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

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

Second 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' Second 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 October 1, 2023, unless otherwise indicated.

The HCPCS coding decisions below will also be included in the October 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 Second Quarter 2023 Drug and Biological HCPCS Applications.

ANGIOMAX RTU (bivalirudin) Injection - HCP230330M0BYU

Topic/Issue

Request to establish a new HCPCS Level II code to identify bivalirudin RTU.

Applicant's suggested language: JXXXX, “Bivalirudin, (Bivalirudin RTU) injection,1 MG”

Summary of Applicant’s Submission

Maia Pharma submitted a request to establish a new HCPCS Level II code to identify ANGIOMAX RTU (bivalirudin) injection. ANGIOMAX RTU (bivalirudin) injection was approved by the Food and Drug Administration (FDA) under a 505(b)(2) New Drug Application (NDA) on July 25, 2019. Bivalirudin RTU injection is indicated for use as an anticoagulant in patients undergoing percutaneous coronary intervention (PCI), including patients with heparin-induced thrombocytopenia and heparin-induced thrombocytopenia and thrombosis syndrome. According to the applicant, the most common anticoagulant used during primary PCI is heparin. However, its effects can be somewhat unpredictable, leading to higher-than-desirable rates of bleeding and blood clots. According to the applicant, bivalirudin is a newer anticoagulant that has more predictable “blood thinning” effects. The recommended dose of bivalirudin RTU injection is an intravenous bolus dose of 0.75 mg/kg, followed immediately by a maintenance infusion of 1.75 mg/kg/h for the duration of the procedure. Five minutes after the bolus dose has been administered, assess activated clotting time (ACT) to determine if an additional bolus of 0.3 mg/kg is needed. For bivalirudin RTU, reconstitution is not required as the vial is already ready to use at 5 mg/ml. Bivalirudin RTU injection is supplied as follows: 250 mg per 50 mL Single-Dose Vial 1 vial per carton and 250 mg per 50 mL Single-Dose Vial 10 vials per carton. Bivalirudin RTU Injection is a refrigerated, ready-to-use, clear to slightly opalescent, colorless to yellow, sterile solution. Each vial contains 250 mg of bivalirudin.

CMS Final HCPCS Coding Decision

CMS is denying the applicant’s request to establish a new HCPCS Level II code for bivalirudin, RTU. ANGIOMAX (bivalirudin) RTU is only utilized in the inpatient setting; therefore, there is no claims processing need to establish a HCPCS Level II code.

Daptomycin in Sodium Chloride Injection - HCP230403BYYAD

Topic/Issue

Request to a establish new HCPCS Level II code to identify Daptomycin in Sodium Chloride Injection.

Applicant's suggested language: JXXXX, "Injection, daptomycin in sodium chloride (baxter), 1 mg"

Summary of Applicant's Submission

Baxter® Healthcare Corporation is submitting a request to establish a new HCPCS Level II code to identify Dapzura RT (Daptomycin in Sodium Chloride Injection). Daptomycin in Sodium Chloride Injection was approved by the Food and Drug Administration (FDA) under the 505(b)(2) New Drug Application (NDA) on January 25, 2022. Daptomycin in Sodium Chloride Injection is a lipopeptide antibacterial drug indicated for the treatment of complicated skin and skin structure infections (cSSSI) and staphylococcus aureus bloodstream infections (bacteremia) in adult and pediatric patients. Daptomycin has clinical utility in the treatment of infections caused by aerobic, Gram-positive bacteria. Daptomycin binds to bacterial cell membranes and causes a rapid depolarization of membrane potential. This loss of membrane potential causes inhibition of DNA, RNA, and protein synthesis, which results in bacterial cell death. Daptomycin in Sodium Chloride Injection does not have any therapeutic equivalents per the FDA's Orange Book, and Baxter® does not anticipate that the drug will not have any therapeutic equivalents per the FDA. According to the applicant Daptomycin in sodium chloride injection is a "single source drug" approved under a unique NDA, Daptomycin in Sodium Chloride Injection should be assigned a new Level II HCPCS code and paid separately by Medicare per section 1847A(c)(6)(D) of the Social Security Act and CMS policy. Daptomycin in Sodium Chloride Injection is administered to adult patients by intravenous infusion over a 30-minute period with a dosage regimen for cSSSI of 4 mg/kg once every 24 or 48 hours (depending on patient's creatinine clearance (CLCR) for 7 to 14 days and for staphylococcus aureus Bacteremia 6 mg/kg once every 24 or 48 hours (depending on patient's CLCR) for 2 to 6 weeks. For pediatric patients, for cSSSI, the drug is administered by intravenous infusion over a 30- to 60-minute period, based on age with dosage ranging from 5 mg/kg once every 24 hours infused over 30 minutes to 10 mg/kg once every 24 hours infused over 60 minutes for up to 14 days. For pediatric patients, for staphylococcus aureus bacteremia, the drug is administered by intravenous infusion over a 30- to 60-minute period, based on age with dosage ranging from 7 mg/kg once every 24 hours infused over 30 minutes to 12 mg/kg once every 24 hours infused over 60 minutes for up to 42 days. Daptomycin in Sodium Chloride Injection is a single-dose frozen, premixed, iso-osmotic, sterile, nonpyrogenic solution containing either 350 milligrams or 500 milligrams of daptomycin, per 50 mL GALAXY® container; or 700 milligrams or 1,000 milligrams daptomycin, per 100 mL GALAXY® container. Daptomycin injection is a clear, slightly yellow solution. Sodium Chloride, USP (0.9%) has been added to adjust osmolality.

CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code J0874, "Injection, daptomycin (baxter), not therapeutically equivalent to j0878, 1 mg"

Cabazitaxel Injection - HCP230403RGB4M

Topic/Issue

Request to a establish new HCPCS Level II code to identify Cabazitaxel Injection.

Applicant's suggested language: JXXXX, “Injection, cabazitaxel (sandoz), 1 mg”

Summary of Applicant’s Submission

Sandoz Inc. (Sandoz) submitted a request to establish a new HCPCS Level II code to identify Cabazitaxel Injection. Cabazitaxel Injection was approved by the Food and Drug Administration (FDA) under a 505(b)(2) New Drug Application (NDA) on January 5, 2023. Cabazitaxel Injection is a microtubule inhibitor indicated in combination with prednisone for treatment of patients with metastatic castration-resistant prostate cancer previously treated with a docetaxel-containing treatment regimen. Cabazitaxel binds to tubulin and promotes its assembly into microtubules while simultaneously inhibiting disassembly. This leads to the stabilization of microtubules, which results in the inhibition of mitotic and interphase cellular functions. Cabazitaxel Injection is a sterile, non-pyrogenic, clear colorless to pale yellow viscous solution and is available in multiple-dose vials in two strengths: 45 mg/4.5 mL and 60 mg/6.0 mL. Each mL contains 10 mg cabazitaxel (anhydrous), 4.5 mg anhydrous citric acid, 198 mg dehydrated alcohol, 560 mg polyethylene glycol 300, and 260 mg polysorbate 80. Cabazitaxel Injection requires dilution prior to intravenous infusion. Cabazitaxel Injection should be diluted in either .9% sodium chloride solution or 5% dextrose solution.

CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code J9064, “Injection, cabazitaxel (sandoz), not therapeutically equivalent to j9043, 1 mg”

Bortezomib Injection - HCP2303301XVKU

Topic/Issue

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

Applicant's suggested language: JXXXX, “Injection, bortezomib (bortezomib rtu), 0.1mg”

Summary of Applicant’s Submission

MAIA submitted a request to establish a new HCPCS Level II code to identify Bortezomib Injection. Bortezomib was approved by the Food and Drug Administration (FDA) under a 505(b)(2) New Drug Application (NDA) on July 27, 2022. Bortezomib Injection is indicated for the treatment of adult patients with multiple myeloma and the treatment of adult patients with mantle cell lymphoma. Multiple myeloma is a cancer of plasma cells where plasma cells become cancerous and grow out of control. Mantle cell lymphoma is a rare type of B cell non-Hodgkin lymphoma (NHL), a cancer of the lymphatic system. As a targeted chemotherapy, Bortezomib Injection works by blocking or slowing down the action of proteasomes inside of cells. The proteasomal system plays a vital role in cellular protein turnover, which is essential for the homeostasis of cells. Bortezomib reversibly binds to the chymotrypsin-like subunit of the 26S proteasome, resulting in its inhibition and preventing the degradation of various pro-apoptotic factors. The accumulation will eventually activate the programmed cell death via caspase-mediated pathways in the neoplastic cells that are usually dependent on the suppression of pro-apoptotic pathways for their proliferation and survival. The recommended starting dose of Bortezomib Injection is 1.3 mg/m^2. Dose must be individualized to prevent over-dosage. Bortezomib Injection is administered intravenously at a concentration of 1 mg/mL or 2.5 mg/mL, as a 3 to 5 second bolus intravenous injection. Bortezomib Injection is a clear, colorless to slightly yellow ready-to-use (RTU), sterile solution supplied as individually cartooned 5 mL vials containing 3.5 mg/3.5 mL (1 mg/ml) or 2 mL vials containing 3.5 mg/1.4 mL (2.5 mg/mL) of Bortezomib Injection. The applicant states presently, there is no HCPCS code assigned to Bortezomib Injection. There are similar products on the market but these are powders that need to be reconstituted whereas Bortezomib injection does not require reconstituting or dilution with sodium chloride, but is ready to be administered.

CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code J9051, “Injection, bortezomib (maia), not therapeutically equivalent to j9041, 0.1 mg”

REZZAYO™ - HCP230403BEED9

Topic/Issue

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

Applicant's suggested language: JXXXX, “injection, rezafungin, 1 mg”

Summary of Applicant’s Submission

Melinta Therapeutics submitted a request to establish a new HCPCS Level II code to identify REZZAYO™ (rezafungin acetate). REZZAYO™ was approved by the Food and Drug Administration (FDA) under a New Drug Application (NDA) on March 22, 2023. REZZAYO™ is an infused echinocandin antifungal drug indicated in patients 18 years of age or older who have limited or no alternative options for the treatment of candidemia and invasive candidiasis. According to the applicant, the mechanism of action for REZZAYO™ is that it inhibits the 1,3-β-D-glucan synthase enzyme complex, which is present in fungal cell walls but not in mammalian cells. This results in inhibition of the formation of 1,3-β-D-glucan, an essential component of the fungal cell wall of many fungi, including candida species. The recommended dose of REZZAYO™ is an initial 400 mg loading dose, followed by a 200 mg dose once weekly thereafter. REZZAYO™ is administered by a healthcare professional, and the route of administration is through intravenous infusion. REZZAYO™ is supplied as a 200 mg sterile white to pale yellow solid (cake or powder) for reconstitution in a single-dose glass vial.

CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code J0349, “Injection, rezafungin, 1 mg”

JESDUVROQ - HCP230403H2VM5

Topic/Issue

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

Applicant's suggested language: JXXXX, “daprodustat, oral, 1mg, (for ESRD on dialysis)”

Summary of Applicant’s Submission

GlaxoSmithKline (GSK) submitted a request to establish a new HCPCS Level II code to identify JESDUVROQ. JESDUVROQ was approved by the Food and Drug Administration (FDA) under a New Drug Application (NDA) on February 1, 2023. JESDUVROQ contains daprodustat, an inhibitor of hypoxia inducible factor (HIF), prolyl 4-hydroxylases (PH)1, PH2 and PH3. According to the applicant, there are currently no other drugs or biologicals with the same active ingredient category/generic name as JESDUVROQ (daprodustat) and therefore, no existing HCPCS Level II codes adequately describe this product. JESDUVROQ is indicated for the treatment of anemia due to chronic kidney disease in adults who have been receiving dialysis for at least four months. JESDUVROQ is a reversible inhibitor of HIF-PH1, PH2 and PH3 (IC50 in the low nM range). This activity results in the stabilization and nuclear accumulation of HIF-1α and HIF-2α transcription factors, leading to increased transcription of the HIF-responsive genes, including erythropoietin. JESDUVROQ is administered orally once daily, with or without food. According to the applicant, a new HCPCS Level II code is needed in order to facilitate payment for JESDUVROQ under the Transitional Drug Add-on Payment Adjustment (TDAPA) policy as part of the End-Stage Renal Disease Prospective Payment System (ESRD PPS). A corresponding TDAPA application was filed along with this HCPCS Level II application.

CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code J0889, “Daprodustat, oral, 1 mg, (for esrd on dialysis)”

SYFOVRE™ - HCP230222WKW9Q

Topic/Issue

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

Applicant's suggested language: JXXXX, “injection, intravitreal pegcetacoplan, 1mg”

Summary of Applicant’s Submission

Apellis Pharmaceuticals, Inc. submitted a request to establish a new HCPCS Level II code to identify SYFOVRE™ (pegcetacoplan) injection for intravitreal use. SYFOVRE™ was approved by the Food and Drug Administration (FDA) under a New Drug Application (NDA) on February 17, 2023. SYFOVRE™ is injected intravitreally and indicated for the treatment of geographic atrophy (GA) secondary to age-related macular degeneration (AMD). According to the applicant, geographic atrophy secondary to age-related macular degeneration affects an estimated 1 million people in the U.S. and is associated with profound visual dysfunction and irreversible vision loss as the disease progresses. The prevalence of GA increases exponentially with age, and the size and location of GA lesions affect visual performance, including reading, driving, low-light vision and central visual acuity. According to the applicant, SYFOVRE™ for intravitreal use is a novel, first-in-class agent in the ophthalmology specialty and the first FDA-approved treatment for geographic atrophy. SYFOVRE™ is supplied as a single dose vial containing 15 mg/0.1 mL. The recommended dose is 15 mg of SYFOVRE™ administered intravitreally by a qualified healthcare professional in each affected eye once every 25 to 60 days to achieve a reduction in the mean rate of GA lesion growth.

CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code J2781, “Injection, pegcetacoplan, intravitreal, 1 mg”

ACTHAR GEL - HCP230403X520K

Topic/Issue

Request to revise existing HCPCS Level II code J0800 to include brand name, ACTHAR GEL.

Applicant's suggested language: J0800, “Injection, corticotropin (Acthar Gel), up to 40 units”

Summary of Applicant’s Submission

Mallinckrodt submitted a request to revise existing HCPCS Level II code J0800 to identify ACTHAR GEL. ACTHAR GEL was approved by the Food and Drug Administration (FDA) under a New Drug Application (NDA) on August 28, 2020. According to the applicant, ACTHAR GEL (repository corticotropin injection) is a naturally sourced complex mixture of adrenocorticotropic hormone analogs and other pituitary peptides. ACTHAR GEL is indicated as monotherapy for the treatment of infantile spasms in infants and children under 2 years of age. ACTHAR GEL is indicated for the treatment of exacerbations of multiple sclerosis in adults. ACTHAR GEL may be used for the following disorders and diseases: rheumatic; collagen; dermatologic; allergic states; ophthalmic; respiratory; and edematous state. According to the applicant, the mechanism of action of ACTHAR GEL in the treatment of infantile spasms is unknown. ACTHAR GEL and endogenous ACTH stimulate the adrenal cortex to secrete cortisol, corticosterone, aldosterone, and a number of weakly androgenic substances. Prolonged administration of large doses of ACTHAR GEL induces hyperplasia and hypertrophy of the adrenal cortex and continuous high output of cortisol, corticosterone and weak androgens. The release of endogenous ACTH is under the influence of the nervous system via the regulatory hormone released from the hypothalamus and by a negative corticosteroid feedback mechanism. Elevated plasma cortisol suppresses ACTH release. ACTHAR GEL is also reported to bind to melanocortin receptors. In the treatment of infantile spasms, the recommended dose is 150 U/m^2 divided into twice daily intramuscular injections of 75 U/m^2. After 2 weeks of treatment, dosing should be gradually tapered and discontinued over a 2-week period. In the treatment of acute exacerbations of multiple sclerosis, daily intramuscular or subcutaneous doses of 80-120 units for 2-3 weeks may be administered. It may be necessary to taper the dose. In the treatment of other disorders and diseases, dosing will need to be individualized depending on the disease under treatment and the medical condition of the patient. It may be necessary to taper the dose. ACTHAR GEL is administered by intramuscular or subcutaneous injections. ACTHAR GEL is supplied as 5 mL multi-dose vial containing 80 USP units per mL.

CMS Final HCPCS Coding Decision

1. Establish a new HCPCS Level II code J0801, “Injection, corticotropin (acthar gel), up to 40 units”

   Effective 10/1/2023

2. Establish a new HCPCS Level II code J0802, “Injection, corticotropin (ani), up to 40 units”

   Effective 10/1/2023

3. Discontinue J0800, “Injection, corticotropin, up to 40 units”

   Effective 9/30/2023

LEQEMBI™ - HCP230329GADFY

Topic/Issue

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

Applicant's suggested language: JXXXX, “Injection, lecanemab-irmb, 10mg”

Summary of Applicant’s Submission

Eisai submitted a request to establish a new HCPCS Level II code to identify Leqembi™ (lecanemab-irmb). Leqembi™ was approved by the Food and Drug Administration (FDA) under the accelerated Biologics License Application (BLA) pathway on January 6, 2023. Leqembi™ is an amyloid beta-directed antibody indicated for the treatment of Alzheimer’s disease. Treatment with Leqembi™ should be initiated in patients with mild cognitive impairment or mild dementia stage of disease, the population in which treatment was initiated in clinical trials. Leqembi™ is a humanized immunoglobulin gamma 1 (IgG1) monoclonal antibody directed against aggregated soluble and insoluble forms of amyloid beta. The accumulation of amyloid beta plaques in the brain is a defining pathophysiological feature of Alzheimer’s disease. Leqembi™ reduces amyloid beta plaques. The recommended dosage is 10 mg/kg that must be diluted then administered as an intravenous infusion over approximately one hour, once every two weeks. Dilution in 250 mL of 0.9% Sodium Chloride Injection, United States Pharmacopeia, is required prior to administration. Leqembi™ is supplied as a solution in single-dose vials of either 500 mg/5 mL (100 mg/mL) or 200 mg/2 mL (100 mg/mL).

CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code J0174, “Injection, lecanemab-irmb, 1 mg”

The effective date aligns with the date when Leqembi™ received traditional FDA approval and aided CMS in efficiently implementing National Coverage Determination (NCD) 200.3.

Effective 07/06/2023

ZYNYZ™ - HCP230327EMAMG

Topic/Issue

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

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

Summary of Applicant's Submission

Incyte submitted a request to establish a new HCPCS Level II code to identify ZYNYZ™ (retifanlimab-dlwr) injection. ZYNYZ™ was approved by the Food and Drug Administration (FDA) under the Biologics License Application (BLA) pathway on March 22, 2023. ZYNYZ™ is indicated for the treatment of adult patients with metastatic or recurrent locally advanced Merkel cell carcinoma (MCC). This indication is approved under accelerated approval based on tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials. ZYNYZ™ is a programmed death receptor-1 (PD-1)–blocking antibody. ZYNYZ™ is a humanized IgG4 kappa monoclonal antibody produced in Chinese hamster ovary cells. ZYNYZ™ has an approximate molecular weight of 148 kDa. ZYNYZ™ injection is a sterile, preservative-free, clear to slightly opalescent, colorless to pale yellow solution for intravenous use. The mechanism of action of ZYNYZ™ is described as follows: Binding of the PD-1 ligands, PD-L1 and PD-L2, to the PD-1 receptor found on T cells, inhibits T-cell proliferation and cytokine production. According to the applicant, upregulation of PD-1 ligands occurs in some tumors, and signaling through this pathway can contribute to inhibition of active T-cell immune surveillance of tumors. ZYNYZ™ binds to the PD-1 receptor, blocks interaction with its ligands PD-L1 and PD-L2, and potentiates T-cell activity. The recommended dosage of ZYNYZ™ is 500 mg administered as an intravenous infusion over 30 minutes every 4 weeks until disease progression, unacceptable toxicity, or up to 24 months. Administer ZYNYZ™ as an intravenous infusion after dilution. ZYNYZ™ is supplied as a 500 mg/20 mL (25 mg/mL), clear to slightly opalescent, colorless to pale yellow solution in a single-dose vial. Each single-dose vial contains 500 mg of retifanlimab-dlwr in 20 mL of solution. Each mL contains 25 mg of retifanlimab-dlwr, glacial acetic acid (0.18 mg), polysorbate 80 (0.1 mg), sodium acetate (0.57 mg), sucrose (90 mg), and Water for Injection, USP. The pH is 5.1. Store refrigerated at 2°C to 8°C (36°F to 46°F) in the original carton to protect from light.

CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code J9345, "Injection, retifanlimab-dlwr, 1 mg"

ALTUVIIIO™ - HCP2303221ULW4

Topic/Issue

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

Applicant's suggested language: JXXXX, “factor viii fc-vwf-xten fusion recomb, 1 IU”

Summary of Applicant’s Submission

Sanofi submitted a request to establish a new HCPCS Level II code to identify ALTUVIIIO™ [antihemophilic factor (recombinant), Fc-VWF-XTEN fusion protein-ehtl]. ALTUVIIIO™ was approved by the Food and Drug Administration (FDA) under the Biologics License Application (BLA) pathway on February 22, 2023. ALTUVIIIO™ is a recombinant DNA-derived, factor VIII concentrate indicated for use in adults and children with hemophilia A (congenital factor VIII deficiency) for routine prophylaxis to reduce the frequency of bleeding episodes, on-demand treatment and control of bleeding episodes, and perioperative management of bleeding. ALTUVIIIO™ [antihemophilic factor (recombinant), Fc-VWF-XTEN fusion protein-ehtl] temporarily replaces the missing coagulation factor VIII needed for effective hemostasis. According to the applicant, ALTUVIIIO™ has demonstrated 3- to 4-fold prolonged half-life relative to other standard and extended half-life factor VIII products. ALTUVIIIO™ is a recombinant factor VIII analogue fusion protein that is independent of endogenous Von Willebrand factor (VWF) in order to overcome the half-life limit imposed by factor VIII-VWF interactions. ALTUVIIIO™ is available as a white to off-white lyophilized powder for reconstitution in single-dose vials containing nominally 250, 500, 750, 1000, 2000, 3000, or 4000 international units (I.U.) per vial. ALTUVIIIO™ is intended to be administered via intravenous infusion after reconstitution.

CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code J7214, “Injection, factor viii/von willebrand factor complex, recombinant (altuviiio), per factor viii i.u.”

NEXOBRID® - HCP230403FWRYM

Topic/Issue

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

Applicant's suggested language: JXXXX, “Anacaulase-bcdb, for topical administration, 8.8% gel, 1 g”

Summary of Applicant’s Submission

Vericel Corporation submitted a request to establish a new HCPCS Level II code to identify NEXOBRID®. NEXOBRID® was approved by the Food and Drug Administration (FDA) under a Biologics License Application (BLA) on December 28, 2022, as a biological product. NEXOBRID® is indicated for eschar removal in adults with deep partial thickness and/or full thickness thermal burns. NEXOBRID® contains anacaulase-bcdb, a mixture of proteolytic enzymes extracted from the stems of pineapple plants that has been sterile filtered and lyophilized. The mixture of enzymes in NEXOBRID® dissolves burn wound eschar. According to the applicant, NEXOBRID® has a novel mechanism of action that has demonstrated early, effective and selective eschar removal. NEXOBRID® is only to be administered by a healthcare provider, and may be applied in up to two applications of 4 hours each, depending on the size and severity of the burn to be treated. A first application may be applied to an area of up to 15% body surface area. A second application may be applied 24 hours later. The total treated area for both applications must not exceed 20% body surface area. NEXOBRID® must be mixed at the patient's bedside within 15 minutes of intended application, and must be applied to a clean, moist wound-bed free of burned epidermis layer and blisters, and covered with an occlusive film dressing for 4 hours. It is expected that NEXOBRID® will be applied to patients in the hospital inpatient setting and the hospital outpatient setting (e.g., emergency room, observation bed). NEXOBRID® is supplied as a sterile, preservative-free, lyophilized powder in a single-dose glass vial that must be mixed in a gel vehicle supplied in a single-dose glass jar prior to topical application. The lyophilized powder and gel vehicle are supplied in a co-packaged kit. There are two kits that will be offered: (1) a mixture of 5 grams of lyophilized powder (containing 4.85 grams of anacaulase-bcdb) in 50 grams of gel vehicle per 2.5% body surface area (for a total of 55 grams of mixed product), and, (2) a mixture of 2 grams of lyophilized powder (containing 1.94 grams of anacaulase-bcdb) in 20 grams of gel vehicle per 1% body surface area (for a total of 22 grams of mixed product).

CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code J7353, “Anacaulase-bcdb, 8.8% gel, 1 gram”

Paragard® T380A 10 Years, Copper Intrauterine Device - HCP2303310YEBY

Topic/Issue

Request to revise an existing HCPCS Level II code J7300 to identify Paragard® T380A 10 Years.

Applicant's suggested language: J7300, “Intrauterine copper contraceptive Paragard T380A 10 year Duration”

Summary of Applicant’s Submission

CooperSurgical submitted a request to revise an existing HCPCS Level II code J7300 to identify Paragard® T380A 10 Years. Paragard® is copper-containing intrauterine system (IUS) indicated for prevention of pregnancy in females of reproductive potential for up to 10 years. Paragard® T380A IUS was approved by the Food and Drug Administration (FDA) in 1984. Existing HCPCS Level II code, J7300, “Intrauterine copper contraceptive” is the current code description for Paragard®. The description that is being requested to be added is “Paragard T380A 10 Years" after the Intrauterine copper contraceptive language. According to the applicant, the existing code is inadequate due to lack of description for IUS. Current CMS coding does not include duration or amount of copper. Again, according to the applicant, there is a new non-hormonal copper intrauterine system (IUS) which is anticipated to come to market late in 2023 or in early 2024. The anticipated IUS is a low-dose copper releasing device indicated for the prevention of pregnancy for up to 3 years, with possible extension to 5 years. CooperSurgical and Paragard® are proactively requesting the description change to avoid confusion for payors when other competitors enter the market. Paragard® is a copper-containing intrauterine system (IUS) indicated for the prevention of pregnancy in females of reproductive potential for up to 10 years. The mechanism of action for Paragard® is that copper is continuously released into the uterine cavity which contributes to the contraceptive effectiveness of Paragard®. Paragard® is an intrauterine system inserted by a licensed provider. Each Paragard® is white, T-Shaped and measured 32 mm horizontally and 36 mm vertically with approximately 176 mg of copper wire wrapped around the vertical arm and approximately 68.7 mg copper wire collar placed on each side of horizontal arms, and with monofilament polyethylene thread tides through the tip of the vertical arm. The T-Body is made of polyethylene with barium sulfate. Each Paragard® is packaged together with an insertion tube, and with a blue flange and solid white rod in a Tyvek polyethylene pouch.

CMS Final HCPCS Coding Decision

CMS is denying the applicant’s request to revise existing HCPCS Level II code J7300 to identify Paragard® T380A 10 Years. This product is the only NDA-approved intrauterine copper contraceptive device/system available for distribution and use at this time; therefore, the current descriptor for HCPCS code J7300 adequately describes the product. The applicant is welcome to submit a new HCPCS Level II coding application for a code revision should the other IUS device, mentioned above by the applicant, receive FDA approval.

NuDYN® DL - HCP230324DA55D

Topic/Issue

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

Applicant's suggested language: QXXXX, “NuDYN® DL Membrane, per square centimeter”

Summary of Applicant’s Submission

Fidia Pharma USA Inc. submitted a request to establish a new HCPCS Level II code to identify NuDYN® DL amnion/chorion membranes. Per the applicant, NuDYN® DL membranes are human amnion/chorion membrane allografts derived from donated human placentas intended to be used as a barrier or wound covering for acute and chronic wounds. NuDYN® DL acts as a physical barrier providing a protective covering for acute and chronic wounds/ulcers such as pressure ulcers, venous ulcers, diabetic ulcers, partial and full-thickness wounds, chronic vascular ulcers, tunneled/undermined wounds, traumatic wounds, (abrasions, lacerations, partial thickness burns, skin tears), wound dehiscence, draining wounds, tunneled / undermined wounds, and surgical wounds such as podiatric, post-laser surgery, post-Moh's surgery, and donor sites/grafts. The NuDYN® DL products are terminally sterilized, single-use, dual layer, dehydrated amniotic and chorionic membrane allografts which are available in various sizes in square centimeters to cover and protect different sizes of wounds/ulcers. They are applied by a physician or other qualified healthcare professional to wounds/ulcers after the wound/ulcer beds are prepared with appropriate debridement. To prevent displacement, the products are fixated with the physician's or qualified healthcare professional's choice of fixation. According to the applicant, the products will fully resorb and do not have to be removed from the wound/ulcer beds.

CMS Final HCPCS Coding Decision

After review of the Food and Drug Administration’s (FDA’s) Tissue Reference Group (TRG) combined letter submitted by the applicant for NuDYN® DL and NuDYN® DL MESH, “NuDYN® DL and NuDYN® DL MESH, 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 Q4285, “Nudyn dl or nudyn dl mesh, per square centimeter”

NuDYN® DL MESH - HCP2303240WKMV

Topic/Issue

Request to establish a new HCPCS Level II code to identify NuDYN® DL MESH.

Applicant's suggested language: QXXXX, “NuDYN® DL MESH Membrane, per square centimeter”

Summary of Applicant’s Submission

Fidia Pharma USA Inc. submitted a request to establish a new HCPCS Level II code to identify NuDYN® DL MESH amnion/chorion membranes in a meshed style. The tissue is processed to cut slits into the membrane to allow the membrane to expand and allow fluid to pass though the membrane. Per the applicant, NuDYN® DL MESH membranes are human amnion/chorion membrane allografts derived from donated human placentas intended to be used as a barrier or wound covering for acute and chronic wounds. NuDYN® DL MESH acts as a physical barrier providing a protective covering for acute and chronic wounds/ulcers such as pressure ulcers, venous ulcers, diabetic ulcers, partial and full-thickness wounds, chronic vascular ulcers, tunneled/undermined wounds, traumatic wounds, (abrasions, lacerations, partial thickness burns, skin tears), wound dehiscence, draining wounds, tunneled / undermined wounds, and surgical wounds such as podiatric, post-laser surgery ,post-Moh's surgery, and donor sites/grafts. The NuDYN® DL MESH products are terminally sterilized, single-use, dual layer, dehydrated amniotic and chorionic membrane allografts which are available in various sizes in square centimeters to cover and protect different sizes of wounds/ulcers. They are applied by a physician or other qualified healthcare professional to wounds/ulcers after the wound/ulcer beds are prepared with appropriate debridement. To prevent displacement, the products are fixated with the physician's or qualified healthcare professional's choice of fixation. According to the applicant, the products will fully resorb and do not have to be removed from the wound/ulcer beds.

CMS Final HCPCS Coding Decision

After review of the Food and Drug Administration’s (FDA’s) Tissue Reference Group (TRG) combined letter submitted by the applicant for NuDYN® DL and NuDYN® DL MESH, “NuDYN® DL and NuDYN® DL MESH, 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 Q4285, “Nudyn dl or nudyn dl mesh, per square centimeter”

NuDYN® SL - HCP2303247H8YP

Topic/Issue

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

Applicant's suggested language: QXXXX, “NuDYN® SL Membrane, per square centimeter”

Summary of Applicant’s Submission

Fidia Pharma USA Inc. submitted a request to establish a new HCPCS Level II code to identify NuDYN® SL dehydrated amnion membrane. NuDYN® SL membranes are human amnion membrane allografts derived from donated human placentas intended to be used as a barrier or wound covering for acute and chronic wounds/ulcers. NuDYN® SL act as a physical barrier by providing a protective covering for acute and chronic wounds/ulcers such as pressure ulcers, venous ulcers, diabetic ulcers, partial and full-thickness wounds, chronic vascular ulcers, tunneled/undermined wounds, traumatic wounds,(abrasions, lacerations, partial thickness burns, skin tears), wound dehiscence, draining wounds, tunneled / undermined wounds, and surgical wounds such as podiatric, post-laser surgery, post-Moh's surgery, and donor sites/grafts. The NuDYN® SL products are terminally sterilized, single-use, dehydrated amniotic membrane allografts which are available in various sizes in square centimeters to cover and protect different sizes of wounds/ulcers. They are applied by a physician or other qualified healthcare professional to wounds/ulcers after the wound/ulcer beds are prepared with appropriate debridement. To prevent displacement, the products are fixated with the physician's or qualified healthcare professional's choice of fixation. According to the applicant, the allografts will fully resorb and do not have to be removed from the wound/ulcer beds.

CMS Final HCPCS Coding Decision

After review of the Food and Drug Administration’s (FDA’s) Tissue Reference Group (TRG) combined letter submitted by the applicant for NuDYN® SL and NuDYN® SLW, “NuDYN® SL and NuDYN® SLW, 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 Q4286, “Nudyn sl or nudyn slw, per square centimeter”

NuDYN® SLW- HCP230324HEJLV

Topic/Issue

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

Applicant's suggested language: QXXXX, “NuDYN® SLW Membrane, per square centimeter

Summary of Applicant’s Submission

Fidia Pharma USA Inc. submitted a request to establish a new HCPCS Level II code to identify NuDYN® SLW amnion membrane in a hydrated style. NuDYN® SLW membranes are human amnion membrane allografts derived from donated human placentas intended to be used as a barrier or wound covering for acute and chronic wounds/ulcers. NuDYN® SLW act as a physical barrier by providing a protective covering for acute and chronic wounds/ulcers such as pressure ulcers, venous ulcers, diabetic ulcers, partial and full-thickness wounds, chronic vascular ulcers, tunneled/undermined wounds, traumatic wounds, (abrasions, lacerations, partial thickness burns, skin tears), wound dehiscence, draining wounds, tunneled / undermined wounds, and surgical wounds such as podiatric, post-laser surgery, post-Moh's surgery, and donor sites/grafts. The NuDYN® SLW products are terminally sterilized, single-use, hydrated amniotic membrane allografts which are available in various sizes in square centimeters to cover and protect different sizes of wounds/ulcers. They are applied by a physician or other qualified healthcare professional to wounds/ulcers after the wound/ulcer beds are prepared with appropriate debridement. To prevent displacement, the products are fixated with the physician's or qualified healthcare professional's choice of fixation. According to the applicant, the allografts will fully resorb and do not have to be removed from the wound/ulcer beds.

CMS Final HCPCS Coding Decision

After review of the Food and Drug Administration’s (FDA’s) Tissue Reference Group (TRG) combined letter submitted by the applicant for NuDYN® SL and NuDYN® SLW, “NuDYN® SL and NuDYN® SLW, 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 Q4286, “Nudyn sl or nudyn slw, per square centimeter”

Acesso TL - HCP2304025NRWR

Topic/Issue

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

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

Summary of Applicant's Submission

Dynamic Medical Services LLC submitted a request to establish a new HCPCS Level II code to identify Acesso TL. Acesso TL is a dehydrated allograft derived from donated human placental birth tissue. Acesso TL is a triple layer human allograft tissue. Acesso TL membrane provides an extracellular matrix scaffold intended for use as a protective wound covering and barrier in acute and chronic wounds including burns. Acesso TL is processed using aseptic techniques and terminally sterilized by electron beam to achieve sterility assurance level of 10-6. Acesso TL is single use only and it has 5-year shelf life. It is restricted to use or ordered of a licensed healthcare professional. Acesso TL membrane is optimized for wound covering, protection and advanced wound treatment. Acesso TL has greater strength, thickness and ease of handling. Acesso TL is natural, biocompatible scaffold that supports tissue growth, minimal processing retains higher molecular weight of hyaluronic acid, maintaining structural tissue strength. The Acesso TL membrane has better tissue adherence than a single- or double-layer amnion membrane, which means that it is more likely to stay in place and promote healing.

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 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, "Acesso TL, when intended for use over the wound and as a barrier or protective coverage…to acute and chronic wounds", appears to meet the criteria for regulation solely under section 361 of the Public Health Service (PHS) Act and the regulations in 21 CFR part 1271." However, in the HCPCS Level II application, it is indicated that "Acesso TL is optimized advanced wound treatment, supports tissue growth and minimal processing retains higher molecular weight of hyaluronic acid. The Acesso TL membrane has better tissue adherence than a single- or double-layer amnion membrane, which means that it is more likely to stay in place and promote healing." Based on this information, it appears that the Acesso 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. 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.

AmnioTX™ - HCP230403YUVHD

Topic/Issue

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

Applicant's suggested language: XXXXX, "Amniotx™ per square centimeter"

Summary of Applicant's Submission

BioSTAR Medical submitted a request to establish a new HCPCS Level II code to identify AmnioTX™. The applicant states that AmnioTX™ is a dehydrated amniotic membrane allograft intended to be used as a wound cover or protective wound barrier. AmnioTX™ is intended to be used to serve a protective wound cover or barrier to offer protection from the surrounding environment in wounds, including surgically created wounds such as ocular repair and reconstruction. AmnioTX™ is intended only for homologous use as a barrier that protects wounds, including surgically created wounds, from the surrounding environment during the wound healing process. AmnioTX™ is available in the following sizes: 2 cm x 2 cm, 2 cm x 4 cm, 4 cm x 4 cm, 4 cm x 6 cm, 4 cm x 7 cm, 5 cm x 5c m, 4 cm x 8 cm, 10 cm x 10 cm, 20 cm x 20 cm. AmnioTX™ is for topical application in one patient on a single occasion, and also packaged and supplied as a dehydrated amniotic allograft membrane packaged in an outer pouch, sealed in an inner pouch. Each pouch features a peel back seal and is also heat sealed to provide a sterile barrier. The package label includes graft details such as dimensions. The allograft is stored at room temperature throughout transport and storage.

CMS Final HCPCS Coding Decision

After review of the Food and Drug Administration's (FDA's) Establishment Registration and Listing for human cells, tissues, and cellular and tissue-based product (HCT/P) described in 21 CFR 127.10, RegenTX Partners LLC is registered as the distributor for AmnioTX™, not BioSTAR Medical. CMS refers the applicant back to the FDA's TRG to obtain Establishment Registration and Listing as the distributor. 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/tissuetissueproducts/tissue-reference-group.

DermaBind™ TL – HCP230215GHEAC

Topic/Issue

Request to revise existing HCPCS Level II code Q4225 to include brand name, DermaBind™ TL.

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 centimeter" to include the brand name DermaBind™ TL, for example, "DermaBind TL, per square centimeter." CMS established a new HCPCS Level II code in Quarter 4, 2021, Q4225 to identify a placental membrane product AmnioBind. According to the applicant, another product exists that has a similar name, properties, and function, necessitating a product name change to avoid confusion of the products. DermaBind™ TL is a terminally sterilized, dehydrated, full thickness placental membrane (PM) allograft consisting of amnion, chorion, and the associated intermediate (spongy) layer (IL). Typically, following debridement, PM allografts are applied to the wound surface to provide a barrier to the environment. The allograft is intended to remain on the site for five to seven days. It is designed for application directly to acute and chronic wounds, is flexible, and is a conforming cover that adheres to complex anatomies. DermaBind™ TL membrane is intended for use as a wound covering. According to the applicant, DermaBind™ TL 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. DermaBind™ TL is identical in every aspect to AmnioBind, save the product name and manufacturer name. The name of the manufacturer has changed from Predictive Biotech to HealthTech Wound Care. DermaBind™ TL is manufactured in the same laboratory using the same equipment by the same technicians. Only the name of the manufacturing entity has changed.

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 “DermaBind™ TL 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. 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.

Sanopellis - HCP230321VEE18

Topic/Issue

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

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

Summary of Applicant’s Submission

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

CMS Final HCPCS Coding Decision

This is a repeat application from Q1 and Q2 of 2022 under application numbers (HCP220104WH2VX and HCP220401W6H7E). The Q1 2022 final decision referred the applicant back to the Food and Drug Administration’s (FDA’s) Tissue Reference Group (TRG) letter submitted by the applicant, to obtain written feedback regarding how the product, consistent with the intended uses described in their Q1 2022 HCPCS Level II application, is appropriately regulated. The Q2 2022 application continued to have inconsistencies between the details provided in the application and the intended uses described in the TRG letter for Sanopellis. Based on the description the applicant provided to FDA, Sanopellis meets the criteria for regulation “when intended to serve as a covering and barrier”. The applicant stated in their application that “Sanopellis Membranes are intended for homologous use and used as a wound covering and to act as a barrier”.

However, after review of the FDA’s Establishment Registration and Listing for human cells, tissues, and cellular and tissue-based product (HCT/P) described in 21 CFR 127.10, the brand name, Sanopellis, was not listed. Accordingly, our decision remains unchanged. The applicant is welcome to submit a complete HCPCS Level II application in a subsequent coding cycle where the information presented to CMS in the application is consistent with written feedback obtained from the FDA’s TRG. Information for submitting questions to the TRG is located at: https://www.fda.gov/vaccines-blood-biologics/tissue-tissue-products/tissue-reference-group.

Fludeoxyglucose F18 - HCP230306TDF6K

Topic/Issue

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

Applicant's Suggested Language: A96XX, “Injection, fluorodeoxyglucose F-18 FDG, therapeutic, up to 15 millicuries”

Summary of Applicant’s Submission

RefleXion Medical Inc. submitted a request to establish a new HCPCS Level II code to identify fludeoxyglucose F18 (FDG)-guided treatment. The RefleXion Medical Radiotherapy System (RMRS), now recently being marketed as SCINTIX™ that uses the fludeoxyglucose F18 (FDG)-guided treatment was authorized for marketing as a Class II device by the Food and Drug Administration (FDA) under section 513(a)(1) of the Food, Drug, and Cosmetics Act on February 1, 2023. Fludeoxyglucose F18 (FDG)-guided treatment includes modeling and precise delivery of FDG-guided external-beam radiation therapy (EBRT), a type of Biology-guided Radiotherapy (BgRT). BgRT with the RMRS is currently indicated for adults with tumor volumes in lung and bone subject to potential motion and positional uncertainty and is delivered in five or fewer fractions. BgRT delivery is distinct from conventional forms of EBRT because it requires an injected radiopharmaceutical to enable ongoing acquisition of emissions data during radiotherapy delivery. These emissions data are used to control where and how much radiation is delivered, through real-time, sub-second latency beam adjustments during treatment. Traditionally, FDG has been used only as a diagnostic agent to produce contrasted images to diagnose and stage cancer. During BgRT delivery, however, the applicant states that FDG is used for the first time in a therapeutic purpose, as it directs EBRT to achieve the treatment’s therapeutic effect in real-time; not for diagnostic, planning, or dosimetric purposes. According to the applicant, the RMRS employs proprietary algorithms that continuously translate radiopharmaceutical emissions data generated by FDG into real-time control mechanisms governing where and how much radiation is delivered. According to the applicant, the therapeutic use of FDG in BgRT is similar in effect and analogous for coding policy to other therapeutic radiopharmaceuticals (e.g., ibritumomab tiuxetan) that use tumor or cell binding properties to determine the location and amount of radiation exposure. We believe the existing HCPCS code for FDG as a diagnostic agent, A9552, “Fluorodeoxyglucose F-18 FDG, diagnostic, per study dose, up to 45 mCi”, is not appropriate for reporting the therapeutic use of FDG in BgRT treatment delivery.

CMS Final HCPCS Coding Decision

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

Magtrace® - HCP211224JJ1BQ

Topic/Issue

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

Applicant's suggested language: QXXXX, "Carboxydextran-coated superparamagnetic iron oxide particles in water containing 0.3% w/v sodium chloride, diagnostic, 2ml study dose"

Summary of Applicant's Submission

Endomag submitted a request to establish a new HCPCS Level II code to identify the single use 2 ml vial of Magtrace®. Magtrace® is a non-radioactive combination device/drug product and assists in localizing lymph nodes draining a breast cancer tumor site as part of a sentinel lymph node biopsy in patients with breast cancer undergoing a mastectomy. Magtrace® is a solution of iron nanoparticles coated with a carboxydextran shell which maps lymphatic drainage to the axilla. It is injected subcutaneously into interstitial breast tissue days or weeks before, or during, the surgery. Magtrace® use eliminates radiation exposure by replacing the use of the radioisotope and the blue dye that may cause severe allergic reactions. Magtrace® consists of a sterile aqueous suspension of carboxydextran-coated superparamagnetic iron oxide particles in water for injection (WFI) containing 0.3% w/v sodium chloride. Magtrace® does not quickly decay and is retained in the sentinel node, which allows injection from 20 minutes to weeks before surgery. Injection may occur prior to the surgery in the physician practice, including freestanding radiology centers, and in the hospital outpatient setting, by a radiologist or surgeon. There is no HCPCS code to report Magtrace®. The codes for nonradioactive, non-contrast visualization adjuncts (Q9968) or nonradioactive contrast imaging material, not otherwise classified, per study (A9698) are not appropriate. Magtrace® is not a visualization adjunct or contrast agent. Magtrace® should not be included in Current Procedural Terminology (CPT®) coding (as suggested by CMS in the prior HCPCS application). This request is only to establish a unique HCPCS code for Magtrace® just as radioisotopes (Technetium/Lymphoseek) have a unique product code for separate reporting from the administration procedure.

CMS Final HCPCS Coding Decision[1]

After a thorough review of prior coding decisions and related policies, we have determined that Magtrace® is a paramagnetic agent and should be similarly situated to other paramagnetic agents with existing codes, such as A9575, A9576, A9577, A9579, A9581, and A9585. As such, CMS has decided to:

Establish a new HCPCS Level II code A9697, "Injection, carboxydextran-coated superparamagnetic iron oxide, per study dose"

[1] Revised on August 1, 2023 to add our final determination, effective October 1, 2023.

CYTALUX™ - HCP220705CNACY

Topic/Issue

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

Applicant's suggested language: “Infusion, pafolacianine, 3.2 mg/1.6 mL”

Summary of Applicant’s Submission

Hull Associates submitted a request on behalf of On Target Laboratories to establish a new HCPCS Level II code to identify Cytalux™. On November 29, 2021, the Food and Drug Administration (FDA) approved the New Drug Application (NDA) for this drug as an optical imaging agent indicated in adult patients with cancer as an adjunct for intraoperative identification of malignant lesions. Cytalux™ (pafolacianine) injection is a sterile, non-pyrogenic, dark bluish green, clear aqueous solution for intravenous use. Each vial contains 3.2 mg (2 mg/mL) pafolacianine (equivalent to 3.4 mg pafolacianine sodium), 14.4 mg sodium chloride, 0.23 mg potassium phosphate monobasic, 1.27 mg sodium phosphate dibasic heptahydrate in 1.6 mL volume. The pH is adjusted with sodium hydroxide and/or hydrochloric acid and is between 7.1 to 7.8. Cytalux™ is an optical imaging agent to be used in adult patients with ovarian cancer as an adjunct for intraoperative identification of malignant lesions. It is comprised of a folic acid analog conjugated with an indocyanine green-like dye for use as a tumor-specific imaging agent which targets folate receptors that are overexpressed in most ovarian cancers. Cytalux™ is to be used with a near-infrared (NIR) imaging system cleared by the FDA for specific use with Cytalux™. Cytalux™ is the first targeted intraoperative molecular imaging agent that illuminates ovarian cancer in real time, enabling the detecting of more cancer for resection. According to the applicant, there is no existing HCPCS Level II code available to describe any drug of the same chemical composition, mechanism of action, and function, and they are requesting to establish a novel code. Cytalux™ is an optical imaging agent indicated in adult patients with ovarian cancer as an adjunct for intraoperative identification of malignant lesions. Cytalux™ is a fluorescent drug that targets folate receptor (FR) which may be overexpressed in ovarian cancer. Pafolacianine binds to FR-expressing cancer cells with nearly 1nM affinity, internalizes via receptor mediated endocytosis, and concentrates in FR-positive cancer tissues. Pafolacianine absorbs light in the NIR region within a range of 760 nm to 785 nm with peak absorption of 776 nm and emits fluorescence within a range of 790 nm to 815 nm with a peak emission of 796 nm. The recommended dose of Cytalux™ is a single intravenous infusion of 0.025 mg/kg diluted in 250 mL of 5% Dextrose Injection, administered over 60 minutes using a dedicated infusion line, 1 hour to 9 hours prior to surgery. Cytalux™ is supplied as a single dose vial for IV administration; Cytalux™ is dark bluish-green, clear aqueous liquid solution provided in an amber glass vial with a rubber closure and crimp seal and each vial contains 3.2 mg of pafolacianine free acid in total 1.6 mL volume to achieve a 2.0 mg/mL concentration.

CMS Final HCPCS Coding Decision[2]

After a thorough review of prior coding decisions and related policies, we have determined that Cytalux™ is an optical imaging agent that should be similarly situated to other optical imaging agents with existing codes, such as A9589. As such, CMS has decided to:

Establish a new HCPCS Level II code A9603, “Injection, pafolacianine, 0.1 mg”

[2] Revised on August 1, 2023 to add our final determination, effective October 1, 2023.

Elucirem™ - HCP220930JQQ56

Topic/Issue

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

Applicant's suggested language: AXXXX, "Injection, gadopiclenol, 1 ml"

Summary of Applicant's Submission

Guerbet LLC submitted a request to establish a new HCPCS Level II code to identify Elucirem™. Elucirem™ (gadopiclenol) vial injection is a gadolinium-based contrast agent indicated in adults and children aged 2 years and older for contrast enhanced magnetic resonance imaging (MRI) to improve detection, visualization, and assist in detection and visualization of lesions with abnormal vascularity in the central nervous system (brain, spine, and associated tissues) and the body (head and neck, thorax, abdomen, pelvis, and the musculoskeletal system). Elucirem™ (gadopiclenol) injection was approved by the Food and Drug Administration (FDA) under a New Drug Application (NDA) on September 21, 2022. Elucirem™ is available in various vial sizes and each vial. According to the applicant, there is no HCPCS code assigned for Elucirem™ (gadopiclenol) and when new-to-market it will be reported with a Not-Otherwise-Classified (NOC) HCPCS code. The applicant mentioned that using a NOC HCPCS code prevents concise tracking of utilization, often results in under-payment, and may result in incorrect billing.

CMS Final HCPCS Coding Decision[3]

After a thorough review of prior coding decisions and related policies, we have determined that gadopiclenol is a paramagnetic agent and should be similarly situated to other paramagnetic agents with existing codes, such as A9575, A9576, A9577, A9579, A9581, and A9585. Furthermore, paragraphs (4)(A) and (6) of sections 1847A(b) of the Social Security Act (the Act) require that the Medicare Part B payment amount for a single source drug or biological be determined using all of the NDCs assigned to it. Section 1847A(b)(5) of the Act further states that the payment limit shall be determined without regard to any special packaging, labeling, or identifiers on the dosage form or product or package. In 2007, CMS issued a program instruction (available at *https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Downloads/051807_coding_annoucement.pdf*), as permitted under section 1847A(c)(5)(C) of the Act, stating that the payment limit for a single source drug or biological will be based on the pricing information for products produced or distributed under the applicable FDA approval (such as a New Drug Application (NDA) or Biologics License Application (BLA)). Therefore, all versions of a single source drug or biological product (or NDCs) marketed under the same FDA approval number (for example, NDA or BLA, including supplements) are considered the same drug or biological for purposes of payments made under section 1847A of the Act and are cross walked to the same billing and payment code. As such, CMS has decided to:

Establish a new HCPCS Level II code A9573, "Injection, gadopiclenol, 1 ml"

[3] Revised on August 1, 2023 to add our final determination, effective October 1, 2023.

Elucirem™ - HCP22093037EYE

Topic/Issue

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

Applicant's suggested language: AXXXX, "Injection, gadopiclenol, per 1 ml, prefilled syringe"

Summary of Applicant's Submission

Guerbet LLC submitted a request to establish a new HCPCS Level II code to identify Elucirem™. Elucirem™ (gadopiclenol) prefilled syringe injection is a gadolinium-based contrast agent indicated in adults and children aged 2 years and older for contrast enhanced magnetic resonance imaging (MRI) to improve detection, visualization, and assist in detection and visualization of lesions with abnormal vascularity in the central nervous system (brain, spine, and associated tissues) and the body (head and neck, thorax, abdomen, pelvis, and the musculoskeletal system). Elucirem™ (gadopiclenol) injection was approved by the Food and Drug Administration (FDA) under a New Drug Application (NDA) on September 21, 2022. Elucirem™ is available in three sizes and packaging. According to the applicant, there is no HCPCS code assigned for Elucirem™ (gadopiclenol) and when new-to-market it will be reported with a Not-Otherwise-Classified (NOC) HCPCS code. The applicant mentioned that using a NOC HCPCS code prevents concise tracking of utilization, often results in under-payment, and may result in incorrect billing.

CMS Final HCPCS Coding Decision[4]

After a thorough review of prior coding decisions and related policies, we have determined that gadopiclenol is a paramagnetic agent and should be similarly situated to other paramagnetic agents with existing codes, including A9575, A9576, A9577, A9579, A9581, A9585. Furthermore, paragraphs (4)(A) and (6) of sections 1847A(b) of the Social Security Act (the Act) require that the Medicare Part B payment amount for a single source drug or biological be determined using all of the NDCs assigned to it. Section 1847A(b)(5) of the Act further states that the payment limit shall be determined without regard to any special packaging, labeling, or identifiers on the dosage form or product or package. In 2007, CMS issued a program instruction (available at *https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Downloads/051807_coding_annoucement.pdf*), as permitted under section 1847A(c)(5)(C) of the Act, stating that the payment limit for a single-source drug or biological will be based on the pricing information for products produced or distributed under the applicable FDA approval (such as a New Drug Application (NDA) or Biologics License Application (BLA)). Therefore, all versions of a single source drug or biological product (or NDCs) marketed under the same FDA approval number (for example, NDA or BLA, including supplements) are considered the same drug or biological for purposes of payments made under section 1847A of the Act and are cross walked to the same billing and payment code. As such, CMS has decided to:

Establish a new HCPCS Level II code A9573, "Injection, gadopiclenol, 1 ml"

[4] Revised on August 1, 2023 to add our final determination, effective October 1, 2023.

VUEWAY™ - HCP221003PJLCW

Topic/Issue

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

Applicant's suggested language: AXXXX, “Injection, gadopiclenol, 1 ml”

Summary of Applicant’s Submission

JR Associates submitted a request to establish a new HCPCS Level II code to identify VUEWAY™. This product is a gadolinium-based contrast agent (GBCA). VUEWAY™ (gadopiclenol) was approved by the Food and Drug Administration (FDA) under a New Drug Application (NDA) on September 21, 2022. VUEWAY™ solution for injection, 485.1 mg/mL is indicated in adults and children age 2 years and older for contrast enhanced magnetic resonance imaging (MRI) to improve detection, visualization and assist in characterization of lesions in the central nervous system (brain, spine, and associated tissues) and the body (head and neck, thorax, abdomen, pelvis, and the musculoskeletal system). According to the applicant, this product provides approximately 2-3 times the contrast enhancement per molecule vs. all other marketed GBCAs and has been approved by the FDA to be administered at a weight-based dose of 0.05 mmol/kg, which is half that of the approved doses of all other general-use GBCAs (0.1 mmol/kg). Gadopiclenol is a paramagnetic macrocyclic non-ionic complex gadolinium that develops a magnetic moment when placed in a magnetic field. The magnetic moment alters the relaxation rates of water protons in its vicinity in the body, leading to an increase in signal intensity (brightness) of tissues. It presents a high relaxivity in water due to its specific chemical structure. It can exchange two water molecules, which are linked to the gadolinium to complete its coordination number in addition to the four nitrogens and the three oxygens of the carboxylate functions of the gadopiclenol chelate. Gadopiclenol solution for injection demonstrates the highest relaxivity in water and serum vs. all currently approved linear and macrocyclic GBCAs at all field strengths. It is due to its high relaxivity, it can be given at half-dose of gadolinium compared to other non-specific GBCAs, while providing the same contrast enhancement. VUEWAY™ is available in single-dose vials, in single-dose pre-filled syringes, and in pharmacy bulk packages. According to the applicant, current HCPCS codes describe specific general use GBCA products. The applicant stated the HCPCS code for unspecified gadolinium products has been reported for several general use GBCAs, all of which lack the contrast enhancement properties that allow for gadopiclenol’s different weight-based dose. According to the applicant, gadopiclenol’s properties warrant a specific HCPCS code.

CMS Final HCPCS Coding Decision[5]

After a thorough review of prior coding decisions and related policies, we have determined that gadopiclenol is a paramagnetic agent and should be similarly situated to other paramagnetic agents with existing codes, including A9575, A9576, A9577, A9579, A9581, A9585. Furthermore, paragraphs (4)(A) and (6) of sections 1847A(b) of the Act require that the Medicare Part B payment amount for a single source drug or biological be determined using all of the NDCs assigned to it. Section 1847A(b)(5) of the Social Security Act (the Act) further states that the payment limit shall be determined without regard to any special

[5] Revised on August 1, 2023 to add our final determination, effective October 1, 2023.

packaging, labeling, or identifiers on the dosage form or product or package. In 2007, CMS issued a program instruction (available at *https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Downloads/051807_coding_annoucement.pdf*), as permitted under section 1847A(c)(5)(C) of the Act, stating that the payment limit for a single source drug or biological will be based on the pricing information for products produced or distributed under the applicable FDA approval (such as a New Drug Application (NDA) or Biologics License Application (BLA)). Therefore, all versions of a single source drug or biological product (or NDCs) marketed under the same FDA approval number (for example, NDA or BLA, including supplements) are considered the same drug or biological for purposes of payments made under section 1847A of the Act and are cross walked to the same billing and payment code. As such, CMS has decided to:

Establish a new HCPCS Level II code A9573, “Injection, gadopiclenol, 1 ml”

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[6], 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[7] to identify the correct billing and payment code for each applicable product.

CMS Final HCPCS Coding Decision

Establish two 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.

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

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

[6] 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.

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

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

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

HCPCS Code	Action	Long Descriptor
J2359	Add	Injection, olanzapine, 0.5 mg
J7519	Add	Injection, mycophenolate mofetil, 10 mg