health care professionals is for application in a physician office, outpatient, or inpatient setting. The dosage is per centimeter square (cm^2), depending on the size of the injury or site of application. Emerge™ Matrix is supplied in various sizes (1x2, 2x2, 2x3, 2x4, 4x4, 4x6, 4x8, 7x7, 8x12 and 9x20 cm) and are stored at ambient room temperature (15-30 °C or 59-86 °F).

CMS Final HCPCS Coding Decision

After review of the Food and Drug Administration’s (FDA’s) Tissue Reference Group (TRG) letter submitted by the applicant, “the Emerge™ Matrix product, when intended to serve as a "barrier or wound cover, appears to meet all the criteria for regulation solely under section 361 of the Public Service (PHS) Act and the regulations in 21 CFR part 1271.” As a result of our review of the TRG’s feedback, CMS has decided to:

Establish a new HCPCS Level II code Q4297, “Emerge matrix, per square centimeter”

Activate Matrix - HCP230629QXKT2

Topic/Issue

Request to establish a new HCPCS Level II code to identify Activate Matrix.

Applicant's suggested language: QXXXX, “Activate™ Matrix, per cm2”

Summary of Applicant's Submission

Activate™ Matrix consists of all three layers of the placental membranes including amnion, intermediate layer and chorion. It is a minimally manipulated human placental membrane product derived from donated placental tissues that retain the structural and functional characteristics of the tissues. The final product is dehydrated, packaged in different size sheets and terminally sterilized by irradiation. Activate™ Matrix is composed of extracellular matrix proteins and serves as a natural, biological barrier or wound cover. Activate™ Matrix is used by or on order for a licensed physician for single patient use. The dosage is per centimeter square (cm^2), depending on the size of the injury or site of application. Activate™ Matrix is supplied in various size and configuration sheets (1x2, 2x2, 2x3, 2x4, 4x4, 4x6, 4x8, 7x7, 8x12 and 9x20 cm) and are stored at ambient temperature (15-30 °C or 59-86 °F).

CMS Final HCPCS Coding Decision

After review of the Food and Drug Administration’s (FDA’s) Tissue Reference Group (TRG) letter submitted by the applicant, “Activate™ Matrix product, when intended to serve as a “barrier or wound cover," appears to meet all the criteria for regulation solely under section 361 of the Public Health Service (PHS) Act and the regulations in 21 CFR part 1271.” As a result of our review of the TRG’s feedback, CMS has decided to:

Establish a new HCPCS Level II code Q4301, “Activate matrix, per square centimeter”

AmnioCore Pro - HCP230703634GU

Topic/Issue

Request to establish a new HCPCS Level II code to identify AmnioCore Pro.

Applicant's suggested language: XXXXX, “AmnioCore Pro, per sq cm”

Summary of Applicant's Submission

Stability Biologics submitted a request to establish a new Level II HCPCS code to identify Amnio Core Pro. AmnioCore Pro is comprised of donated human tissue that has been screened, recovered and serologically/microbiologically tested at Certified Laboratory Improvement Amendments (CLIA) certified labs in adherence with Food and Drug Administration (FDA), State and American Association of Tissue Banks (AATB) requirements. AmnioCore Pro is a significantly different allograft compared to all other AmnioCore brands. AmnioCore Pro is unique in that it is comprised of amniotic membrane and chorionic membrane, whereas all other AmnioCore brands are comprised of only amnionic membranes. The AmnioCore Pro is a dual layer allograft with an amnion inferior surface and a chorion superior surface. The addition of the chorion provides additional active angiogenic growth factors compared to just amnion layers allografts to provide an exceptional barrier. AmnioCore Pro comes in sizes of 2x3, 3.3, 3x4, 3x4, 4x4, 4x6, 4x8, 6x6, 6x9, 10x10, 6x16, 9x20 cm as well as a 16mm disc.

CMS Final HCPCS Coding Decision

After review of the FDA’s Tissue Reference Group (TRG) letter submitted by the applicant, “AmnioCore Pro and AmnioCore Pro+, when intended for use as a “barrier” and “covering,” appear to meet all the criteria for regulation solely under section 361 of the Public Health Service (PHS) Act and the regulations in 21 CFR part 1271”. As a result of our review of the TRG’s feedback, CMS has decided to:

Establish a new HCPCS Level II HCPCS code Q4298, “Amniocore pro, per square centimeter”

AmnioCore Pro+ - HCP230703E11A2

Topic/Issue

Request to establish a new HCPCS Level II code to identify AmnioCore Pro+.

Applicant's suggested language: XXXXX, “AmnioCore Pro+, per sq cm”

Summary of Applicant's Submission

Stability Biologics submitted a request to establish a new Level II HCPCS code to identify AmnioCore Pro+. AmnioCore Pro+ is comprised of donated human tissue that has been screened, recovered and serologically/microbiologically tested at Certified Laboratory Improvement Amendments (CLIA) certified labs in adherence with Food and Drug Administration (FDA), State and American Association of Tissue Banks (AATB) requirements. AmnioCore Pro+ is an exclusive and bioactive allograft different from AmnioCore Pro and other AmnioCore brands. The AmnioCore Pro+ is a three-layer allograft comprised of amniotic membrane and chorionic membrane, whereas AmnioCore Pro is a dual layer amnion/chorion graft all the other AmnioCore brands are comprised of only amnionic membranes. The AmnioCore Pro+ is a three-layer allograft with an amnion inferior surface, chorion inner layer, and an amnion superior surface. The addition of the chorion provides additional active angiogenic growth factors compared to just amnion and the extra tissue layer provided a significant increase in tensile strength compared to the AmnioCore Pro, thereby providing an exclusive and outstanding barrier. AmnioCore Pro+ comes in 12 sizes of 2x3, 3.3, 3x4, 3x4, 4x4, 4x6, 4x8, 6x6, 6x9, 10x10, 6x16, 9x20 cm as well as a 16mm disc (see marketing materials).

CMS Final HCPCS Coding Decision

After review of the FDA’s Tissue Reference Group (TRG) letter submitted by the applicant, “AmnioCore Pro and AmnioCore Pro+, when intended for use as a “barrier” and “covering,” appear to meet all the criteria for regulation solely under section 361 of the Public Health Service (PHS) Act and the regulations in 21 CFR part 1271”. As a result of our review of the TRG’s feedback, CMS has decided to:

Establish a new HCPCS Level II code Q4299, “Amnicore pro+, per square centimeter”

Amnio Quad-Core - HCP230628M73KK

Topic/Issue

Request to establish a new HCPCS Level II code to identify Amnio Quad-Core.

Applicant's suggested language: XXXXX, “Amnio Quad-Core, per sq cm”

Summary of Applicant's Submission

Stability Biologics, submitted a request to establish a new Level II HCPCS code to identify Amnio Quad-Core. Amnio Quad-Core is comprised of donated human tissue that has been screened, recovered and serologically/microbiologically tested at Certified Laboratory Improvement Amendments (CLIA) certified labs in adherence with Food and Drug Administration (FDA), State and American Association of Tissue Banks (AATB) requirements. Amnio Quad-Core is a four-layer allogeneic amniotic membrane allograft for use as a barrier and applied as a single use covering. Amnio Quad-Core comes in sizes of 2x3, 4x4, and 4x8 cm.

CMS Final HCPCS Coding Decision

After review of the Food and Drug Administration’s (FDA’s) Tissue Reference Group (TRG) letter submitted by the applicant, “Amnio Tri-Core Amniotic Membrane Sheets and Amnio Quad-Core Amniotic Membrane Sheets, when intended for use as a barrier and as a covering, appear to meet all the criteria for regulation solely under section 361 of the Public Health Service (PHS) Act and the regulations in 21 CFR part 1271.” As a result of our review of the TRG’s feedback, CMS has decided to:

Establish a new HCPCS Level II code Q4294, "Amnio quad-core, per square centimeter"

GRAFIX PLUS - HCP230623GBT5M

Topic/Issue

Request to establish a new HCPCS Level II code to identify GRAFIX PLUS.

Applicant's suggested language: QXXXX, “GRAFIX PLUS, per square centimeter”

Summary of Applicant's Submission

Smith and Nephew submitted a request to establish a new Level II HCPCS code to identify GRAFIX PLUS. GRAFIX PLUS is a lyophilized human placental chorionic membrane based skin substitute product. GRAFIX PLUS is indicated for use in the treatment of acute and chronic wounds. The product acts as a wound cover, wrap, and barrier, including surgically created wounds. The dosage (i.e., size of product used) will vary based upon wound size. The product is applied to the wound bed as a barrier, wrap, or cover. GRAFIX PLUS will be supplied in up to eight sizes and is packaged between two pieces of plastic mesh backing in a heat-sealed foil and Tyvek pouch to provide a sterile barrier.

CMS Final HCPCS Coding Decision[1]

After review of the Food and Drug Administration’s (FDA’s) Tissue Reference Group (TRG) letter submitted by the applicant, “Grafix PLUS, when intended as a wound cover, wrap, and 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.” As a result of our review of the TRG’s feedback, CMS has decided to:

Establish a new HCPCS Level II code Q4304, “Grafix plus, per square centimeter”

This recommendation applies solely to the GRAFIX PLUS product described in your submission of January 31, 2023, when intended for use as a “wound cover, wrap, and barrier.”

[1] Revised on October 27, 2023 to establish a new HCPCS Level II code, effective January 1, 2024.

HCPCS Level II Codes for Various FDA Approvals under the 505(b)(2) or Biologics License Application (BLA) Pathways and Products "Not Otherwise Classified" - HCP220517FAENJ

CMS has been reviewing its approach for establishing HCPCS Level II codes to identify products approved under the 505(b)(2) NDA or the BLA pathways after October 2003. These products are not rated as therapeutically equivalent to their reference listed drug in the Food and Drug Administration's (FDA) Orange Book[2], and are therefore considered single source products. Also, this effort will help reduce use of the not otherwise classified (NOC) codes.

In order to conform with the general approach used for the assignment of products paid under section 1847A of the Social Security Act (the Act) to HCPCS codes as described at the following CMS link: https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Downloads/051807_coding_annoucement.pdf. CMS is making several code changes, including manufacturer specific codes to identify products approved under separate 505(b)(2) NDA or BLA pathways. Since the products are approved under separate 505(b)(2) NDAs and are not rated as therapeutically equivalent by the FDA in the Orange Book, they are single source drugs based on the statutory definition of "single source drug" in section 1847A(c)(6) of the Act. Because these are single source drugs, there is a programmatic need for each product to have a unique billing and payment code.

In cases where certain products meet the statutory definition of a "multiple source drug" in section 1847A(c)(6) of the Act, CMS will remove the brand name of the drug from any existing HCPCS code as needed as it will accommodate any associated generic product(s), if approved and marketed, that are rated as therapeutically equivalent.

Due to the complexity and nuanced nature of the differences between each product, we encourage providers to rely on the Average Sales Price (ASP) HCPCS-NDC crosswalk[3] to identify the correct billing and payment code for each applicable product.

CMS Final HCPCS Coding Decision

Establish nine new HCPCS Level II codes to separately identify products approved by the FDA after October 2003, and not rated as therapeutically equivalent to a reference listed product in an existing code.

See Appendix A for a complete list of new HCPCS Level II codes that we are establishing. We will be accepting feedback on the language in the code descriptors for each code in an upcoming biannual public meeting.

CMS intends to continue our review in subsequent HCPCS code application quarterly cycles to separately identify products approved under the 505(b)(2) NDA or the BLA pathways after

[2] The FDA's Orange Book, officially entitled, *Approved Drug Products With Therapeutic Equivalence Evaluations,* identifies drug products approved on the basis of safety and effectiveness by the FDA, and is published at the following FDA link: https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm.

[3] The ASP crosswalks are maintained by CMS on a quarterly basis to support ASP-based Medicare Part B payments only. The quarterly ASP crosswalks are published at the following CMS link:https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/2022-asp-drug-pricing-files.

October 2003, and not rated as therapeutically equivalent to a reference listed product in an existing code, as well as products that have been “not otherwise classified”.

Appendix A: HCPCS Level II Codes for Products Approved by the FDA Under the 505(b)(2) NDA or BLA Pathways and Products "Not Otherwise Classified"

HCPCS Code[4]	Action	Long Descriptor
J0391	Add	Injection, artesunate, 1 mg
J0688	Add	Injection, cefazolin sodium (hikma), not therapeutically equivalent to j0690, 500 mg
J0873	Add	Injection, daptomycin (xellia) not therapeutically equivalent to j0878, 1 mg
J1596	Add	Injection, glycopyrrolate, 0.1 mg
J1939	Add	Injection, bumetanide, 0.5 mg
S0171[5]	Delete	Injection, bumetanide, 0.5 mg
J2404	Add	Injection, nicardipine, 0.1 mg
J2679	Add	Injection, fluphenazine hcl, 1.25 mg
J3425[6]	Add	Injection, hydroxocobalamin, intramuscular, 10 mcg
J9052	Add	Injection, carmustine (accord), not therapeutically equivalent to j9050, 100 mg
S0166[7]	Delete	Injection, olanzapine, 2.5 mg

[4] Revised on December 7, 2023 to remove the addition of J1246 as dinutuximab is intended for inpatient use.
[5] Revised on November 16, 2023 to note that the effective date for this deletion is 12/31/2023.
[6] Revised on December 28, 2023 to include "intramuscular" in the long descriptor.
[7] Revised on November 16, 2023 to note that the effective date for this deletion is 9/30/2023.