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

Fourth 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' Fourth Quarter 2023 Drug and Biological HCPCS code application review cycle. Each individual summary includes the request number; topic/issue; summary of the applicant's submission as written by the applicant with occasional non-substantive editorial changes made by CMS; and CMS' final HCPCS coding decision. All new coding actions will be effective April 1, 2024, unless otherwise indicated.

The HCPCS coding decisions below will also be included in the April 2024 HCPCS Quarterly Update, pending publication by CMS in the coming weeks at: https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update

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

CMS has a long-standing convention to assign dose descriptors in the smallest amount that could be billed in multiple units to accommodate a variety of doses and support streamlined billing. This long-standing policy makes coding more robust and facilitates accurate payment and reporting of the exact dose administered, as only 999 units can appear on a claim line for Medicare fee-for-service using the CMS-1500 form. In addition, CMS will use the generic or chemical name if there are no other similar chemical products on the market. If there are multiple products on the market with the same generic or chemical name, and a unique code is warranted based on the statutory definition of "single source drug" in section 1847A(c)(6) of the Social Security Act, CMS will further distinguish a new code by using the brand name or manufacturer name. CMS generally creates codes for products themselves, without specifying a route of administration in the code descriptor, as there might be multiple routes of administration for the same product. Drugs that fall under this category should be billed with either JA modifier for the intravenous infusion of the drug or billed with JB modifier for subcutaneous injection of the drug. The dose descriptors assigned to codes established in this quarterly coding cycle are in alignment with these policies.

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

BALFAXAR® - HCP230914LXYJ9

Topic/Issue

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

Applicant's suggested language: JXXXX, "Prothrombin complex concentrate, human-lans, 1 mcg"

Summary of Applicant's Submission

Octapharma submitted a request to establish a new HCPCS Level II code to identify BALFAXAR® (Prothrombin complex concentrate, human-lans). BALFAXAR® was approved by the Food and Drug Administration (FDA) under the Biologics License Application (BLA) pathway on July 21, 2023. BALFAXAR® is a human plasma-derived, purified, virus inactivated and nanofiltered non-activated Prothrombin Complex Concentrate (PCC) containing the coagulation factors II, VII, IX, and X and antithrombotic proteins C and S. BALFAXAR® is supplied as a lyophilized powder for reconstitution for intravenous use. The actual potency printed on the vial label represents the potency of factor IX. BALFAXAR® is sterile, endotoxin-free, and does not contain preservatives. No albumin is added as a stabilizer, and the excipients are heparin and sodium citrate. The diluent for reconstitution of the lyophilized powder is sterile water for injection. The administration of BALFAXAR® provides a rapid increase in plasma levels of the vitamin K-dependent coagulation factors (FII, FVII, FIX, FX) and antithrombotic proteins C and S. Together they are referred to/known as the prothrombin complex. BALFAXAR® can temporarily correct the coagulation defect of patients with deficiency of one or several of these factors. Measurement of INR prior to treatment and close to the time of dosing is important because coagulation factors may be unstable in patients with need for an urgent surgery and other invasive procedures. The dosing for BALFAXAR® is individualized based on the patient's current pre-dose international normalized ratio (INR) value, and body weight. The actual potency per vial of factor IX is stated on the carton. The potencies of factors II, VII, IX and X, proteins C and S are indicated as ranges. Vitamin K is administered concurrently to patients receiving BALFAXAR® to maintain vitamin K-dependent clotting factor levels once the effects of BALFAXAR® have diminished. Dose ranging within pre-treatment INR groups has not been studied in randomized clinical trials of BALFAXAR®. Intravenous BALFAXAR® is a sterile, white to ice-blue lyophilized powder for reconstitution for intravenous use. It is provided in a single-dose vial with a nominal strength of 500 factor IX units in 20 mL reconstitution volume and 1000 Factor IX units in 40 mL reconstitution volume per vial.

CMS Final HCPCS Coding Decision

1. Establish a new HCPCS Level II code J7165, "Injection, prothrombin complex concentrate, human-lans, per i.u. of factor ix activity"

   Effective April 1, 2024

2. Discontinue HCPCS Level II code C9159, “Injection, prothrombin complex concentrate (human), balfaxar, per i.u. of factor ix activity”

   Effective March 31, 2024

POMBILITI™ - HCP2309296TFRY

Topic/Issue

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

Applicant's suggested language: JXXXX, “Injection, cipaglucosidase alfa-atga (POMBILITI), per 5 mg”

Summary of Applicant's Submission

Amicus Therapeutics submitted a request to establish a new HCPCS Level II code to identify POMBILITI™ (cipaglucosidase alfa-atga). POMBILITI™ was approved by the Food and Drug Administration (FDA) under the Biologics License Application (BLA) pathway on September 28, 2023. POMBILITI™ is a hydrolytic lysosomal glycogen specific enzyme that, in combination with OPFOLDA™, is indicated for the treatment of adult patients with late-onset Pompe disease, weighing ≥40 kg and who are not improving on their current enzyme replacement therapy. Pompe disease is caused by deficiency of the lysosomal enzyme acid-alpha glucosidase (GAA). Deficiency of GAA leads to the accumulation of glycogen in the lysosomes of various tissues which leads to progressive loss of muscle and respiratory function. POMBILITI™, which must be used in combination with the enzyme stabilizer OPFOLDA™, provides an exogenous source of GAA to degrade accumulated glycogen. POMBILITI™ is internalized into cells and is transported into the lysosome where it can degrade the accumulated glycogen. OPFOLDA™ binds with, stabilizes, and reduces inactivation of POMBILITI™ in the blood after infusion. The recommended dosage of POMBILITI™ is 20 mg/kg (of actual body weight) administered every other week as an intravenous infusion over approximately 4 hours. The POMBILITI™ infusion should begin approximately 1 hour after, but no more than 3 hours after, oral administration of OPFOLDA™. If the POMBILITI™ infusion cannot be started within 3 hours of oral administration of OPFOLDA™, it should not be administered. POMBILITI™ is packaged in 105 mg single-dose vials for reconstitution.

CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code J1203, “Injection, cipaglucosidase alfa-atga, 5 mg”

OPFOLDA™ - HCP2309293Q0XD

Topic/Issue

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

Applicant's suggested language: JXXXX, “Miglustat (OPFOLDA™), oral, 65 mg”

Summary of Applicant's Submission

Amicus Therapeutics submitted a request to establish a new HCPCS Level II code to identify OPFOLDA™ (miglustat). OPFOLDA™ was approved by the Food and Drug Administration (FDA) under a 505(b)(2) New Drug Application (NDA) on September 28, 2023. OPFOLDA™ is approved for use in combination with POMBILITI™ (cipaglucosidase alfa-atga) injection, as a treatment for late onset Pompe disease (LOPD). Pompe disease is caused by deficiency of the lysosomal enzyme acid-alpha glucosidase. OPFOLDA™ is a N-alkylated iminosugar, a synthetic analog of D-glucose. The pharmacologic class is enzyme stabilizer. OPFOLDA™ is indicated, in combination with POMBILITI™, for the treatment of adult patients with LOPD, weighing ≥ 40 kg and who are not improving on their current enzyme replacement therapy. OPFOLDA™ binds with, stabilizes, and reduces inactivation of POMBILITI™ in the blood after infusion. The recommended dosage of OPFOLDA™ (based on actual body weight) is 260 mg (4 capsules) for patients weighing ≥ 50 kg and 195 mg (3 capsules) for patients weighing ≥ 40 kg and < 50 kg. For patients with moderate or severe renal impairment, the recommended dose is 195 mg (3 capsules) for patients weighing > 50 kg and 130 mg (2 capsules) for patients weighing ≥ 40 kg and < 50 kg. OPFOLDA™ is administered orally every other week approximately 1 hour before the start of each POMBILITI™ infusion (also administered every other week). Prior to administration of OPFOLDA™, the patient must fast for at least two hours. This fast should continue for two hours after OPFOLDA™ administration. If the POMBILITI™ infusion cannot be started within 3 hours of oral administration of OPFOLDA™, POMBILITI™ in combination with OPFOLDA™ should be rescheduled at least 24 hours after OPFOLDA™ was last taken. OPFOLDA™ is supplied in 65 mg capsules, packaged in a 4-count bottle, a 25-count bottle, or a 100-count bottle.

CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code J1202, “Miglustat, oral, 65 mg”

To facilitate beneficiary access treatment of late-onset Pompe disease with miglustat in combination with cipaglucosidae alfa-atga, we are creating a new code, G0138, describing the service of administration of cipaglucosidase alfa-atga (Pombiliti), which includes the intravenous administration of cipaglucosidase alfa-atga, the provider or supplier’s acquisition cost of miglustat, clinical supervision, and oral administration of miglustat.

Establish a new HCPCS Level II code G0138, “Intravenous infusion of cipaglucosidase alfa-atga, including provider/supplier acquisition and clinical supervision of oral administration of miglustat in preparation of receipt of cipaglucosidase alfa-atga”

VEOPOZ™ - HCP230925FQYFA

Topic/Issue

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

Applicant's suggested language: JXXXX, “pozelimab-bbfg (VEOPOZ), 1mg”

Summary of Applicant's Submission

Regeneron submitted a request to establish a new HCPCS Level II code to identify VEOPOZ™ (pozelimab-bbfg). VEOPOZ™ was approved by the Food and Drug Administration under the Biologics License Application (BLA) pathway on August 18, 2023. VEOPOZ™ is a human, monoclonal immunoglobulin G4^P (IgG4^P) antibody directed against the terminal complement protein C5 that inhibits terminal complement activation by blocking cleavage of C5 into C5a (anaphylatoxin) and C5b, thereby blocking the formation of the membrane-attack complex (C5b-C9, a structure mediating cell lysis). VEOPOZ™ is a complement inhibitor indicated for the treatment of adult and pediatric patients 1 year of age and older with CD55-deficient protein-losing enteropathy, also known as CHAPLE disease. The recommended dose of VEOPOZ™ is a loading dose of 30 mg/kg by intravenous infusion followed by weekly weight-based doses by subcutaneous injection. Each vial contains 400 mg pozelimab-bbfg in 2 mL of solution with a pH of 5.8.

CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code J9376, “Injection, pozelimab-bbfg, 1 mg”

EYLEA® HD - HCP230828GPB3B

Topic/Issue

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

Applicant's suggested language: JXXXX, “Injection, aflibercept, 8mg”

Summary of Applicant's Submission

Regeneron Pharmaceuticals Inc. submitted a request to establish a new HCPCS Level II code to identify EYLEA® HD (aflibercept). EYLEA® HD was approved by the Food and Drug Administration (FDA) under the Biologics License Application (BLA) pathway on August 18, 2023. EYLEA® HD is supplied as 8 mg in 0.07 mL solution and indicated for the treatment of neovascular (wet) age-related macular degeneration (nAMD), diabetic macular edema (DME), and diabetic retinopathy (DR). The recommended dose for EYLEA® HD for nAMD and DME is 8 mg administered by intravitreal injection every 4 weeks (approximately every 28 days plus or minus 7 days) for the first three doses, followed by 8 mg via intravitreal injection once every 8 to 16 weeks, plus or minus 1 week. The recommended dose for EYLEA® HD for DR is 8 mg administered by intravitreal injection every 4 weeks (approximately every 28 days plus or minus 7 days) for the first three doses, followed by 8 mg via intravitreal injection once every 8 to 12 weeks, plus or minus 1 week. EYLEA® HD is supplied in two presentations: a vial-only presentation consisting of a single-dose vial containing a solution of 8 mg in 0.07 mL as the primary container in a carton, and a convenience-kit presentation consisting of a single-dose vial containing a solution of 8 mg in 0.07 mL co-packaged in a carton with a syringe, filter needle, and injection needle.

CMS Final HCPCS Coding Decision

1. Establish a new HCPCS Level II code J0177, “Injection, aflibercept hd, 1 mg”

   Effective April 1, 2024

2. Discontinue HCPCS Level II code C9161, “Injection, aflibercept hd, 1 mg”

   Effective March 31, 2024

TYRUKO® - HCP230927ENYE4

Topic/Issue

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

Applicant's suggested language: QXXXX, “Injection, natalizumab-sztn, biosimilar, (tyruko), 1 mg”

Summary of Applicant's Submission

Sandoz Inc. submitted a request to establish a new HCPCS Level II code to identify TYRUKO® (natalizumab-sztn). TYRUKO® was approved by the Food and Drug Administration (FDA) under the Biologics License Application (BLA) pathway on August 24, 2023. It is approved as a biosimilar to TYSABRI® (natalizumab). TYRUKO® is an integrin receptor antagonist indicated as a monotherapy for the treatment of adults with relapsing forms of multiple sclerosis, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease. TYRUKO® is also indicated for inducing and maintaining clinical response and remission in adult patients with moderately to severely active Crohn's disease (CD) who have had inadequate response to, or are unable to tolerate, conventional CD therapies and inhibitors of tumor necrosis factor alpha. TYRUKO® is a sterile, preservative-free, colorless and clear to slightly opalescent solution for dilution prior to intravenous infusion and is supplied as one 300 mg per 15 mL single-dose vial per carton. TYRUKO® is infused intravenously over one hour, every four weeks.

CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code Q5134, “Injection, natalizumab-sztn (tyruko), biosimilar, 1 mg”

TALVEY™ - HCP230829U2RCH

Topic/Issue

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

Applicant's suggested language: XXXXX, "Injection, talquetamab-tgvs, per mg, for subcutaneous injection"

Summary of Applicant's Submission

Johnson & Johnson Health Care Systems Inc. submitted a request to establish a new HCPCS Level II code to identify TALVEY™ (talquetamab-tgvs). TALVEY™ was approved by the Food and Drug Administration (FDA) under the Biologics License Application (BLA) pathway on August 9, 2023. TALVEY™ is a bispecific G protein–coupled receptor, family C, group 5, member D (GPRC5D)-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 therapies, including a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 monoclonal antibody. This indication is approved under accelerated approval based on response rate. Patients receiving TALVEY™ undergo step-up dosing through subcutaneous injection on either a weekly or biweekly (every two weeks) basis. Patients on the weekly dosing schedule will receive three priming doses (dosage determined by body weight) during the five-day step-up phase of treatment. The first step-up dose (0.01 mg/kg) on day 1, a second step-up dose (0.06 mg/kg) on day 3, a third step-up dose (0.4 mg/kg) on day 5, and their first treatment dose (0.4 mg/kg) once per week thereafter. Patients on the biweekly dosing schedule receive four priming doses during the seven-day step-up phase of treatment. The first step-up dose (0.01 mg/kg) on day 1, the second step-up dose (0.06 mg/kg) on day 3, the third step-up dose (0.4 mg/kg) on day 5, and the fourth step-up dose (0.8 mg/kg) on day 7, and treatment doses once every 2 weeks thereafter. Patients must maintain a minimum of 6 days between weekly doses and a minimum of 12 days between biweekly (every two weeks) doses. TALVEY™ is provided in two dosage forms and strengths: 3 mg/ 1.5 mL (2 mg/mL) in a single-dose vial and 40 mg/mL (40 mg/mL) in a single-dose vial.

CMS Final HCPCS Coding Decision[1]

1. Establish a new HCPCS Level II code J3055, "Injection, talquetamab-tgvs, 0.25 mg"

   Effective April 1, 2024

2. Discontinue HCPCS Level II code C9163, "Injection, talquetamab-tgvs, 0.25 mg"

   Effective March 31, 2024

[1] Revised on February 5, 2024 to correct the code language for C9163.

ABECMA® - HCP2309298FDFB

Topic/Issue

Request to revise existing HCPCS Level II code Q2055, “Idecabtagene vicleucel, up to 460 million autologous b-cell maturation antigen (bcma) directed car-positive t cells, including leukapheresis and dose preparation procedures, per therapeutic dose” to identify ABECMA®.

Applicant's suggested language: Q2055, “Idecabtagene vicleucel, up to 510 million autologous b-cell maturation antigen (bcma) directed car-positive t cells, including leukapheresis and dose”

Summary of Applicant's Submission

Bristol Myers Squibb submitted a request to revise existing HCPCS Level II code Q2055 to increase the maximum dosage in the code descriptor for ABECMA® (idecabtagene vicleucel). ABECMA® was approved by the Food and Drug Administration (FDA) under the Biologics License Application (BLA) pathway on March 26, 2021. The current indication for ABECMA® is for the treatment of adult patients with relapsed or refractory multiple myeloma after four or more prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody. A supplemental BLA supporting a new indication for the treatment of adult patients with relapsed or refractory multiple myeloma who have received an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody and a new recommended dose range of 300 to 510 x 10^6 CAR-positive T-cells was approved by the FDA on April 4, 2024. The route of administration is intravenous infusion, and ABECMA® is for autologous use. In terms of packaging, ABECMA® is supplied in one or more infusion bag(s) containing a frozen suspension of genetically modified autologous T-cells in 5% dimethyl sulfoxide. Each infusion bag of ABECMA® is individually packaged in a metal cassette.

CMS Final HCPCS Coding Decision[2]

Revise existing HCPCS Level II code Q2055, “Idecabtagene vicleucel, up to 460 million autologous b-cell maturation antigen (bcma) directed car-positive t cells, including leukapheresis and dose preparation procedures, per therapeutic dose” to instead read Q2055, “Idecabtagene vicleucel, up to 510 million autologous b-cell maturation antigen (bcma) directed car-positive t cells, including leukapheresis and dose preparation procedures, per therapeutic dose.”

Effective April 4, 2024

[2] Revised on April 25, 2024 to update the long descriptor for Q2055 with an effective April 4, 2024.

APHEXDA™ - HCP23092829FLC

Topic/Issue

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

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

Summary of Applicant's Submission

BioLineRx, Ltd. submitted a request to establish a new HCPCS Level II code to identify APHEXDA™ (motixafortide). APHEXDA™ was approved by the Food and Drug Administration (FDA) under a new drug application (NDA) on September 8, 2023. APHEXDA™ is a hematopoietic stem cell mobilizer indicated for use in combination with filgrastim (G-CSF) to mobilize hematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in patients with multiple myeloma. For APHEXDA™, the recommended dosage is 1.25 mg/kg actual body weight, administered via subcutaneous injection 10 to 14 hours prior to initiation of apheresis. If medically necessary, a second dose of APHEXDA™ can be administered 10 to 14 hours prior to a third apheresis. APHEXDA™ is packaged in single use vials of 62 mg as a lyophilized powder in a single-dose vial for reconstitution prior to patient administration.

CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code J2277, "Injection, motixafortide, 0.25 mg"

TOFIDENCE™ - HCP230930EXAUT

Topic/Issue

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

Applicant's suggested language: QXXXX, “Injection, tocilizumab-bavi, biosimilar (tofidence) for intravenous use, 1 mg”

Summary of Applicant's Submission

Biogen Inc. submitted a request to establish a new HCPCS Level code to identify TOFIDENCE™ (tocilizumab-bavi). TOFIDENCE™ was approved by the Food and Drug Administration (FDA) under the Biologics License Application (BLA) pathway on September 29, 2023. It is approved as a biosimilar to ACTEMRA® (tocilizumab). TOFIDENCE™ is indicated for treatment of patients with rheumatoid arthritis (RA), polyarticular juvenile idiopathic arthritis (pJIA), and systemic juvenile idiopathic arthritis (sJIA). For patients with RA, the recommended starting dose is 4 mg per kg every 4 weeks followed by an increase to 8 mg per kg every 4 weeks based on clinical response, but doses exceeding 800 mg per infusion are not recommended. For patients with pJIA, the recommended dose is 8 mg per kg or 10mg per kg every 4 weeks. For patients with sJIA, the recommended dose is 8 mg per kg or 12mg per kg every 2 weeks. TOFIDENCE™ is supplied in single-dose vials containing 80 mg/4 mL, 200 mg/10 mL, or 400 mg/20 mL for further dilution prior to intravenous infusion.

CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code Q5133, “Injection, tocilizumab-bavi (tofidence), biosimilar, 1 mg”

DAXXIFY™ - HCP230922DBN27

Topic/Issue

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

Applicant's suggested language: JXXXX, “daxibotulinumtoxinA-lanm, for injection 0.1mL”

Summary of Applicant's Submission

Revance Therapeutics submitted a request to establish a new HCPCS Level code to identify DAXXIFY™ (daxibotulinumtoxinA-lanm). DAXXIFY™ was approved by the Food and Drug Administration (FDA) under a Biologics License Application (BLA) on September 7, 2022, and a supplemental BLA on August 11, 2023. The original indication for DAXXIFY™ is for adults with glabellar lines, which is an aesthetics indication; and the newer indication is to treat adults with cervical dystonia (CD). For CD, the recommended dose is 125 units to 250 units given intramuscularly as a divided dose among affected muscles. DAXXIFY™ is a sterile lyophilized powder supplied in a single-dose vial containing 50 units or 100 units.

CMS Final HCPCS Coding Decision

1. Establish a new HCPCS Level II code J0589, “Injection, daxibotulinumtoxina-lanm, 1 unit”

   Effective April 1, 2024

2. Discontinue HCPCS Level II code C9160, “Injection, daxibotulinumtoxina-lanm, 1 unit”

   Effective March 31, 2024

ELFREXIO™ - HCP230922GDMUD

Topic/Issue

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

Applicant's suggested language: JXXXX, "Injection, elranatamab-bcmm, 1 mg"

Summary of Applicant's Submission

Pfizer, Inc. submitted a request to establish a new HCPCS Level II code to identify ELREXFIO™ (elranatamab-bcmm). ELFREXIO™ was approved by the Food and Drug Administration (FDA) under the Biologics License Application (BLA) pathway on August 14, 2023. ELREXFIO™ is a bispecific B-cell maturation antigen (BCMA)-directed CD3 T-cell engager. ELREXFIO™ is 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. ELFREXIO™ binds BCMA on plasma cells, plasma blasts, and multiple myeloma cells and CD3 on T-cells leading to cytolysis of the BCMA-expressing cells. ELFREXIO™ activated T-cells, caused proinflammatory cytokine release, and resulted in multiple myeloma cell lysis. Step-up dose on day 1 of 12 mg and step-up on day 4 of 32 mg may be administered in the hospital outpatient or inpatient setting. The full treatment dose of 76 mg weekly, from week 2 to week 24, is administered in the hospital outpatient setting. For patients who have received at least 24 weeks of treatment with ELREXFIO™ and have achieved a response, the 76 mg dose interval should transition to an every-2-week schedule starting on week 25. Treatment should continue with ELREXFIO™ 76 mg until disease progression or unacceptable toxicity. ELREXFIO™ is administered via subcutaneous injection only. ELREXFIO™ should be administered by a qualified healthcare professional. Pre-treatment medications should be administered prior to each dose in the ELREXFIO™ step-up dosing schedule. ELREXFIO™ is supplied at a concentration of 40 mg/mL in either 76 mg/1.9 mL or 44 mg/1.1 mL single-dose vials.

CMS Final HCPCS Coding Decision

1. Establish a new HCPCS Level II code J1323, "Injection, elranatamab-bcmm, 1 mg"

   Effective April 1, 2024

2. Discontinue HCPCS Level II code C9165, "Injection, elranatamab-bcmm, 1 mg"

   Effective March 31, 2024

ENTYVIO® - HCP2309291G1UY

Topic/Issue

Request to revise an existing HCPCS Level II code J3380, “Injection, vedolizumab, 1 mg” to identify ENTYVIO®.

Applicant’s suggested language: J3380, “injection, vedolizumab, intravenous, 1 mg”

Summary of Applicant's Submission

Takeda Pharmaceuticals America, Inc. submitted a request to revise an existing HCPCS Level II code J3380, “Injection, vedolizumab, 1 mg” to identify ENTYVIO® (vedolizumab). ENTYVIO® was approved by the Food and Drug Administration (FDA) under Biologics License Application (BLA) pathway on May 20, 2014. ENTYVIO® is a humanized monoclonal antibody designed to specifically antagonize the alpha4beta7 integrin, inhibiting the binding of alpha4beta7 integrin to intestinal mucosal addressin cell adhesion molecule 1 (MAdCAM-1), but not vascular cell adhesion molecule 1 (VCAM-1). ENTYVIO® intravenous (IV) is indicated in adults for the treatment of moderately to severely active ulcerative colitis (UC) and moderately to severely active Crohn's disease. The recommended dosage is 300 mg administered via a 30-minute intravenous infusion at 0, 2 and 6 weeks and then thereafter every 8 weeks. It is packaged in an individual carton containing a 300 mg single-dose vial. The current HCPCS Level II code and descriptor were first effective on January 1, 2016. ENTYVIO® injection, for subcutaneous use and ENTYVIO® PEN injection, for subcutaneous use (referred to collectively as ENTYVIO® SC) were approved by the FDA on September 27, 2023. ENTYVIO® SC is packaged in an individual carton as either a single-dose prefilled syringe with needle safety device or a single-dose prefilled pen that contains 108 mg/0.68 mL solution. Both dosage forms are for use only in adults with UC in clinical response or remission after at least two initial doses of ENTYVIO® IV. The recommended ENTYVIO® SC maintenance dosage in UC is 108 mg administered every two weeks. The ENTYVIO® SC BLA (761133) is separate from the ENTYVIO® IV BLA (125476). This request is to revise the descriptor for HCPCS Level II code J3380 to make clear that this HCPCS Level II code is specific to ENTYVIO® IV by distinguishing it from ENTYVIO® SC.

CMS Final HCPCS Coding Decision

CMS is approving the applicant’s request to revise existing HCPCS Level II code J3380, to make clear that this HCPCS Level II code is specific to ENTYVIO® IV by distinguishing it from ENTYVIO® SC, because each of these products is approved under its own BLA, 125476 and 761133 respectively.

Revise existing HCPCS Level II code J3380, “Injection, vedolizumab, 1 mg” to read, “Injection, vedolizumab, intravenous, 1 mg”

HEPZATO - HCP230929E3F4W

Topic/Issue

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

Applicant's suggested language: XXXXX, “Injection, melphalan (HEPZATO), 1 mg”

Summary of Applicant's Submission

Delcath Systems Inc. submitted a request to establish a new HCPCS Level II code to identify HEPZATO (melphalan). HEPZATO™ KIT was approved by the Food and Drug Administration (FDA) under a 505(b)(2) New Drug Application (NDA) on August 14, 2023. HEPZATO™ KIT consists of melphalan (HEPZATO) for injection and the hepatic delivery system (HDS). HEPZATO is an alkylating drug indicated as a liver-directed treatment for adult patients with uveal melanoma with unresectable hepatic metastases affecting less than 50% of the liver and no extrahepatic disease, or extrahepatic disease limited to the bone, lymph nodes, subcutaneous tissues, or lung that is amenable to resection or radiation. The HDS is used to perform percutaneous hepatic perfusion (PHP), an intensive local hepatic chemotherapy procedure in which melphalan is delivered intra-arterially to the liver with simultaneous extracorporeal filtration of hepatic venous blood return (hemofiltration). The HEPZATO™ KIT allows for isolation of the hepatic arterial inflow and venous outflow, which allows melphalan to be delivered directly to unresectable liver metastases, while sparing healthy liver tissue. Patients will receive up to 6 treatments. The recommended dose is 3 mg/kg based on ideal body weight, with a maximum absolute dose of 220 mg during a single HEPZATO treatment. The drug is infused over 30 minutes followed by a 30-minute washout period. The HEPZATO™ KIT, including HEPZATO (melphalan) for injection for intra-arterial use with the HDS, is FDA approved and sold as a co-packaged single kit. There is a single National Drug Code number for the entire kit. HEPZATO includes 50 mg freeze-dried (lyophilized) melphalan powder per vial in 5 single dose vials, intended for reconstitution with the supplied diluents. HEPZATO™ KIT will come in two sizes, 50 mm and 62 mm. These lengths describe the distance between the balloons on the double balloon catheter. Melphalan, the drug constituent part of the combination product, confers the primary mode of action. Existing melphalan hydrochloride is FDA approved at 0.25 mg/kg via intravenous infusion for patients with multiple myeloma and is not substitutable for the melphalan hydrochloride in the HEPZATO™ KIT which is approved at 3.0 mg/kg via intraarterial delivery for patients with metastatic ocular melanoma.

CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code J9248, “Injection, melphalan (hepzato), 1 mg”

RYKINDO® - HCP23092711Y54

Topic/Issue

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

Applicant's suggested language: JXXXX, “Injection, risperidone, (RYKINDO), 0.5 mg”

Summary of Applicant's Submission

Luye Pharma USA, Ltd submitted a request to establish a new HCPCS Level II code to identify RYKINDO® (risperidone). RYKINDO® was approved by the Food and Drug Administration (FDA) under a 505(b)(2) New Drug Application (NDA) on January 13, 2023. RYKINDO® is an atypical antipsychotic for extended-release injectable suspension, for intramuscular use. RYKINDO® is indicated for the treatment of adults with schizophrenia, and as a monotherapy or adjunctive therapy to lithium or valproate for the maintenance treatment of adults with bipolar I disorder. RYKINDO® is a monoaminergic antagonist. RYKINDO® extended-release injectable suspension, for intramuscular use is, when fully mixed, a white suspension, available in strengths of 12.5 mg, 25 mg, 37.5 mg, or 50 mg. RYKINDO® should be administered every 2 weeks by intramuscular gluteal injection. Each injection should be administered by a health care professional. RYKINDO® is provided as a single-dose kit consisting of a vial containing a white to almost white powder, a pre-filled syringe containing 2 mL of a colorless, clear diluent, a vial adapter, and a needle.

CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code J2801, “Injection, risperidone (rykindo), 0.5 mg”

FOCINVEZ™ - HCP2309291Y73D

Topic/Issue

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

Applicant's suggested language: JXXXX, "Injection, fosaprepitant (amneal), not therapeutically equivalent to J1453, per 1mg"

Summary of Applicant's Submission

Amneal Pharmaceuticals, Inc. submitted a request to establish a new HCPCS Level II code to identify FOCINVEZ™ (fosaprepitant injection). FOCINVEZ™ was approved by the Food and Drug Administration (FDA) under a 505(b)(2) New Drug Application (NDA) on August 22, 2023. FOCINVEZ™ is a single-dose, ready-to-use formulation of fosaprepitant injection indicated for use in adults and pediatric patients 6 months of age and older, in combination with other antiemetic agents, for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy (HEC) including high-dose cisplatin and with initial and repeat courses of moderately emetogenic cancer chemotherapy (MEC). FOCINVEZ™ is supplied as a clear and colorless 150 mg per 50 mL solution in a single-dose glass vial that is ready-to-use for intravenous infusion, and dilution is not required. FOCINVEZ™ is administered approximately 30 minutes prior to chemotherapy. In adults, the recommended dose of FOCINVEZ™ is 150 mg, which is the entire volume of the single-dose vial (50 mL), administered over 20 to 30 minutes. In pediatrics, the volume to be administered from the injection vial is based on the required dose per the patient’s age and/or weight in kilograms (kg). The recommended dosage for pediatrics is 150 mg administered over 30 minutes for patients ages 12 years to 17 years; 4 mg/kg administered over 60 minutes for patients ages 2 years to less than 12 years; or 5 mg/kg administered over 60 minutes for patients ages 6 months to less than 12 years.

CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code J1434, “Injection, fosaprepitant (focinvez), 1 mg”

Melphalan Hydrochloride Injection - HCP230928M647F

Topic/Issue

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

Applicant's suggested language: JXXXX, “Melphalan hydrochloride injection (apotex) 90mg/ml”

Summary of Applicant's Submission

Apotex submitted a request to establish a new HCPCS Level II code to identify Melphalan Hydrochloride Injection. Melphalan Hydrochloride Injection was approved by the Food and Drug Administration (FDA) under a 505(b)(2) New Drug Application (NDA) on August 18, 2023. Melphalan Hydrochloride Injection is indicated for the palliative treatment of patients with multiple myeloma for whom oral therapy is not appropriate. The recommended dosage is 16 mg/m^2 administered intravenously over 15 to 20 minutes at 2-week intervals for 4 doses, then, after adequate recovery from toxicity, at 4-week intervals. Melphalan Hydrochloride Injection is supplied as a clear colorless to yellow solution in a carton containing one 90 mg per 1 mL amber glass multiple-dose vial for dilution.

CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code J9249, “Injection, melphalan (apotex), 1 mg”

Cyclophosphamide Injection - HCP230929Y89KX

Topic/Issue

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

Applicant's suggested language: JXXXX, “Injection, cyclophosphamide (sandoz), 100mg”

Summary of Applicant's Submission

Sandoz Inc. submitted a request to establish a new HCPCS Level II code to identify cyclophosphamide injection. Cyclophosphamide injection was approved by the Food and Drug Administration (FDA) under a 505(b)(2) New Drug Application (NDA) on September 12, 2023. Cyclophosphamide injection is indicated for the treatment of adult patients with malignant diseases, including malignant lymphomas: Hodgkin’s lymphoma, lymphocytic lymphoma, mixed-cell type lymphoma, histiocytic lymphoma, Burkitt’s lymphoma; multiple myeloma, leukemias, mycosis fungoides, neuroblastoma, adenocarcinoma of ovary, retinoblastoma, breast carcinoma. This cyclophosphamide product is not indicated for use in pediatric patients due to the alcohol and propylene glycol content in this product. Cyclophosphamide injection is administered intravenously. Cyclophosphamide injection is supplied as a sterile ready-to-dilute, clear, colorless to pale-yellow solution in a multiple-dose vial available as 500 mg/5 mL, 1,000 mg/10 mL, and 2,000 mg/20 mL.

CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code J9074, “Injection, cyclophosphamide (sandoz), 5 mg”

BRIXADI™ - HCP230524M0HG0

Topic/Issue

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

Applicant's suggested language:

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

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

Summary of Applicant's Submission

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

CMS Final HCPCS Coding Decision[3]

CMS has reviewed its Q3 2023 published determination to establish one HCPCS Level II code for BRIXADI™. After further consideration of the complexities related to the weekly and monthly dosing under the same NDA, which differs from most other drugs that are weight-based in their dosing, CMS will finalize the decision to:

1. Establish a new HCPCS Level II code J0577, "Injection, buprenorphine extended-release (brixadi), less than or equal to 7 days of therapy"

   Effective April 1, 2024

2. Establish a new HCPCS Level II code J0578, "Injection, buprenorphine extended release (brixadi), greater than 7 days and up to 28 days of therapy"

   Effective April 1, 2024

3. Discontinue HCPCS Level II code J0576, "Injection, buprenorphine extended-release (brixadi), 1 mg"

   Effective March 31, 2024

Because all versions of a single source drug or biological product (or National Drug Codes (NDCs)) marketed under the same FDA approval number (for example, NDA or Biologics License Application (BLA), including supplements) are considered the same drug or biological for purposes of payments made under section 1847A of the Social Security Act, the payment limits for both J0577 and J0578 will be calculated using all the NDCs marketed under the applicable FDA approval.

[3] Revised on March 4, 2024, to update the code descriptor for HCPCS Level II code J0578.

IZERVAY™ - HCP2309123TW9W

Topic/Issue

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

Applicant's suggested language: JXXXX, “Injection, avacincaptad pegol intravitreal solution, 0.1 mL”

Summary of Applicant's Submission

Iveric Bio submitted a request to establish a new HCPCS Level II code to identify IZERVAY™. IZERVAY™ was approved by the Food and Drug Administration (FDA) under a New Drug Application (NDA) on August 4, 2023. IZERVAY™ is indicated for the treatment of geographic atrophy secondary to age-related macular degeneration (AMD). IZERVAY™ contains avacincaptad pegol sodium, a complement inhibitor. Avacincaptad pegol is a ribonucleic acid (RNA) aptamer, covalently bound to an approximately 43-kiloDalton branched polyethylene glycol molecule. IZERVAY™ is a sterile, clear to slightly opalescent, colorless to slightly yellowish solution. The recommended dose for IZERVAY™ is 2 mg/ 0.1 mL (20 mg/mL single-dose vial) administered by intravitreal injection to each affected eye once monthly (approximately every 28 plus or minus 7 days) for up to 12 months. Each dose of 0.1 mL solution contains 2 mg avacincaptad pegol (oligonucleotide basis), 0.198 mg dibasic sodium phosphate heptahydrate, 0.0256 mg monobasic sodium phosphate monohydrate, and 0.83 mg sodium chloride. IZERVAY™ is formulated in water for injection, with a target potential of hydrogen (pH) of 7.3. IZERVAY™ does not contain an anti-microbial preservative. Following a single dose of avacincaptad pegol, maximum avacincaptad pegol plasma concentrations (Cmax) are estimated to occur approximately 7 days post-dose and mean coefficient of variation (CV%) free avacincaptad pegol plasma Cmax is estimated to be 68.4 ng/mL (57.8%) in patients with neovascular AMD (nAMD). Based on a population pharmacokinetic analysis of patients with nAMD, predicted steady state avacincaptad pegol Cmax is 83.9 ng/mL after monthly intravitreal administration of avacincaptad pegol 2 mg. In humans, avacincaptad pegol plasma concentrations are predicted to be approximately 7,000-fold lower than vitreal concentrations.

CMS Final HCPCS Coding Decision[4]

1. Establish a new HCPCS Level II code J2782, “Injection, avacincaptad pegol, 0.1 mg”

   Effective April 1, 2024

2. Discontinue HCPCS Level II code C9162, “Injection, avacincaptad pegol, 0.1 mg”

   Effective March 31, 2024

[4] Revised on March 4, 2024, to correct the code description for HCPCS Level II code J2782.

YCANTH™ - HCP2308253MDW8

Topic/Issue

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

Applicant's suggested language: JXXXX, “Cantharidin for topical administration, 0.7%, per 3.2 mg single-use applicator”

Summary of Applicant's Submission

Verrica Pharmaceuticals Inc. submitted a request to establish a new HCPCS Level II code to identify YCANTH™. YCANTH™ was approved by the Food and Drug Administration (FDA) under a New Drug Application (NDA) on July 21, 2023. YCANTH™ is indicated for the topical treatment of molluscum contagiosum in adult and pediatric patients 2 years of age and older. YCANTH™ contains a proprietary formulation of cantharidin delivered via a single-use applicator, allowing for precise topical dosing and targeted administration. YCANTH™ topical solution is a light violet to dark purple, slightly viscous liquid for topical administration. Each mL of YCANTH™ topical solution contains 7 mg of active ingredient cantharidin (0.7%), a lipophilic compound. Cantharidin is a vesicant. The pharmacodynamics of cantharidin in the treatment of molluscum contagiosum and its mechanism of action are unknown. YCANTH™ is administered topically by a healthcare professional every 3 weeks as needed. No more than two YCANTH™ applicators can be used during a single treatment session. All healthcare professionals should receive a training prior to preparation and administration of YCANTH™. YCANTH™ is supplied as a topical solution in a sealed glass ampule contained within a single-use applicator and enclosed in a protective paperboard sleeve. Each ampule of YCANTH™ contains approximately 0.45 mL of 0.7% cantharidin solution. Each YCANTH™ single-use applicator contains 3.2 mg of cantharidin (0.7%). YCANTH™ is available in a carton of 6 single-use applicators and a carton of 12 single-use applicators.

CMS Final HCPCS Coding Decision

1. Establish a new HCPCS Level II code J7354, “Cantharidin for topical administration, 0.7%, single unit dose applicator (3.2 mg)”

   Effective April 1, 2024

2. Discontinue HCPCS Level II code C9164, “Cantharidin for topical administration, 0.7%, single unit dose applicator (3.2 mg)”

   Effective March 31, 2024

American Amnion™ - HCP231002YT3ER

Topic/Issue

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

Applicant's suggested language: XXXXX, “American Amnion™, per square centimeter”

Summary of Applicant's Submission

BioStem Technologies submitted a request to establish a new HCPCS Level II code to identify American Amnion™. American Amnion™ is a decellularized human amniotic allograft product derived from placental tissues are sterilized by e-beam irradiation. American Amnion™ is intended for use as a protective covering for soft tissue wounds. American Amnion™ is dehydrated, packaged in different size sheets and terminally sterilized by e-beam irradiation.

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, “American Amnion, when intended for use as a protective barrier from the surrounding environment for acute and chronic wounds including partial and full thickness 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 Q4307, "American amnion, per square centimeter"

This coding decision applies to the American Amnion™ product described in the application and accompanying FDA TRG Letter dated August 28, 2023, when intended for use as a “protective barrier from the surrounding environment for acute and chronic wounds including partial and full thickness wounds.”

American Amnion AC™ - HCP231002BLWWV

Topic/Issue

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

Applicant's suggested language: XXXXX, “American Amnion AC™, per square centimeter”

Summary of Applicant's Submission

BioStem Technologies submitted a request to establish a new HCPCS Level II code to identify American Amnion AC™. American Amnion AC™ is a decellularized human amniotic and chorionic allograft product derived from placental tissues are sterilized by e-beam irradiation. American Amnion AC™ is intended for use as a protective covering for soft tissue wounds. American Amnion AC™ is dehydrated, packaged in different size sheets and terminally sterilized by e-beam irradiation.

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, “American Amnion AC™, when intended for use as a protective barrier from the surrounding environment for acute and chronic wounds including partial and full thickness 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 Q4306, “American amnion ac, per square centimeter”

This coding decision applies to the American Amnion AC™ product described in the application and accompanying FDA TRG Letter dated August 28, 2023, when intended for use as a “protective barrier from the surrounding environment for acute and chronic wounds including partial and full thickness wounds.”

American Amnion AC Tri-Layer™ - HCP231002755DK

Topic/Issue

Request to establish a new HCPCS Level II code to identify American Amnion AC Tri-Layer™.

Applicant's suggested language: XXXXX, “American Amnion AC Tri-Layer™, per square centimeter”

Summary of Applicant's Submission

BioStem Technologies submitted a request to establish a new HCPCS Level II code to identify American Amnion AC Tri-Layer™. Amnion AC Tri-Layer™ is a decellularized human amniotic, intermediate, and chorionic allograft product derived from placental tissues are sterilized by e-beam irradiation. American Amnion AC Tri-Layer™ is intended for use as a protective covering for soft tissue wounds. American Amnion AC Tri-Layer™ is dehydrated, packaged in different size sheets and terminally sterilized by e-beam irradiation.

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, American Amnion AC Tri Layer™, when intended for use as a “protective barrier from the surrounding environment for acute and chronic wounds including partial and full thickness 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 Q4305, "American amnion ac tri-layer, per square centimeter"

This coding decision applies to the American Amnion AC Tri-Layer™ product described in the application and accompanying FDA TRG Letter dated August 28, 2023, when intended for use as a “protective barrier from the surrounding environment for acute and chronic wounds including partial and full thickness wounds.”

Procenta®- HCP231002TYWBY

Topic/Issue

Request to revise existing HCPCS Level II code Q4244, “Procenta, per 200 mg” to identify other various dosage options available for Procenta®.

Applicant's suggested language: Q4244, “Procenta® 100mg, coverage ≤2cm2; Procenta® 200mg, coverage >2cm2 up to 6 cm2; Procenta® 300mg, coverage >6 cm2 up to 10 cm2; Procenta® 400mg, coverage >10 cm2 up to 14 cm2”

Summary of Applicant's Submission

Lucina BioSciences, LLC submitted a request to revise existing HCPCS Level II code Q4244, “Procenta, per 200 mg” to identify other dosage options for Procenta®. Procenta® is a sterile, human placental tissue allograft, which is non-viable, hydrated, fully conformable, and intended to serve as a cover, to offer protection from the surrounding environment, or to retain fluid when applied to soft tissue defects. Existing HCPCS Level II code Q4244 established in 2020 for Procenta® pre-dates receipt by Lucina BioSciences of the Final Response Letter from Food and Drug Administration’s (FDA’s) Tissue Reference Group (TRG) on August 19, 2020. This revision is to ensure that the language in the HCPCS Level II code is consistent with that of the TRG Final Response Letter.

CMS Final HCPCS Coding Decision

1. Establish a new HCPCS Level II code Q4310, “Procenta, per 100 mg”

   Effective April 1, 2024

2. Discontinue HCPCS Level II code Q4244, “Procenta, per 200 mg”

   Effective March 31, 2024

This coding decision applies to the Procenta® product described in the application and accompanying FDA TRG Letter dated August 19, 2020, when intended to “serve as a cover, to offer protection from the surrounding environment, or to retain fluid.”

Sanopellis - HCP2309260RN86

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 HCPCS Level II code to identify Sanopellis. Sanopellis, an amniotic membrane product used as a wound covering and to act as a barrier for full and partial-thickness, chronic and acute wounds.

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, “Sanopellis product, when intended for use to serve as a covering and a barrier”, appears to meet the criteria for regulation solely under section 361 of the Public Health Service (PHS) Act and the regulations in 21 CFR part 1271. As a result of our review of the TRG’s feedback, CMS has decided to:

Establish a new HCPCS Level II code Q4308, "Sanopellis, per square centimeter"

This coding decision applies to the Sanopellis product described in the application and accompanying FDA TRG Letter dated November 29, 2021, when intended for use as a “covering and a barrier.”

VIA Matrix - HCP230929HVGKV

Topic/Issue

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

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

Summary of Applicant's Submission

VIVEX Biologics submitted a request to establish a new HCPCS Level II code to identify VIA Matrix. VIA Matrix is a semi-transparent, collagenous membrane allograft obtained with consent from healthy mothers during cesarean section delivery. The VIA Matrix amnion allograft is a full thickness amnion-chorion allograft. The intended use of VIA Matrix includes the management of wounds, to protect wounds or burns from the surrounding environment to acute and chronic wounds.

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, “VIA Matrix, when intended for use to protect wounds or burns from the surrounding environment to acute and chronic wounds,” appears to meet the criteria for regulation solely under section 361 of the Public Health Service (PHS) Act and the regulations in 21 CFR part 1271. As a result of our review of the TRG’s feedback, CMS has decided to:

Establish a new HCPCS Level II code Q4309, "Via matrix, per square centimeter"

This coding decision applies to the Via Matrix product described in the application and accompanying FDA TRG Letter dated September 14, 2023, when intended for use “to protect wounds or burns from the surrounding environment to acute and chronic wounds.”

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) New Drug Application (NDA) or the Biologics License Application (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[5], 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 "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-National Drug Code (NDC) crosswalk[6] to identify the correct billing and payment code for each applicable product.

CMS Final HCPCS Coding Decision

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

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

[5] 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.

[6] 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	Action	Long Descriptor
J0208	Revise	Injection, sodium thiosulfate (pedmark), 100 mg
J0209	Add	Injection, sodium thiosulfate (hope), 100 mg
J0612	Revise	Injection, calcium gluconate, not otherwise specified, 10 mg
J0613	Revise	Injection, calcium gluconate (wg critical care) not therapeutically equivalent to J0612, 10 mg
J0650	Add	Injection, levothyroxine sodium, not otherwise specified, 10 mcg
J0651	Add	Injection, levothyroxine sodium (fresenius kabi) not therapeutically equivalent to J0650, 10 mcg
J0652	Add	Injection, levothyroxine sodium (hikma) not therapeutically equivalent to J0650, 10 mcg
J1010	Add	Injection, methylprednisolone acetate, 1 mg
J1020*	Delete	Injection, methylprednisolone acetate, 20 mg
J1030*	Delete	Injection, methylprednisolone acetate, 40 mg
J1040*	Delete	Injection, methylprednisolone acetate, 80 mg
J1840*	Delete	Injection, kanamycin sulfate, up to 500 mg
J1850*	Delete	Injection, kanamycin sulfate, up to 75 mg
J3424[7]	Add	Injection, hydroxocobalamin, intravenous, 25 mg
J2919	Add	Injection, methylprednisolone sodium succinate, 5 mg
J2920*	Delete	Injection, methylprednisolone sodium succinate, up to 40 mg
J2930*	Delete	Injection, methylprednisolone sodium succinate, up to 125 mg
J9073	Add	Injection, cyclophosphamide (ingenus), 5 mg
J9070*	Delete	Cyclophosphamide, 100 mg
J9075	Add	Injection, cyclophosphamide, not otherwise specified, 5mg
J9250*	Delete	Methotrexate sodium, 5 mg

* The effective date for the discontinuation of this code is March 31, 2024.

[7] Revised on February 16, 2024 to update the dose descriptor to represent the least common denominator.