DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard,
Baltimore, Maryland 21244-1850

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

First 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' First Quarter 2023 Drug and Biological HCPCS code application review cycle. Each individual summary includes the request number; topic/issue; summary of the applicant's request as written by the applicant with occasional non-substantive editorial changes made by CMS; and CMS' final HCPCS coding decision. All new coding actions will be effective July 1, 2023, unless otherwise indicated.

The HCPCS coding decisions below will also be included in the July 2023 HCPCS Quarterly Update, pending publication by CMS in the coming weeks at: https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update

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

CMS has a long-standing convention to assign dose descriptors in the smallest amount that could be billed in multiple units to accommodate a variety of doses and support streamlined billing. This long-standing policy makes coding more robust, and facilitates accurate payment and reporting of the exact dose administered, as only 999 units can appear on a claim line for Medicare fee-for-service using the CMS-1500 form. 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 (for example, see application number HCP220517FAENJ). 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 First Quarter 2023 Drug and Biological HCPCS Applications.

IMJUDO® - HCP221027TX83V

Topic/Issue

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

Applicant's suggested language: JXXXX, "Injection, tremelimumab-actl, 1 mg"

Summary of Applicant's Submission

AstraZeneca Pharmaceuticals LP submitted a request to establish a new HCPCS Level II code to identify IMJUDO® (tremelimumab-actl) injection. IMJUDO® was approved by the Food and Drug Administration (FDA) under the Biologics License Application (BLA) pathway on October 21, 2022. IMJUDO® is a cytotoxic T-lymphocyte-associated antigen 4 (CTLA-4) blocking antibody indicated, in combination with durvalumab, for the treatment of adult patients with unresectable hepatocellular carcinoma (uHCC). CTLA-4 is a negative regulator of T-cell activity. Tremelimumab-actl is a monoclonal antibody that binds to CTLA-4 and blocks the interaction with its ligands CD80 and CD86, releasing CTLA-4-mediated inhibition of T-cell activation. In synergistic mouse tumor models, blocking CTLA-4 activity resulted in decreased tumor growth and increased proliferation of T-cells in tumors. IMJUDO® is administered as an intravenous infusion over 60 minutes after dilution. The recommended dose for patients with a body weight of 30 kg and more is a single dose of IMJUDO® 300 mg followed by durvalumab 1,500 mg at day 1 of cycle 1, and then continue durvalumab 1,500 mg as a single agent every 4 weeks. The recommended dose for patients with a body weight of less than 30 kg is a single dose of IMJUDO® 4 mg/kg followed by durvalumab 20 mg/kg at day 1 of cycle 1, and then continue durvalumab 4 mg/kg as a single agent every 4 weeks. IMJUDO® is administered prior to durvalumab on the same day. IMJUDO® is a solution supplied in a carton containing one single-dose vial as 25 mg/1.25 mL, or 300 mg/15 mL. IMJUDO® is a unique biological and no current specific HCPCS code adequately describes this product.

CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code J9347, "Injection, tremelimumab-actl, 1 mg"

Briumvi™ - HCP22122940858

Topic/Issue

Request to establish a new HCPCS Level II code to identify Briumvi™ (ublituximab-xiiy).

Applicant's suggested language: JXXXX, "(ublituximab-xiiy) injection, for intravenous use, 1mg"

Summary of Applicant's Submission

TG Therapeutics submitted a request to establish a new HCPCS Level II code to identify Briumvi™ (ublituximab-xiiy). Briumvi™ was approved by the Food and Drug Administration (FDA) under the Biologics License Application (BLA) pathway on December 28, 2022. Briumvi™ is FDA-approved as a cytolytic antibody indicated for the treatment of relapsing forms of multiple sclerosis, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults. Briumvi™ is a sterile, clear to opalescent, colorless to slightly yellow, preservative-free solution for intravenous use supplied as a carton containing one 150 mg/6 mL (25 mg/mL) single-dose vial. According to the applicant, Briumvi™ is approved by the FDA under the BLA pathway and therefore under section 1847A of the Social Security Act is a single source drug and requires a unique HCPCS code.

CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code J2329, "Injection, ublituximab-xiiy, 1mg"

ADSTILADRIN® - HCP221230X526D

Topic/Issue

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

Applicant's suggested language: JXXXX, "(nadofaragene firadenovec-vncg) (ADSTILADRIN) suspension, 1 mL, for intravesical use"

Summary of Applicant's Submission

Ferring Pharmaceuticals, Inc. submitted a request to establish a new HCPCS Level II code to identify ADSTILADRIN®. ADSTILADRIN® was approved by the Food and Drug Administration (FDA) under the Biologics License Application (BLA) pathway on December 16, 2022. ADSTILADRIN® is a non-replicating adenoviral vector-based gene therapy. The recommended dose of ADSTILADRIN® is 75 mL at a concentration of 3 x 10^11 viral particles (vp)/mL instilled once every three months into the bladder via a urinary catheter. According to the applicant, no current HCPCS Level II codes represent ADSTILADRIN® adenovirus vector-based gene therapy for intravesical use for the treatment of adult patients with high-risk Bacillus Calmette-Guérin unresponsive non-muscle invasive bladder cancer with carcinoma in situ with or without papillary tumors.

CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code J9029, "Injection, nadofaragene firadenovec-vncg, per therapeutic dose"

ADSTILADRIN® is a non-replicating adenoviral vector-based gene therapy with a recommended dosage of 75 mL at a concentration of 3 x 10^11 viral particles (vp)/mL instilled once every three months into the bladder via a urinary catheter. To help ensure consistency with previously established HCPCS Level II codes related to viral particles (vp)/mL within the vector-based gene therapies, J9029 is best described per therapeutic dose instead of volume.

IDACIO® - HCP221221RBCX4

Topic/Issue

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

Applicant's Suggested Language: QXXXX, "Adalimumab-aacf injection, for subcutaneous use, biosimilar, (IDACIO), 1mg"

Summary of Applicant's Submission

Fresenius Kabi submitted a request to establish a new HCPCS level II code to identify IDACIO®, (adalimumab-aacf). IDACIO® (adalimumab-aacf) was approved by the Food and Drug Administration (FDA) under the Biologic License Application (BLA) pathway on December 13, 2022. It is FDA approved as a biosimilar to Humira® (adalimumab). IDACIO® is a tumor necrosis factor blocker indicated for reducing signs and symptoms of rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease, ulcerative colitis and plaque psoriasis. IDACIO® is intended for use under the guidance and supervision of a physician and is a subcutaneous injection. IDACIO® is a clear and colorless to pale yellow solution with a concentration of 40 mg/0.8 mL available in either a single-dose pen (IDACIO® Pen), or a single-dose prefilled glass syringe. According to the applicant, a unique HCPCS code is needed for reimbursement as a single source drug or biological under Section 1847A of the Social Security Act. The applicant stated that IDACIO® is statutorily defined under the Social Security Act as a biosimilar and as such must receive its own unique HCPCS code to effectuate current reimbursement criteria.

CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code Q5131, "Injection, adalimumab-aacf (idacio), biosimilar, 20 mg"

ELAHERE™ - HCP221123FE13T

Topic/Issue

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

Applicant's suggested language: XXXXX, "mirvetuximab soravtansine-gynx injection, for intravenous use, 1 mg"

Summary of Applicant's Submission

ImmunoGen Inc. submitted a request to establish a new HCPCS Level II code to identify ELAHERE™. ELAHERE™ was approved by the Food and Drug Administration (FDA) under the Biologics License Application (BLA) pathway on November 14, 2022. ELAHERE™ (mirvetuximab soravtansine-gynx) injection, is for intravenous (IV) use. According to the applicant, ELAHERE™ is a first-in-class antibody-drug conjugate (ADC) directed against folate receptor alpha, a cell-surface protein highly expressed in ovarian cancer. According to the applicant, this drug was granted accelerated approval for the treatment of adult patients with folate receptor alpha-positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer, who have received 1 to 3 prior system treatment regimens. According to the applicant, ELAHERE™ was approved based on objective response rate and duration of response from the pivotal SORAYA trial and is the first FDA approved ADC for platinum-resistance disease. ELAHERE™ injection is supplied as a sterile, preservative-free, clear to slightly opalescent, colorless solution containing 100 mg/20 mL for IV infusion, supplied in a carton containing one (1) 100 mg/20 mL single-dose vial. The recommended dose of ELAHERE™ is 6 mg/kg adjusted ideal body weight administered as IV infusion every 3 weeks until disease progression or unacceptable toxicity. According to the applicant, there is no current HCPCS Level II code that identifies 'mirvetuximab soravtansine-gynx.' According to the applicant, it is critical that a unique HCPCS Level II code is made available for ELAHERE™ to minimize potential barriers to access, i.e., provider's prolonged manual claims submission or uncertainty of correct reimbursement of claims for patients with folate receptor alpha-positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer, who have received 1 to 3 prior systemic treatment regimens.

CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code J9063, "Injection, mirvetuximab soravtansine-gynx, 1 mg"

LUNSUMIO™ - HCP221223Y7VKA

Topic/Issue

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

Applicant's suggested language: JXXXX, “Injection, lunsumio, mosunetuzumab-axgb, 1 mg/mL”

Summary of Applicant’s Submission

Genentech submitted a request to establish a new HCPCS Level II code to identify LUNSUMIO™. LUNSUMIO™ was approved by the Food and Drug Administration (FDA) under the Biologics License Application (BLA) pathway on December 1, 2022. LUNSUMIO™ (mosunetuzumab-axgb) is a bispecific CD20-directed CD3 T-cell engager indicated for the treatment of adult patients with relapsed or refractory follicular lymphoma after two or more lines of systemic therapy. LUNSUMIO™ is designed to enable a patient’s own immune system to target and eradicate B-cells, including those that cause malignant disease. In contrast to bispecific T-cell engager molecules that are based on peptide fragments, LUNSUMIO™ was engineered with proprietary modifications in the amino acid sequence, which abrogates its binding to Fc gamma receptor of immune effector cells such as natural killer cells, monocyte/macrophages and neutrophils, and significantly reduces Fc effector functions gamma. Its pharmacokinetic profile is supportive of intermittent dosing. LUNSUMIO™ is administered by a healthcare professional as an intravenous infusion through a dedicated infusion line. LUNSUMIO™ is supplied as 1 mg/mL solution in a single-dose vial and as 30 mg/30 mL (1 mg/mL) solution in a single-dose vial. According to the applicant, there are no permanent HCPCS Level II codes that adequately describe LUNSUMIO™.

CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code J9350, “Injection, mosunetuzumab-axgb, 1 mg”

REBYOTA® - HCP221221N617A

Topic/Issue

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

Applicant's suggested language: JXXXX, “Fecal microbiota, live – jslm (REBYOTA) instillation, 150 mL”

Summary of Applicant’s Submission

Ferring Pharmaceuticals requests to establish a new HCPCS Level II code to identify REBYOTA® (fecal microbiota, live – jslm). REBYOTA® was approved by the Food & Drug Administration (FDA) under the Biologics License Application (BLA) pathway on November 30, 2022. REBYOTA® is indicated for the prevention of recurrence of Clostridioides difficile infection (CDI) in individuals 18 years of age and older, following antibiotic treatment for recurrent CDI. REBYOTA® is a 150 mL single dose microbiota suspension for rectal administration. According to the applicant no existing HCPCS code specifically describes this product. REBYOTA® is manufactured from human fecal matter sourced from qualified donors. The human fecal matter is tested for a panel of transmissible pathogens. The fecal microbiota suspension is the filtrate generated by processing the fecal matter in a predefined ratio with a solution of polyethylene glycol (PEG) 3350 and saline. Each 150 mL dose of REBYOTA® contains between 1x10^8 and 5x10^10 colony forming units (CFU) per mL of fecal microbes including greater than 1x10^5 CFU/mL of Bacteroides, and contains not greater than 5.97 grams of PEG 3350 in saline.

CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code J1440, “Fecal microbiota, live - jslm, 1 ml”

TECVAYLI™ - HCP221128T0GPA

Topic/Issue

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

Applicant's suggested language: JXXXX, “Injection, teclistamab-cqyv, per mg, for subcutaneous injection”

Summary of Applicant’s Submission

Johnson & Johnson Health submitted a request to establish a new HCPCS Level II code to identify TECVAYLI™ (teclistamab-cqyv). TECVAYLI™ was approved by the Food and Drug Administration (FDA) under an Accelerated Biologics License Application (BLA) pathway on October 25, 2022. TECVAYLI™ is a bispecific B-cell maturation antigen - directed CD3 T-cell engager indicated for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 monoclonal antibody. TECVAYLI™ is provided in two dosage forms and strengths 30 mg/3 mL (10 mg/mL) in a single-dose vial, and 153 mg/1.7 mL (90 mg/mL) in a single-dose vial.

CMS Final HCPCS Coding Decision

1. Establish a new HCPCS Level II code J9380, "Injection, teclistamab-cqyv, 0.5 mg"

   Effective 7/1/2023

2. Discontinue C9148, “Injection, teclistamab-cqyv, 0.5 mg”

   Effective 6/30/2023

TZIELD™ - HCP22121511GN0

Topic/Issue

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

Applicant's suggested language: JXXXX, “Injection, tepluzimab-mzwv, 1 mcg”

Summary of Applicant’s Submission

Provention Bio, Inc. submitted a request to establish a new HCPCS Level II code to identify TZIELD™ (teplizumab-mzwv). TZIELD™ was approved by the Food and Drug Administration (FDA) under a Biologics License Application (BLA) pathway on November 17, 2022. Its function is as a CD3-directed antibody to delay the onset of Stage 3 type 1 diabetes (T1D) in adult and pediatric patients aged 8 years and older with Stage 2 T1D. According to the applicant, no permanent “J” code is available to accurately describe TZIELD™. TZIELD™ received Priority Review and Breakthrough Therapy designations from the FDA for the indication to delay onset of T1D. The mechanism may involve partial agonistic signaling and deactivation of pancreatic beta cell auto-reactive T lymphocytes. Teplizumab-mzwv leads to an increase in the proportion of regulatory T-cells and of exhausted CD8+ T-cells in peripheral blood. TZIELD™ dosage varies over a 14-day period with dosage based on micrograms per square meter (mcg/m^2), calculated based on body surface area.

CMS Final HCPCS Coding Decision

1. Establish a new HCPCS Level II code J9381, "Injection, teplizumab-mzwv, 5 mcg"

   Effective 7/1/2023

2. Discontinue C9149, “Injection, teplizumab-mzwv, 5 mcg”

   Effective 6/30/2023

Bendamustine Hydrochloride - HCP2212301TV9B

Topic/Issue

Request to establish a new HCPCS Level II code to identify bendamustine hydrochloride.

Applicant's suggested language: JXXXX, "Bendamustine hydrochloride injection (Apotex) 1mg"

Summary of Applicant's Submission

Apotex Corp. submitted a request to establish a new HCPCS Level II code to identify a formulation of bendamustine hydrochloride injection. Bendamustine hydrochloride was approved by the Food and Drug Administration (FDA) under a 505(b)(2) New Drug Application (NDA) on December 7, 2022. According to the applicant, there is a programmatic need for a unique HCPCS Level II code for use by commercial payers and the Medicare and Medicaid program because this is a 505(b)(2) single source drug that (consistent with the Social Security Act and CMS' November 1, 2022 statements in its Q4 HCPCS decisions) must be reimbursed based on its ASP (average sales price). Bendamustine hydrochloride injection is an alkylating drug indicated for treatment of adult patients with chronic lymphocytic leukemia (CLL), whose efficacy relative to first line therapies other than chlorambucil has not been established, and indolent B-cell non-Hodgkins lymphoma (NHL) that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen. Bendamustine is a bifunctional mechlorethamine derivative containing a purine-like benzimidazole ring. Mechlorethamine and its derivatives form electrophilic alkyl groups. These groups form covalent bonds with electron-rich nucleophilic moieties, resulting in interstrand DNA crosslinks. The bifunctional covalent linkage can lead to cell death via several pathways. Bendamustine is active against both quiescent and dividing cells. According to the applicant, the exact mechanism of action of bendamustine remains unknown. For CLL, it is dosed as 100 mg/m^2 infused intravenously over 30 minutes on days 1 and 2 of a 28-day cycle, up to 6 cycles. For NHL, it is dosed as 120 mg/m^2 infused intravenously over 60 minutes on days 1 and 2 of a 21-day cycle, up to 8 cycles. It is supplied as 100 mg/4 mL (25 mg/mL) in an intravenous injection. It is a clear and colorless to yellow solution in a multiple-dose vial. Bendamustine hydrochloride injection is supplied in individual cartons of 5 mL clear multiple-dose vials containing 100 mg of bendamustine hydrochloride 100 mg/4 mL (25 mg/mL).

CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code J9058, "Injection, bendamustine hydrochloride (apotex), 1 mg"

Paclitaxel Protein-Bound Particles - HCP221230EQDJE

Topic/Issue

Request to establish a new HCPCS Level II code to identify Paclitaxel Protein-Bound Particles.

Applicant's suggested language: JXXXX, "Injection, paclitaxel protein-bound particles (American Regent), 1 mg"

Summary of Applicant's Submission

American Regent, Inc. submitted a request to establish a new HCPCS Level II code to identify Paclitaxel Protein-Bound Particles. Paclitaxel Protein-Bound Particles was approved by the Food and Drug Administration (FDA) under a 505(b)(2) New Drug Application (NDA) on July 27, 2022. According to the applicant, a new unique HCPCS Level II code is needed, to able to report Paclitaxel Protein-Bound Particles for Injectable Suspension (Albumin-Bound) in alignment with the October 2022 CMS coding decision that NDA 505(b)(2) single source products approved after October 2003 that are not rated as therapeutically equivalent to a reference listed product in an existing code should receive a unique HCPCS Level II code. Paclitaxel Protein-Bound Particles for Injectable Suspension (Albumin-Bound) is a microtubule inhibitor indicated for the treatment of and administered intravenously (IV) by a healthcare professional for the following indications. Metastatic breast cancer after failure of combination chemotherapy for metastatic disease or relapse within 6 months of adjuvant chemotherapy; prior therapy should have included an anthracycline unless clinically contraindicated. The recommended dosage here is 260 mg/m^2 IV over 30 minutes every 3 weeks. Another indication is for locally advanced or metastatic non-small cell lung cancer (NSCLC) as a first-line treatment in combination with carboplatin in patients who are not candidates for curative surgery or radiation therapy. The recommended dosage here is 100 mg/m^2 IV over 30 minutes on days 1, 8, and 15 of each 21-day cycle; administer carboplatin on day 1 of each 21-day cycle immediately after Paclitaxel Protein-Bound Particles. Other indications for this drug product also include metastatic adenocarcinoma of the pancreas as a first-line treatment in combination with gemcitabine. The recommended dosage here is 125 mg/m^2 IV over 30 to 40 minutes on days 1, 8, and 15 of each 28-day cycle, administering gemcitabine on days 1, 8, and 15 of each 28-day cycle immediately after Paclitaxel Protein-Bound Particles. Paclitaxel Protein-Bound Particles is supplied as a white to yellow, sterile, lyophilized powder for reconstitution with 20 mL of 0.9% sodium chloride injection, prior to IV infusion. Each single-dose vial contains 100 mg of paclitaxel (bound to human albumin), approximately 900 mg of human albumin (containing sodium caprylate and sodium acetyltryptophanate), and sodium hydroxide and hydrochloric acid for pH adjustment. Each mL of reconstituted suspension contains 5 mg paclitaxel formulated as albumin-bound particles. Paclitaxel Protein-Bound Particles is free of solvents. Again, this drug is a microtubule inhibitor that promotes the assembly of microtubules from tubulin dimers and stabilizes microtubules by preventing depolymerization. This stability results in the inhibition of the normal dynamic reorganization of the microtubule network that is essential for vital interphase and mitotic cellular functions. Paclitaxel induces abnormal arrays or "bundles" of microtubules throughout the cell cycle and multiple asters of microtubules during mitosis.

CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code J9259, “Injection, paclitaxel protein-bound particles (american regent) not therapeutically equivalent to j9264, 1 mg”

BYFAVO®- HCP2212216BDFL

Topic/Issue

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

Applicant's suggested language: JXXXX, “Injection, remimazolam (BYFAVO®), per 1 mg”

Summary of Applicant’s Submission

Eagle Pharmaceuticals, Inc. submitted a request to establish a new HCPCS Level II code to identify BYFAVO® (remimazolam). BYFAVO® was approved by the Food and Drug Administration (FDA) under a New Drug Application (NDA) on July 2, 2022. The FDA approved indication is for the induction and maintenance of procedural sedation in adults undergoing procedures lasting 30 minutes or less. BYFAVO® is described by the applicant as a novel, injectable benzodiazepine offered as a lyophilized powder with each glass, single-patient-use vial containing 20mg BYFAVO® for reconstitution, equivalent to 27.2 mg remimazolam besylate. According to the applicant, BYFAVO® is a unique single source drug used in hospital and physician clinic settings, and no current HCPCS code accurately describes it. For all indicated uses, BYFAVO® is administered by intravenous injection with dosage individualized and titrated to desired clinical effect at the discretion of the physician. Based on the general condition of the patient, the initial dosage recommendation is to administer 2.5 mg to 5 mg over 1-minute time period. If necessary, supplemental doses of 1.25 mg to 2.5 mg may be administered intravenously over a 15 second time period. At least 2 minutes must elapse prior to the administration of any supplemental dose.

CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code J2249, “Injection, remimazolam, 1 mg”

Baxter's Bendamustine Hydrochloride Injection - HCP2301039JE20

Topic/Issue

Request to establish a new HCPCS Level II code to identify Baxter's bendamustine hydrochloride (HCl) injection.

Applicant's suggested language: JXXXX, “Injection, bendamustine HCl (Baxter)”

Summary of Applicant’s Submission

Baxter Healthcare Corporation submitted a request to establish a new HCPCS Level II code to identify Baxter's bendamustine HCl injection. Baxter’s bendamustine HCl injection was approved by the Food and Drug Administration (FDA) under a 505(b)(2) New Drug Application (NDA) on December 15, 2022. Baxter’s bendamustine HCl is indicated for the treatment of adult patients with chronic lymphocytic leukemia (CLL) and indolent B-cell non-Hodgkin’s lymphoma (NHL) that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen. The recommended dosage is 100 mg/m^2 administered intravenously over 30 minutes on days 1 and 2 of a 28-day cycle, up to 6 cycles for CLL, and 120 mg/m^2 administered intravenously over 60 minutes on days 1 and 2 of a 21-day cycle, up to 8 cycles for NHL. Baxter’s bendamustine HCl injection is supplied in individual cartons of 6 mL clear multiple-dose vials containing 100 mg of bendamustine hydrochloride as a clear, colorless to yellow solution.

CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code J9059, “Injection, bendamustine hydrochloride (baxter), 1 mg”

VIVIMUSTA - HCP221220YYLWC

Topic/Issue

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

Applicant's suggested language: JXXXX, “Injection, bendamustine hydrochloride (Vivimusta), 1 mg”

Summary of Applicant’s Submission

Slayback Pharma, LLC. submitted a request to establish a new HCPCS Level II code to identify VIVIMUSTA. VIVIMUSTA was approved by the Food and Drug Administration (FDA) under a 505(b)(2) New Drug Application (NDA) on December 7, 2022. VIVIMUSTA is a vascular endothelial growth factor inhibitor for intraocular injection. VIVIMUSTA (bendamustine hydrochloride injection) is a single source drug product indicated for the treatment of adult patients with chronic lymphocytic leukemia (CLL) and indolent B-cell non-Hodgkin lymphoma (NHL) that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen. The active ingredient in VIVIMUSTA is bendamustine hydrochloride, an alkylating agent. VIVIMUSTA is believed to cause cell death by forming covalent bonds with electron-rich nucleophilic moieties, resulting in interstrand DNA crosslinks. For CLL, the recommended dosage is 100 mg/m^2 infused intravenously over 20 minutes on days 1 and 2 of a 28-day cycle for up to 6 cycles. For NHL, the recommended dosage is 120 mg/m^2 infused intravenously over 20 minutes on days 1 and 2 of a 21-day cycle for up to 8 cycles. VIVIMUSTA is a sterile clear, colorless to yellow ready-to-dilute solution for intravenous use. VIVIMUSTA is supplied in individual cartons of 5 mL clear glass multiple-dose vials providing 100 mg bendamustine hydrochloride per 4 mL. According to the applicant other bendamustine hydrochloride injections have been assigned HCPCS codes.

CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code J9056, “Injection, bendamustine hydrochloride (vivimusta), 1 mg”

Sezaby™ - HCP230103GEMP1

Topic/Issue

Request to the establish a new HCPCS Level II code to describe Sezaby™.

Applicant's suggested language: JXXXX, “Phenobarbital Sodium for injection (SEZABY), 1mL”

Summary of Applicant’s Submission

Sun Pharmaceutical Industries Ltd. (Sun Pharma) submitted a request to the establish a new HCPCS Level II code to describe Sezaby™ (phenobarbital sodium for injection). Sezaby™ was approved by the Food and Drug Administration (FDA) as an Orphan Drug under a 505(b)(2) New Drug Application (NDA) on November 18, 2022. Sezaby™ is indicated for the treatment of neonatal seizures in term and preterm infants. Sezaby™ is infused intravenously every 8-12 hours over a 5-day course of therapy and is only provided in a 100mg lyophilized power vial that must be reconstituted for single use. The loading dose of 20 mg/kg is administered by intravenous infusion over 15 minutes into a large peripheral vein. If clinically indicated, at least 15 minutes after completion of the initial loading dose, a second loading dose may be administered over the subsequent 15 minutes as 20mg/kg for term infants or 10 mg/kg for preterm infants. The maximum loading dose is 40 mg/kg. Maintenance dosage begins 8-12 hours after the initial loading dose at 4.5 mg/kg/day given in 2 or 3 divided doses for up to 5 days. According to the applicant, Sezaby™ is the only product indicated for the treatment of neonatal seizures in term and preterm infants. The applicant suggests there is a programmatic need for a unique HCPCS code for use by commercial payers and the Medicaid program. According to the applicant, Sezaby™ can be used in the outpatient setting and therefore a unique code for this 505(b)(2) single source drug must be assigned.

CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code J2561, “Injection, phenobarbital sodium (sezaby), 1 mg”

SUNLENCA® - HCP23010391F0Y

Topic/Issue

Request to establish a new HCPCS Level II code to identify SUNLENCA® (lenacapavir).

Applicant's suggested language: JXXXX, “lenacapavir, for subcutaneous injection, 1mL”

Summary of Applicant’s Submission

Gilead Sciences submitted a request to establish a new HCPCS Level II code to identify SUNLENCA® (lenacapavir), for subcutaneous use. SUNLENCA® was approved by the Food and Drug Administration (FDA) under a New Drug Application (NDA) on December 22, 2022. SUNLENCA® is FDA-approved as a human immunodeficiency virus type 1 (HIV-1) capsid inhibitor, to be used in combination with other antiretroviral(s); and is indicated for the treatment of HIV-1 infection in heavily treatment-experienced adults with multidrug resistant HIV-1 infection failing their current antiretroviral regimen due to resistance, intolerance, or safety considerations. The applicant states that SUNLENCA® functions as a novel, first-in-class capsid inhibitor that is critical at multiple stages of the HIV replication cycle. According to the applicant, no existing code adequately describes SUNLENCA® injection because it is a unique drug that is not therapeutically equivalent to any other product. The form of SUNLENCA® that is the subject of this application is administered by a healthcare provider through subcutaneous injection and is supplied in a dosing kit containing 2 single-dose clear glass vials, each containing sufficient volume to allow withdrawal of 463.5mg/1.5mL (309mg/mL) of lenacapavir. The applicant describes lenacapavir as a multistage, selective inhibitor of HIV-1 capsid function that directly binds to the interface between capsid protein subunits in hexamers and inhibits HIV-1 replication by interfering with multiple essential steps of the viral lifecycle, including capsid-mediated nuclear uptake of HIV-1 proviral DNA (by blocking nuclear import proteins binding to capsid), virus assembly and release (by interfering with Gag/Gag-Pol functioning, reducing production of capsid protein subunits), and capsid core formation (by disrupting the rate of capsid subunit association, leading to malformed capsids). The recommended dosing of SUNLENCA® begins with one of two initiation options followed by once every 6-months maintenance dosing. For option 1, day 1 includes 927mg taken by subcutaneous injection (2 x 1.5mL injections) as well as 600mg taken orally (2 x 300mg tablets); then day 2 includes 600mg taken orally. For option 2, day 1 includes 600mg taken orally; then day 2 includes 600mg taken orally; then day 8 includes 300mg taken orally; then day 15 includes 927mg taken by subcutaneous injections. The maintenance dosing includes 927mg taken by subcutaneous injection every 6 months (26 weeks) from the date of the last injection.

CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code J1961, “Injection, lenacapavir, 1 mg”

Pemetrexed - HCP221228MYGB8

Topic/Issue

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

Applicant's suggested language: JXXXX, "Injection, pemetrexed ditromethamine (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 (ditromethamine) for injection. Pemetrexed was approved by the Food and Drug Administration (FDA) under a 505(b)(2) New Drug Application (NDA) pathway on June 10, 2022. According to the applicant, existing codes do not accurately represent Pemetrexed for injection. According to the applicant, to be in alignment with the CMS coding decision for NDA 505(b)(2)-approved products after October 2003, single source products not rated as therapeutically equivalent to a reference-listed product in an existing code should receive a unique HCPCS Level II code. Pemetrexed 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. Pemetrexed 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. 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's limitation of use is that it is not indicated for the treatment of patients with squamous cell NSCLC. Pemetrexed is supplied as a sterile lyophilized powder in single-dose vials to be reconstituted for IV infusion. Each 100 mg vial of Pemetrexed for injection contains 100 mg Pemetrexed (equivalent to 157 mg pemetrexed ditromethamine), and 106 mg mannitol. Each 500 mg vial of Pemetrexed for injection contains 500 mg Pemetrexed (equivalent to 783 mg pemetrexed ditromethamine), and 500 mg mannitol. Additional premedication and concomitant medications to mitigate toxicity should be administered as outlined in the prescribing information. Pemetrexed for injection disrupts folate-dependent metabolic processes essential for cell replication. In vitro studies show that Pemetrexed inhibits thymidylate synthase (TS), dihydrofolate reductase, and glycinamide ribonucleotide formyltransferase (GARFT), which are folate-dependent enzymes involved in the de novo biosynthesis of thymidine and purine nucleotides. Pemetrexed is taken into cells by membrane carriers such as the reduced folate carrier and membrane folate-binding protein transport systems. Once in the cell, Pemetrexed is converted to polyglutamate forms by the enzyme folylpolyglutamate synthetase. The polyglutamate forms are retained in cells and are inhibitors of TS and GARFT.

CMS Final HCPCS Coding Decision[1]

Establish a new HCPCS Level II code J9323, "Injection, pemetrexed ditromethamine, 10 mg"

[1] Revised on May 23, 2023 to revise the long descriptor for J9323.

Sincalide Injection - HCP230103LTYT6

Topic/Issue

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

Applicant's suggested language: JXXXX, “Sincalide injection, extended life”

Summary of Applicant’s Submission

Maia Pharmaceuticals, Inc. submitted a request to establish a new HCPCS Level II code to identify Sincalide. Sincalide was approved by the Food and Drug Administration (FDA) under a 505(b)(2) New Drug Application (NDA) on November 22, 2022. Sincalide injection is a cholecystokinin analog indicated in adults to stimulate gallbladder contraction, to be assessed by various methods of diagnostic imaging, or to be obtained by a duodenal aspiration sample of concentrated bile for analysis of cholesterol, bile salts, phospholipids, and crystals. Sincalide can stimulate pancreatic secretion in combination with secretin prior to obtaining a duodenal aspirate for analysis of enzyme activity, composition, and can accelerate the transit of a barium meal through the small bowel, thereby decreasing the time and extent of radiation associated with fluoroscopy and x-ray examination of the intestinal tract.

CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code J2806, “Injection, sincalide (maia) not therapeutically equivalent to j2805, 5 micrograms”

Sodium Phenylacetate and Sodium Benzoate Injection - HCP230103BD8AQ

Topic/Issue

Request to establish a new HCPCS Level II code to identify Sodium Phenylacetate and Sodium Benzoate injection.

Applicant's suggested language: XXXXX, “Sodium Phenylacetate/Sodium Benzoate 10%, per ml"

Summary of Applicant’s Submission

Maia Pharmaceuticals, Inc. submitted a request to establish a new HCPCS Level II code to identify Sodium Phenylacetate and Sodium Benzoate Injection. Sodium Phenylacetate and Sodium Benzoate Injection was approved by the Food and Drug Administration (FDA) under a 505(b)(2) New Drug Application (NDA) on June 10, 2021. Sodium Phenylacetate and Sodium Benzoate Injection is indicated as adjunctive therapy in pediatric and adult patients for the treatment of acute hyperammonemia and associated encephalopathy in patients with deficiencies in enzymes of the urea cycle. Sodium phenylacetate and sodium benzoate are metabolically active compounds that can serve as alternatives to urea for the excretion of waste nitrogen. Phenylacetate conjugates with glutamine in the liver and kidneys to form phenylacetylglutamine, via acetylation. Phenylacetylglutamine is excreted by the kidneys via glomerular filtration and tubular secretion. The nitrogen content of phenylacetylglutamine per mole is identical to that of urea (both contain two moles of nitrogen). Two moles of nitrogen are removed per mole of phenylacetate when it is conjugated with glutamine. Similarly, preceded by acylation, benzoate conjugates with glycine to form hippuric acid, which is rapidly excreted by the kidneys by glomerular filtration and tubular secretion. One mole of hippuric acid contains one mole of waste nitrogen. Thus, one mole of nitrogen is removed per mole of benzoate when it is conjugated with glycine. Sodium Phenylacetate and Sodium Benzoate Injection must be diluted with sterile 10% Dextrose Injection (D10W) before administration. The dilution and dosage of Sodium Phenylacetate and Sodium Benzoate Injection are determined by weight for neonates, infants, and young children, and by body surface area for larger patients, including older children, adolescents, and adults. Sodium phenylacetate and sodium benzoate is administered as an injection. Sodium Phenylacetate and Sodium Benzoate Injection 10% per 10% is a clear and almost colorless solution supplied in a sterile, non-pyrogenic, single-dose glass vial. Both sodium phenylacetate and sodium benzoate solutions are physically and chemically stable for up to 24 hours at room temperature and room lighting conditions.

CMS Final HCPCS Coding Decision

It is our understanding there are very little to no Medicare claims volume or utilization for the drug approved under this NDA. The reference listed drug for this application is Ammonul. Ammonul is approved under an NDA and there are several ANDAs that are therapeutically equivalent. We have noticed none of these products have a unique HCPCS Level II code. We welcome information from the applicant, other manufacturers of related NDAs/ANDAs, and other insurers who are currently paying for this product or associated NDAs to demonstrate a claims processing need for a unique HCPCS Level II code. We will be accepting feedback on establishing a new HCPCS Level II code in an upcoming biannual public meeting.

Lidocidex™ - HCP221122V2EJB

Topic/Issue

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

Applicant's suggested language: XXXXX, "Lidocidex dexamethasone phosphate with lidocaine HCL injection, USP 5mg/10mg/1.5ml (3.33mg/6.67mg/ml) 1.5ml Single Use Vial"

Summary of Applicant's Submission

Nubratori RX submitted a request to establish a new HCPCS Level II code to identify Lidocidex™. Lidocidex™ is registered with the Food and Drug Administration (FDA) and produced by Nubratori RX's FDA registered outsourcing facility. This is not a compound that is compounded by a pharmacist in a traditional pharmacy setting, as previously interpreted by CMS in the first quarter of 2022. According to the applicant, Lidocidex™ allows for the clinically significant advantage of a combination of a short-acting anesthetic and short-acting corticosteroid in a single-use sterile vial for use in hospitals, surgery centers, urgent care centers, by licensed health care providers. According to the applicant, there are currently no HCPCS Level II codes for this dosage-specific combination of injectable local anesthetic and corticosteroid. Its indication is for use as a short-acting local anesthesia and local anti-inflammatory to be used when the healthcare provider deems the use clinically significant. Lidocidex™ acts as an anti-inflammatory injected corticosteroid (dexamethasone) combined with a pain-relieving anesthetic (lidocaine). The dosage for this product is dexamethasone phosphate and lidocaine HCL, 5mg/10mg/1.5ml (3.33mg/6.67mg/ml), administered by intra-articular, subcutaneous, and soft tissue injection, and is packaged as a 1.5 ml sterile solution in a 2 ml amber single-use vial per carton.

CMS Final HCPCS Coding Decision

Lidocidex™ is not an FDA-approved drug. It is a compounded drug that is compounded in an FDA registered outsourcing facility. As such, Lidocidex™ is not suitable for HCPCS Level II coding as CMS does not establish unique HCPCS Level II codes for compounded drugs.

EPIEFFECT® - HCP221216K1GE5

Topic/Issue

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

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

Summary of Applicant’s Submission

MiMedx Group, Inc. submitted a request to establish a new HCPCS Level II code to identify EPIEFFECT®. EPIEFFECT® is a minimally manipulated, lyophilized, non-viable cellular allograft derived from human amniotic membrane. Amniotic membrane is a thin, collagenous membrane composed of multiple layers that surrounds the fetus within the mother’s uterus. EPIEFFECT® includes the amnion layer, intermediate layer, and chorion layers of the human placental tissue. EPIEFFECT® is intended for use as a barrier, to provide a protective environment in acute and chronic wounds. EPIEFFECT® is provided sterile and is intended for one-time use. According to the applicant, there is no HCPCS code that currently exists for EPIEFFECT®. EPIEFFECT® is supplied in 2 cm x 3 cm, 3 cm x 5 cm, 4 cm x 4 cm, 5 cm x 6 cm and 7 cm x 7 cm sheets. EPIEFFECT® is supplied in a carton that can be stored at room temperature and has a 5-year shelf life.

CMS Final HCPCS Coding Decision

After review of the Food and Drug Administration’s (FDA) Tissue Reference Group (TRG) letter submitted by the applicant, “EPIEFFECT®, when intended for use as a barrier, to provide a protective environment in 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 Q4278, “Epieffect, per square centimeter”

ORION Amniotic Membrane - HCP221230DVW57

Topic/Issue

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

The applicant did not submit any suggested language.

Summary of Applicant's Submission

Legacy Medical Consultant, LLC submitted a request to establish a new HCPCS Level II code to identify ORION Amniotic Membrane. ORION Amniotic Membrane is a sterile dehydrated dual layered human amniotic membrane allograft. ORION Amniotic 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, ORION Amniotic Membrane may be applied directly to the wound and should only be used in one patient, on a single occasion. ORION 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. ORION Amniotic Membrane 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, "Orion Amnion 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 Q4276, "Orion, per square centimeter"

WoundPlus™ Membrane - HCP221231M04NB

Topic/Issue

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

Applicant's suggested language: QXXXX, “WoundPlus™ Membrane, per square centimeter”

Summary of Applicant’s Submission

Skye Biologics submitted a request to establish a new HCPCS Level II code to identify WoundPlus™ Membrane. WoundPlus™ Membrane consists of dehydrated and devitalized human derived amniotic membrane that has been processed with HydraTek™ technology. WoundPlus™ Membrane is a single layer amnion-only membrane allograft intended for use as a barrier, wrap or cover for acute and chronic wounds. WoundPlus™ Membrane may be applied topically to the wound and should only be used in one patient. Additional WoundPlus™ Membrane may be applied for the duration of the wound, weekly, or at the discretion of the health care practitioner. Healthcare practitioners use sterile forceps to topically apply the allograft over the intended site. The forceps used are selected by the healthcare practitioner, and are not provided with the product. WoundPlus™ Membrane processed in a sterile clean room environment, sterilized post-packaging, and supplied in single one-time-use sterile packaging. WoundPlus™ Membrane is provided in various sizes. Dosing or sizing is dependent on the size of the wound. WoundPlus™ Membrane is stored at ambient temperature, with a 5-year shelf life.

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, “WoundPlus™ Membrane or E-Graft 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 Q4277, "Woundplus membrane or e-graft, per square centimeter"

Acesso DL - HCP221228EGVT7

Topic/Issue

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

Applicant's suggested language: QXXXX, "ADL per sq. cm"

Summary of Applicant's Submission

Dynamic Medical Services LLC submitted a request to establish a new HCPCS Level II code to identify Acesso DL. Acesso DL is a dehydrated allograft derived from donated human placental birth tissue. Acesso DL is a dual layer amniotic membrane. Acesso DL provides an extracellular matrix scaffold intended for use as a protective wound covering and barrier in acute and chronic wounds including burns. Acesso DL Membrane is applied topically, directly to the wound. It is processed using aseptic techniques and terminally sterilized by electron beam to achieve sterility assurance level of 10-6. Acesso DL is for single use only and it has a 5-year shelf life. The smallest product size is 2 cm x 2 cm. According to the applicant, Acesso DL membrane is optimized for advanced wound treatment. Acesso DL is angiogenic, anti-inflammatory, and immune-privileged, derived from multiple amnion layers to provide improved handling and natural, biocompatible scaffold that supports tissue growth.

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 DL product information submitted to CMS as part of the HCPCS Level II application appears to differ from the information that was submitted to the FDA's TRG. Based on the TRG letter, "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 PHS Act and the regulations in 21 CFR part 1271." However, in the HCPCS Level II application, it is indicated that "Acesso DL membrane is a sterile allograft optimized for wound covering, protection & advanced wound treatment. Acesso DL is angiogenic, anti-inflammatory, and immune-privileged, derived from multiple amnion layers to provide improved handling and natural, biocompatible scaffold that supports tissue growth" Based on this information, it appears that the Acesso DL 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-tissueproducts/tissue-reference-group.

Xcell Amnio Matrix®- HCP221102UV6P4

Topic/Issue

Request to establish a new HCPCS Level II code to identify Xcell Amnio Matrix®.

Applicant's suggested language: QXXXX, "Xcell Amnio Matrix, per sq. cm"

Summary of Applicant's Submission

Precise Bioscience submitted a request to establish a new HCPCS Level II code to identify Xcell Amnio Matrix®. Xcell Amnio Matrix® is a lyophilized amniotic membrane allograft that is aseptically processed to preserve the native extracellular matrix and endogenous proteins. Xcell Amnio Matrix® acts as a barrier and provide protective coverage from the surrounding environment for acute and chronic wounds such as partial and full thickness wounds, pressure sores/ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds, trauma wounds and draining wounds. The product is applied directly to the wound site. The dosage for Xcell Amnio Matrix® amniotic membrane allograft is per square centimeter. Xcell Amnio Matrix® is available in various sizes. According to the applicant, current HCPCS Level II codes available for reporting synthetic and biologic wound covering technologies are product and brand specific.

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, "Xcell Amnio Matrix®, when intended for use as a cover or barrier, 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 Q4280, "Xcell amnio matrix, per square centimeter"

CYGNUS Dual - HCP221222CNE9P

Topic/Issue

Request to establish a new HCPCS Level II code to identify CYGNUS Dual.

Applicant's suggested language: QXXXX, “Cygnus Dual, per square centimeter”

Summary of Applicant’s Submission

VIVEX Biologics submitted a request to establish a new HCPCS Level II code to identify CYGNUS Dual. CYGNUS Dual is a semi-transparent, collagenous membrane allograft obtained with consent from healthy mothers during cesarean section delivery. The CYGNUS Dual amnion allograft is derived from the amnion layer of the fetal membrane and is processed using aseptic techniques. The product is terminally sterilized via electron-beam irradiation. CYGNUS Dual is supplied in a single use package with one unit per package and may be stored at ambient conditions for up to 5 years. A variety of sizes is available. According to the applicant, existing HCPCS Level II codes do not adequately describe CYGNUS Dual since Q codes are product specific.

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, “CYGNUS Dual, for use as a tissue barrier or wound covering, appears to be regulated 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 Q4282, "Cygnus dual, per square centimeter"

Barrera™ SL and Barrera™ DL - HCP230103CCYLE

Topic/Issue

Request to establish a new HCPCS Level II code to identify Barrera™ SL and Barrera™ DL.

Applicant's suggested language: QXXXX, “Barrera SL & Barrera DL, per sq. cm”

Summary of Applicant’s Submission

RegenTx Partners submitted a request to establish a new HCPCS Level II code to identify Barrera™ SL and Barrera™ DL. Barrera™ SL and Barrera™ DL are dehydrated amniotic membrane allograft. Barrera™ SL and Barrera™ DL are intended to serve as a protective wound cover or barrier to offer protection from the surrounding environment in wounds, including surgically created wounds. Barrera™ SL and Barrera™ DL are supplied in a single layer form or dual layer form. Barrera™ SL and Barrera™ DL are for topical application in one patient on a single occasion. The dosage for Barrera™ SL and Barrera™ DL amniotic membrane allograft is per square centimeter. Barrera™ is available in various sizes. Barrera™ SL and Barrera™ DL are packaged in an outer pouch, sealed in an inner pouch. Each pouch features a peel back seal and are also heat sealed to provide a sterile barrier. The allograft is stored at room temperature throughout transport and storage. According to the applicant, currently available HCPCS Level II codes for human tissue skin substitute technologies are product and brand specific.

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, “Barrera™ SL and Barrera™ DL, when intended as a wound cover and for use as a barrier that protects wounds… from the surrounding environment, 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.” As a result of our review of the TRG’s feedback, CMS has decided to:

Establish a new HCPCS Level II code Q4281, "Barrera sl or barrera dl, per square centimeter"

Esano™ A - HCP230102GTNT4

Topic/Issue

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

Applicant's suggested language: QXXXX, “Esano A, per square centimeter”

Summary of Applicant’s Submission

Evolution Biologyx, LLC submitted a request to establish a new HCPCS Level II code to identify Esano™ A. Esano™ A is a single-layer, decellularized, dehydrated human amniotic membrane allograft that is intended for use as a cover or barrier for acute and chronic wounds and to provide protective coverage from the surrounding environment for acute and chronic wounds. Esano™ A dosage is per square centimeter, depending on the size of the wound. Following standard wound preparation, Esano™ A is applied directly to the wound; it adheres to the wound bed without fixation. Esano™ A is supplied 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, “Esano™ A, 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 Q4272, “Esano a, per square centimeter”

Esano™ AAA - HCP230102FBBUR

Topic/Issue

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

Applicant's suggested language: QXXXX, “Esano AAA, per square centimeter”

Summary of Applicant’s Submission

Evolution Biologyx, LLC submitted a request to establish a new HCPCS Level II code to identify Esano™ AAA. Esano™ AAA is a tri-layer, decellularized, dehydrated human amniotic membrane allograft that is intended for use as a cover or barrier for acute and chronic wounds and to provide protective coverage from the surrounding environment for acute and chronic wounds. Esano™ AAA dosage is per square centimeter, depending on the size of the wound. Following standard wound preparation, Esano™ AAA is applied directly to the wound; it adheres to the wound bed without fixation. Esano™ AAA is supplied 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, “Esano AAA and Esano, when intended for use “as a cover or to protect from the surrounding environment” and for “use as a barrier”, meets 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 Q4273, “Esano aaa, per square centimeter”

Esano™ AC - HCP23010227PXJ

Topic/Issue

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

Applicant's suggested language: QXXXX, “Esano AC, per square centimeter”

Summary of Applicant’s Submission

Evolution Biologyx, LLC submitted a request to establish a new HCPCS Level II code to identify Esano™ AC. Esano™ AC is a dual-layer, decellularized, dehydrated human amniotic membrane allograft that is intended for use as a cover or barrier for acute and chronic wounds and to provide protective coverage from the surrounding environment for acute and chronic wounds. Esano™ AC dosage is per square centimeter, depending on the size of the wound. Following standard wound preparation, Esano™ AC is applied directly to the wound; it adheres to the wound bed without fixation. Esano™ AC is supplied 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, “Esano™ AC, 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 Q4274, "Esano ac, per square centimeter"

Esano™ ACA - HCP2301024E2PA

Topic/Issue

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

Applicant's suggested language: QXXXX, “Esano ACA, per square centimeter”

Summary of Applicant’s Submission

Evolution Biologyx, LLC submitted a request to establish a new HCPCS Level II code to identify Esano™ ACA. Esano™ ACA is a tri-layer, decellularized, dehydrated human amniotic membrane allograft that is intended for use as a cover or barrier for acute and chronic wounds and to provide protective coverage from the surrounding environment for acute and chronic wounds. Esano™ ACA dosage is per square centimeter, depending on the size of the wound. Following standard wound preparation, Esano™ ACA is applied directly to the wound; it adheres to the wound bed without fixation. Esano™ ACA is supplied 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, “Esano™ 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 Q4275, “Esano aca, per square centimeter”

Biovance® 3L - HCP2301035NTN1

Topic/Issue

Request to establish a new HCPCS Level II code to identify Biovance® 3L.

Applicant's suggested language: XXXXX, “Biovance Tri-layer or Biovance 3L, per square centimeter”

Summary of Applicant’s Submission

RMBB Health submitted a request to establish a new HCPCS Level II code to identify Biovance® 3L. Biovance® 3L is a triple-layer decellularized, dehydrated human amniotic membrane, sterilized using e-beam irradiation. Biovance® 3L is intended to be used as a cover or to protect from the surrounding environment in wound and surgical repair and reconstruction procedures. Biovance® 3L units are measured by determination of the dimension of the wounded area. Biovance® 3L sheets may be trimmed to customize for the shape of the wound. Biovance® 3L is packaged as a sterile product in sealed, single-use pouches and is available in multiple sizes ranging from 10 mm disk to 10cm x 12cm 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, “it appears the triple-layer, decellularized, dehydrated human amniotic membrane product, when intended for use as a “cover or to protect from the surrounding environment”, meets 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 stated in the TRG letter, “Your inquiry describes an amniotic membrane product that will be branded as Biovance Tri-layer and Biovance 3L.” As a result of our review of the TRG’s feedback, CMS has decided to:

Establish a new HCPCS Level II code Q4283, “Biovance tri-layer or biovance 3l, per square centimeter”

DermaBind SL™ - HCP221222WTHK1

Topic/Issue

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

The applicant did not submit any suggested language.

Summary of Applicant's Submission

HealthTech Wound Care submitted a request to establish a new HCPCS Level II code to identify DermaBind SL™. DermaBind SL™ is an amnion derived allograft for management of wounds and burn injuries. DermaBind SL™ is a sterile, single use, dehydrated allograft derived from donated human amnion membrane. DermaBind SL™ acts as a cover and a barrier that offers protection from the surrounding environment. The intended use of DermaBind SL™ includes the management of wounds, such as, partial and full thickness wounds, pressure sores/ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, surgical wounds, trauma wounds, and draining wounds. DermaBind SL™ is intended for external application, dosage is per sq. cm, depending on the size of the wound, and it can be reapplied as needed. Following standard wound preparation, DermaBind SL™ is applied directly to the wound, adhering to the wound bed without fixation. DermaBind SL™ is fully resorbable and does not have to be removed from the wound bed. DermaBind SL™ 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, "DermaBind SL™, 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 Q4284, "Dermabind sl, per square centimeter"

DermaBind DL™ - HCP221222RDFG2

Topic/Issue

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

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

Summary of Applicant’s Submission

HealthTech Wound Care submitted a request to establish a new HCPCS Level II code to identify DermaBind DL™. DermaBind DL™ is a dehydrated human amnion/chorion membrane allograft comprised of an extracellular matrix 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 DL™ membrane is intended for use as a wound covering. This product is an allograft tissue intended for homologous use for the repair, reconstruction and replacement of skin at the discretion of a physician. DermaBind DL™ is packaged in Tyvek® pouches and terminally sterilized.

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 DermaBind DL™ product information submitted to CMS as part of the HCPCS Level II application appears to differ from the information that was submitted to the FDA’s TRG. Based on the TRG letter, “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.” However, in the HCPCS Level II application, it is indicated that “[t]his product is an allograft tissue intended for homologous use for the repair, reconstruction and replacement of skin at the discretion of a physician.” Based on this information, it appears that the DermaBind DL™ 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-tissueproducts/tissue-reference-group.

DermaBind™ TL - HCP23010340TXN

Topic/Issue

Request to revise an existing HCPCS Level II code Q4225 "AmnioBind, per square centimeter" to instead read "DermaBind TL, per square centimeter".

Applicant's suggested language: Q4225, “DermaBind TL, per square centimeter”

Summary of Applicant’s Submission

HealthTech Wound Care submitted a request to revise an existing HCPCS Level II code Q4225 "AmnioBind, per square cm" to include the brand name DermaBind™ TL. DermaBind™ TL is a dehydrated human amnion/chorion membrane allograft comprised of an extracellular matrix that is rich in collagen, fibrin, and elastin fibers native to the tissue. It is designed for application directly to acute and chronic wounds. DermaBind™ TL membrane is intended for use as a wound covering. It is an allograft tissue intended for homologous use for the repair, reconstruction and replacement of skin at the discretion of a physician. DermaBind™ TL is packaged in Tyvek® pouches and is terminally sterilized.

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 DermaBind™ TL product information submitted to CMS as part of the HCPCS Level II application appears to differ from the information that was submitted to the FDA’s TRG. Based on the TRG letter, 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.” However, in the HCPCS Level II application, it is indicated that “this product is an allograft tissue intended for homologous use for the repair, reconstruction, and replacement of the recipient’s tissue at the discretion of a physician.” Based on this information, it appears that the DermaBind™ TL 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. In addition, CMS would like to be certain that DermaBind™ TL and AmnioBind are the same product. As a result, CMS refers the applicant to the FDA to confer with the TRG to make sure that these two products are identical.

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-tissueproducts/tissue-reference-group.

DermaBind CH™ - HCP221222UEBYU

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

HealthTech 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 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™ membrane is intended for use as a wound covering. This product is an allograft tissue intended for homologous use for the repair, reconstruction and replacement of skin at the discretion of a physician. DermaBind CH™ is packaged in Tyvek® pouches and terminally sterilized.

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 DermaBind CH™ product information submitted to CMS as part of the HCPCS Level II application appears to differ from the information that was submitted to the FDA’s TRG. Based on the TRG letter, “DermaBind CH™, 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.” However, in the HCPCS Level II application, it is indicated that “[t]his product is an allograft tissue intended for homologous use for the repair, reconstruction and replacement of skin at the discretion of a physician.” Based on this information, it appears that the DermaBind CH™ 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-tissueproducts/tissue-reference-group.

VENDAJE AC™ - HCP221003Q72KG

Topic/Issue

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

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

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 minimally manipulated human amniotic and chorionic membrane product derived from placental tissues that retains the structural and functional characteristics of the tissues. VENDAJE AC™ is an allograft tissue intended for homologous use at the direction of a physician. VENDAJE AC™ is to be used topically or on the surface of the skin as a protective/wound covering or barrier for soft tissue wounds. The final product is dehydrated, packaged in different size sheets and terminally sterilized by irradiation. The submitted VENDAJE AC™ Instructions for Use document states, "This allograft is restricted to homologous use for the repair, replacement, reconstruction, or augmentation of human 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, the VENDAJE AC™ product information, specifically the product's Instructions for Use, submitted to CMS as part of the HCPCS Level II application appears to differ from the information that was submitted to the FDA's TRG. Based on the TRG letter, "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." However, the product's Instructions for Use states, "This allograft is restricted to homologous use for the repair, replacement, reconstruction, or augmentation of human tissue." According to the FDA's Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use guidance for industry and FDA staff, available at https://www.fda.gov/media/109176/download, "homologous use means the repair, reconstruction, replacement, or supplementation of a recipient's cells or tissues with an HCT/P that performs the same basic function or functions in the recipient as in the donor." VENDAJE™ AC, however, is derived from placental tissue and is does not appear to be used for repair, replacement, reconstruction and augmentation; but, rather, the amniotic membrane provides protection and acts as a barrier and covering. Based on this information, it appears that the VENDAJE AC™ 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-tissueproducts/tissue-reference-group.

Membrane Wrap-Hydro™ - HCP221229FGU85

Topic/Issue

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

Applicant's suggested language: QXXXX, "Membrane Wrap - Hydro ™, per square centimeter"

Summary of Applicant's Submission

BioLab Sciences Inc. is requesting a new HCPCS Level II code to identify Membrane Wrap-Hydro™. Membrane Wrap-Hydro™ is a minimally manipulated, human amniotic allograft membrane, hydrated in saline solution, which contains extracellular matrix components to support cellular attachment and proliferation for tissue repair. The product is terminally e-beam sterilized to provide extended shelf life. Membrane Wrap-Hydro™ is indicated for chronic and acute wounds. After preparation of the wound site the human amnion allograft is surgically applied to the wound surface by the healthcare provider and secured in place using the clinician's choice of fixation. As determined by the clinician, a reapplication may be necessary. The route of administration is topical, applying the product over the wound. The product serves as a supportive barrier and provides protective coverage 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. According to the applicant, currently there are no codes that are being billed to payers for the Membrane Wrap-Hydro™.

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 Membrane Wrap-Hydro™ product information submitted to CMS as part of the HCPCS Level II application appears to differ from the information that was submitted to the FDA's TRG. Based on the TRG letter, "Membrane Wrap-Hydro, when intended for "use as a barrier and protective covering for 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 "Membrane Wrap-Hydro is a minimally manipulated, human amniotic allograft membrane, hydrated in saline solution, which contains extracellular matrix components to support cellular attachment and proliferation for tissue repair." Based on this information, it appears that the Membrane Wrap-Hydro™ 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-tissueproducts/tissue-reference-group.

Amnio Tri-Core - HCP221206PD9UL

Topic/Issue

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

Applicant's suggested language: QXXXX, "Amnio Tri-Core, per sq. cm"

Summary of Applicant's Submission

Stability Biologics submitted a request to establish a new HCPCS Level II code to identify Amnio Tri-Core. Amnio Tri-Core is comprised of donated human tissue that has been screened. Human amniotic membrane is a thin, collagenous membrane derived from the placenta. Amnio Tri-Core is a triple layer amniotic tissue allograft, providing barrier. Amnio-Tri-Core is primarily and customarily used to treat acute and chronic wounds as well as burns. According to the applicant, Amnio Tri-Core allografts are processed based upon protocols and is initially disinfected to a 10-6 log reduction with a validated disinfecting process. An additional assurance of safety is achieved by terminally sterilizing each allograft. Amnio Tri-Core allografts should be stored in a clean, dry environment at ambient conditions (15-30 degree Celsius). According to the applicant, existing HCPCS Level II codes do not adequately describe Amnio Tri-Core.

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 Amnio Tri-Core product information submitted to CMS as part of the HCPCS Level II application appears to differ from the information that was submitted to the FDA's TRG. Based on the TRG letter, "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." However, in the HCPCS Level II application, it is indicated that "Amnio Tri-Core is primarily and customarily used to treat acute and chronic wounds as well as burns." Based on this information, it appears that the Amnio Tri-Core 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-tissueproducts/tissue-reference-group.

Amnio Quad-Core - HCP22120676CYM

Topic/Issue

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

Applicant's suggested language: QXXXX, "Amnio Quad-Core, per sq. cm"

Summary of Applicant's Submission

Stability Biologics submitted a request to establish a new HCPCS Level II code to identify Amnio Quad-Core. Amnio Quad-Core is comprised of donated human tissue that has been screened. Human amniotic membrane is a thin, collagenous membrane derived from the placenta. Amnio Quad-Core is a triple layer amniotic tissue allograft, providing barrier. Amnio Quad-Core is primarily and customarily used to treat acute and chronic wounds as well as burns. According to the applicant, Amnio Quad-Core allografts are processed based upon protocols and is initially disinfected to a 10-6 log reduction with a validated disinfecting process. An additional assurance of safety is achieved by terminally sterilizing each allograft. Amnio Quad-Core allografts should be stored in a clean, dry environment at ambient conditions (15-30 degree Celsius). According to the applicant, existing HCPCS Level II codes do not adequately describe Amnio Quad-Core.

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 Amnio Quad-Core product information submitted to CMS as part of the HCPCS Level II application appears to differ from the information that was submitted to the FDA's TRG. Based on the TRG letter, "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." However, in the HCPCS Level II application, it is indicated that "Amnio Quad-Core is primarily and customarily used to treat acute and chronic wounds as well as burns." Based on this information, it appears that the Amnio Quad-Core 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-tissueproducts/tissue-reference-group.

Complete™ AA - HCP221229RY347

Topic/Issue

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

Applicant's suggested language: QXXXX, "Complete™ AA, per sq. cm"

Summary of Applicant's Submission

Samaritan Biologics LLC submitted a request to establish a new HCPCS Level II code to identify Complete™ AA. Complete™ AA is a two-layer amnion-amnion derived allograft to serve as a barrier and provide protective coverage from the surrounding environment to acute and chronic wounds. Complete™ AA provides fully resorbable biological scaffold that permits cell infiltration, vascularization, and formation of new tissue in the wound bed. Complete™ AA is a sterile, single use, dehydrated allograft derived from donated human amnion membrane. Complete™ AA is dosed per square centimeter and can be reapplied as needed. Following standard wound preparation, Complete™ AA is applied directly to the wound; it is a fully resorbable graft and adheres to the wound bed without fixation. Complete™ AA is supplied in a variety of sizes. According to the applicant, there is currently no HCPCS Level II code available to describe Complete™ AA.

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 Complete™ AA product information submitted to CMS as part of the HCPCS Level II application appears to differ from the information that was submitted to the FDA's TRG. Based on the TRG letter, "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." However, in the HCPCS Level II application, it is indicated that "Complete™ AA provides fully resorbable biological scaffold that permits cell infiltration, vascularization, and formation of new tissue in the wound bed." Based on this information, it appears that the Complete™ AA 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-tissueproducts/tissue-reference-group.

Complete™ ACA - HCP22122921CXA

Topic/Issue

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

Applicant's suggested language: QXXXX, "Complete™ ACA, per sq. cm"

Summary of Applicant's Submission

Samaritan Biologics LLC submitted a request to establish a new HCPCS Level II code to identify Complete™ ACA. Complete™ ACA is 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 provides fully resorbable biological scaffold that permits cell infiltration, vascularization, and formation of new tissue in the wound bed. Complete™ ACA is a sterile, single use, dehydrated allograft derived from donated human amnion chorion membrane. Complete™ ACA is dosed per square centimeter and it can be reapplied as needed. Following standard wound preparation, Complete™ ACA is applied directly to the wound, it is fully resorbable and does not have to be removed from the wound bed. Complete™ ACA adheres to the wound bed without fixation. Complete™ ACA is supplied in a variety of sizes. According to applicant, there is currently no HCPCS Level II code available to describe Complete™ ACA.

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 Complete™ ACA product information submitted to CMS as part of the HCPCS Level II application appears to differ from the information that was submitted to the FDA's TRG. Based on the TRG letter, "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." However, in the HCPCS Level II application, it is indicated that "Complete™ ACA provides fully resorbable biological scaffold that permits cell infiltration, vascularization, and formation of new tissue in the wound bed." Based on this information, it appears that the Complete™ ACA 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-tissueproducts/tissue-reference-group.

Young Fresh Frozen Plasma (yFFP) - HCP220818UGHBK

Topic/Issue

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

Applicant's suggested language: XXXXX, "Young Fresh Frozen Plasma (yFFP): Young Fresh Frozen Plasma is FDA approved 21CFR640.30 blood plasma that is exclusively collected and carefully pathogen-screened from sex identified 18 – 25-year-old volunteer donors."

Summary of Applicant's Submission

Spectrum Plasma submitted a request to establish a new HCPCS Level II code to identify young fresh frozen plasma (yFFP). According to the applicant, this is a repeat application submitted by Solutionology Health LLC under application number HCP220308JVR7E in the second quarter of 2022. The applicant state yFFP is used for the treatment of inflammatory neurodegenerative diseases (e.g., Parkinson's disease, Alzheimer's disease and other inflammatory polyneuropathies), systemic inflammation and other age-related conditions. yFFP contains a young protein profile, high levels of growth factors including higher levels of cytokines and insulin like growth factors (IGFs) 1 and 2, chemokines - including CCL11/Eotaxin, Osteocalcin, antioxidants, anti-inflammatory balance and brain stimulating neuroprotective factors. yFFP's route of administration is interstitial, subcutaneous, intravenous infusions, or via therapeutic plasma exchange. yFFP is available in 200 mL units. According to the applicant, and in response to regulatory determination 21 CFR 640.30, plasma is an approved biologic since 1938.

CMS Final HCPCS Coding Decision

The Code of Federal Regulations, 21 CFR 640.30, does not state the indication for the treatment of inflammatory neurodegenerative diseases, as mentioned within the application for yFFP. Again, CMS refers the applicant to the FDA's Tissue Reference Group (TRG) to obtain written feedback regarding how the product, consistent with its intended uses described in the HCPCS Level II application, is appropriately regulated. After obtaining the FDA's written feedback, the applicant is welcome to submit a complete HCPCS Level II application in a subsequent coding cycle. Information for submitting questions to the FDA's TRG is located at:
https://www.fda.gov/vaccines-blood-biologics/tissue-tissue-products/tissue-reference-group

HEMGENIX® - HCP2212201P4UJ

Topic/Issue

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

Applicant's suggested language: JXXXX, "(Injection, etranacogene dezaparvovec-drlb (HEMGENIX), per therapeutic dose)"

Summary of Applicant's Submission

CSL Behring, LLC, submitted a request to establish a new HCPCS Level II code to HEMGENIX® (etranacogene dezaparvovec-drlb). HEMGENIX® was approved by the Food and Drug Administration (FDA) under the Biologics License Application (BLA) pathway on November 11, 2022. The applicant stated that this is the first and only one-time gene therapy for adults with hemophilia B. HEMGENIX® is indicated for the treatment of adults with Hemophilia B (congenital Factor IX deficiency) who currently use Factor IX prophylaxis therapy, or have current or historical life-threatening hemorrhage, or have repeated, serious spontaneous bleeding episodes. HEMGENIX® can be administered only once. According to the applicant, HEMGENIX® (etranacogene dezaparvovec-drlb) is an adeno-associated viral vector-based gene therapy for intravenous infusion after dilution. HEMGENIX® results in an increase in circulating Factor IX activity, increasing blood levels of Factor IX and thereby limiting bleeding episodes. A single intravenous infusion of HEMGENIX® results in cell transduction and increase in circulating Factor IX activity in patients with Hemophilia B. HEMGENIX® is a non-replicating recombinant adeno-associated virus stereotype 5 (AAV5) containing a codon-optimized DNA sequence of the gain-of-function Padua variant of human Factor IX, under control of a liver-specific promotor 1. The AAV5 vector carries the Padua gene variant of Factor IX to the target cells in the liver, generating factor IX proteins that are 5x-8x more active than normal. These genetic instructions remain in the target cells, but generally do not become a part of a person's own DNA. Once delivered, the new genetic instructions allow the cellular machinery to produce stable levels of factor IX. The recommended dose of HEMGENIX® is 2 x 10^13 genome copies per kilogram (kg) of body weight, or 2 milliliters (mL) per kg body weight, administered as an intravenous infusion after dilution with 0.9% normal saline. The patient's dose is calculated as follows: HEMGENIX® dose (in mL) = patient's body weight (in kilograms) x 2. HEMGENIX® is administered as a single-dose intravenous infusion through a peripheral venous catheter. HEMGENIX® is supplied as a customized kit to meet dosing requirements for each patient. Each kit includes at least 10 (ten) vials and up to 48 (forty-eight) vials, and each vial contains 10 mL of HEMGENIX®. The total number of vials in each kit corresponds to the dosing requirement for the individual patient depending on the patient's body weight. Each kit delivers the pertinent therapeutic dose to the patient based on his/her weight. The vials are for single-dose only. According to the applicant, there is no other product with the same chemical formulation or mechanism of action as HEMGENIX® and thus there is no existing code that adequately describes the product. The applicant suggests the code should be in the J7XXX series, where coders look for blood clotting factor products.

CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code J1411, “Injection, etranacogene dezaparvovec-drlb, per therapeutic dose”. Due to the unique programmatic needs within the hospital outpatient settings, this code will be effective April 1, 2023.

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

1. Establish twenty-seven new HCPCS Level II codes to separately identify products approved under the 505(b)(2) NDA or the BLA pathways after October 2003, and not rated as therapeutically equivalent to a reference listed product in an existing code.

2. Revise or delete existing HCPCS Level II codes, as needed, to separately identify multiple source drugs and single source drugs.

See Appendix A for a complete list of new and revised 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.

[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.

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 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
J0137	Add	Injection, acetaminophen (hikma) not therapeutically equivalent to j0131, 10 mg
J0206	Add	Injection, allopurinol sodium, 1 mg
J0216	Add	Injection, alfentanil hydrochloride, 500 micrograms
J0457	Add	Injection, aztreonam, 100 mg
S0073	Delete	Injection, aztreonam, 500 mg
J0665	Add	Injection, bupivicaine, not otherwise specified, 0.5 mg
S0020	Delete	Injection, bupivicaine hydrochloride, 30 ml
J0736	Add	Injection, clindamycin phosphate, 300 mg
J0737	Add	Injection, clindamycin phosphate (baxter), not therapeutically equivalent to j0736, 300 mg
S0077	Delete	Injection, clindamycin phosphate, 300 mg
J1576	Add	Injection, immune globulin (panzyga), intravenous, non-lyophilized (e.g., liquid), 500 mg
J1805	Add	Injection, esmolol hydrochloride, 10 mg
J1806	Add	Injection, esmolol hydrochloride (wg critical care) not therapeutically equivalent to j1805, 10 mg
J1811	Add	Insulin (fiasp) for administration through dme (i.e., insulin pump) per 50 units
J1812	Add	Insulin (fiasp), per 5 units
J1813	Add	Insulin (lyumjev) for administration through dme (i.e., insulin pump) per 50 units
J1814	Add	Insulin (lyumjev), per 5 units
J1836	Add	Injection, metronidazole, 10 mg
S0030	Delete	Injection, metronidazole, 500 mg
J1920	Add	Injection, labetalol hydrochloride, 5 mg
J1921[5]	Add	Injection, labetalol hydrochloride (hikma) not therapeutically equivalent to j1920, 5 mg
J1941	Add	Injection, furosemide (furoscix), 20 mg
J2305	Add	Injection, nitroglycerin, 5 mg
J2370	Delete	Injection, phenylephrine hcl, up to 1 ml
J2371	Add	Injection, phenylephrine hydrochloride, 20 micrograms
J2372	Add	Injection, phenylephrine hydrochloride (biorphen), 20 micrograms
J2426	Revise	Injection, paliperidone palmitate extended release (invega sustenna), 1 mg
J2427	Add	Injection, paliperidone palmitate extended release (invega hafyera, or invega trinza), 1 mg
J2598	Add	Injection, vasopressin, 1 unit
J2599[6]	Add	Injection, vasopressin (american regent) not therapeutically equivalent to j2598, 1 unit
J7213	Add	Injection, coagulation factor ix (recombinant), ixinity, 1 i.u.

[4] Revised on May 23, 2023 to remove J9321, which was a duplicative code to J9297.
[5] Revised on July 5, 2023 to change the long descriptor.
[6] Revised on April 28, 2023 to change the long descriptor.

J9322	Add	Injection, pemetrexed (bluepoint) not therapeutically equivalent to j9305, 10 mg