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

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

First Quarter, 2024 HCPCS Coding Cycle

This document presents a summary of each HCPCS Level II code application and CMS' coding decision for each application processed in CMS' First Quarter 2024 Drug and Biological HCPCS Level II 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 July 1, 2024, unless otherwise indicated.

The HCPCS Level II coding decisions below will also be included in the July 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 First Quarter 2024 Drug and Biological HCPCS Applications.

WEZLANA™ (SC)- HCP231222H2NEF

Topic/Issue

Request to establish a new HCPCS Level II code to identify WEZLANA™ subcutaneous injection (SC).

Applicant's suggested language: QXXXX, “Ustekinumab-auub (wezlana), biosimilar, for subcutaneous injection, 1 mg”

Summary of Applicant's Submission

Amgen submitted a request to establish a new HCPCS Level II code to identify WEZLANA™ (SC) (ustekinumab-auub). WEZLANA™ (SC) was approved by the Food and Drug Administration (FDA) under the Biologics License Application (BLA) pathway on October 31, 2023. WEZLANA™ (SC) for subcutaneous injection is a human interleukin -12 and -23 antagonist. WEZLANA™ (SC) is indicated for the treatment of adult patients with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy; active psoriatic arthritis; moderately to severely active Crohn’s disease; and moderately to severely active ulcerative colitis. WEZLANA™ (SC) is also indicated for the treatment of pediatric patients 6 years and older with moderate to severe plaque psoriasis, who are candidates for phototherapy or systemic therapy and active psoriatic arthritis. The recommended dosage of WEZLANA™ (SC) varies based on indication as well as weight of patient. WEZLANA™ (SC) is packaged in a 45 mg/0.5 mL single-dose vial, a 45 mg/0.5mL single-dose prefilled syringe and a 90 mg/mL single-dose prefilled syringe. A WEZLANA™ intravenous infusion formulation was approved under a separate BLA and is the subject of a separate HCPCS Level II code application.

CMS Final HCPCS Coding Decision

CMS is approving the applicant’s request to establish a new HCPCS Level II code to identify WEZLANA™ (SC), as it is approved under its own unique BLA, 761285, and to distinguish it from WEZLANA™ (IV) which also has a unique BLA, 761331, and is the subject of a separate HCPCS Level II code application.

Establish a new HCPCS Level II code Q5137, “Injection, ustekinumab-auub (wezlana), biosimilar, subcutaneous, 1 mg”

WEZLANA™ (IV) - HCP23122240QKC

Topic/Issue

Request to establish a new HCPCS Level II code to identify WEZLANA™ intravenous infusion (IV).

Applicant's suggested language: QXXXX, “Ustekinumab-auub (wezlana), biosimilar, for intravenous injection, 1 mg”

Summary of Applicant's Submission

Amgen submitted a request to establish a new HCPCS Level II code to identify WEZLANA™ (IV) (ustekinumab-auub). WEZLANA™ (IV) was approved by the Food and Drug Administration (FDA) under the Biologics License Application (BLA) pathway on October 31, 2023. WEZLANA™ (IV) for intravenous infusion is a human interleukin -12 and -23 antagonist. WEZLANA™ (IV) is indicated for the treatment of adult patients with moderately to severely active Crohn’s disease and moderately to severely active ulcerative colitis. A single IV induction dose of WEZLANA™ (IV) is administered using a weight-based dosage regimen (260 mg in patients up to 55 kg, 390 mg in patients greater than 55 kg to 85 kg, and 520 mg in patients greater than 85 kg). Following the initial single IV infusion, a maintenance regimen is recommended with WEZLANA™ (SC) for subcutaneous injection. WEZLANA™ (IV) is packaged in a single-dose vial (130 mg/26 mL). A WEZLANA™ subcutaneous injection was approved under a separate BLA and is the subject of a separate HCPCS Level II code application.

CMS Final HCPCS Coding Decision

CMS is approving the applicant’s request to establish a new HCPCS Level II code to identify WEZLANA™ (IV), as it is approved under its own unique BLA, 761331, and to distinguish it from WEZLANA™ (SC) which also has a unique BLA, 761285, and is the subject of a separate HCPCS Level II code application.

Establish a new HCPCS Level II code Q5138, “Injection, ustekinumab-auub (wezlana), biosimilar, intravenous, 1 mg”

LOQTORZI™ - HCP231205KTPFY

Topic/Issue

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

Applicant's suggested language: JXXXX, “Injection, toripalimab-tpzi, 1 mg”

Summary of Applicant's Submission

Coherus BioSciences submitted a request to establish a new HCPCS Level II code to identify LOQTORZI™ (toripalimab-tpzi) injection. LOQTORZI™ was approved by the Food and Drug Administration (FDA) under the under Biologics License Application (BLA) pathway on October 27, 2023. LOQTORZI™ is indicated in combination with cisplatin and gemcitabine, for first-line treatment of adults with metastatic or with recurrent locally advanced nasopharyngeal carcinoma (NPC) and as a single agent for the treatment of adults with recurrent unresectable or metastatic NPC with disease progression on or after a platinum-containing chemotherapy. LOQTORZI™ is supplied in a carton containing one 240 mg/6 mL (40 mg/mL) single-dose vial. LOQTORZI™ is administered intravenously. The recommended dosage for first-line NPC is 240 mg every three weeks until disease progression, unacceptable toxicity, or up to 24 months. The recommended dosage for recurrent NPC is 3 mg/kg every two weeks until disease progression or unacceptable toxicity.

CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code J3263, “Injection, toripalimab-tpzi, 1 mg”

ZYMFENTRA - HCP2312115CRM0

Topic/Issue

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

The applicant did not submit any suggested language.

Summary of Applicant's Submission

Celltrion USA, Inc. submitted a request to establish a new HCPCS Level II code to identify ZYMFENTRA (infliximab-dyyb). ZYMFENTRA was approved by the Food and Drug Administration (FDA) under the Biologics License Application (BLA) pathway on October 20, 2023. ZYMFENTRA is subcutaneous formulation of the tumor necrosis factor blocker, infliximab, indicated in adults for maintenance treatment of moderate to severe ulcerative colitis or moderate to severe Crohn's disease following a 10-week IV induction of infliximab. Starting at week 10 and thereafter the recommended dosage for maintenance treatment in ulcerative colitis and Crohn's disease is 120 mg subcutaneously once every two weeks. To switch patients who are responding to maintenance therapy with an infliximab product administered intravenously, administer the first subcutaneous dose of ZYMFENTRA in place of the next scheduled intravenous infusion and every two weeks thereafter. ZYMFENTRA is a clear, colorless to pale brown solution available as 120 mg/mL in a single-dose prefilled syringe, 120 mg/mL in a single-dose prefilled syringe with needle shield, and 120 mg/mL in a single-dose prefilled pen.

CMS Final HCPCS Coding Decision[1]

Establish a new HCPCS Level II code J1748, "Injection, infliximab-dyyb (zymfentra), 10 mg"

[1] Revised on April 19, 2024 to account for the drug being a reference drug and not a biosimilar.

OMVOH™ - HCP2311295LNB6

Topic/Issue

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

Applicant's suggested language: JXXXX, “Injection, mirikizumab-mrkz, 300 mg, intravenous”

Summary of Applicant's Submission

ADVI Health, Eli Lilly and Company submitted a request to establish a new HCPCS Level II code to identify OMVOH™ (mirikizumab-mrkz). OMVOH™ was approved by the Food and Drug Administration (FDA) under the Biological License Application (BLA) pathway on October 26, 2023. OMVOH™ is an interleukin-23 antagonist indicated for the treatment of adults with moderately to severely active ulcerative colitis. The recommended induction dosage is 300 mg administered by intravenous infusion over at least 30 minutes at weeks 0, 4, and 8. The recommended maintenance dosage is 200 mg administered by subcutaneous injection (given as two consecutive injections of 100 mg each) at week 12, and every 4 weeks thereafter. OMVOH™ is supplied as one 300 mg/15 mL single-dose vial for intravenous infusion, or two 100 mg/mL single-dose prefilled pens for subcutaneous use.

CMS Final HCPCS Coding Decision

1. Establish a new HCPCS Level II code J2267, “Injection, mirikizumab-mrkz, 1 mg”

   Effective July 1, 2024

2. Discontinue HCPCS Level II code C9168, “Injection, mirikizumab-mrkz, 1 mg”

   Effective June 30, 2024

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 the JA modifier for the intravenous infusion of the drug or billed with the JB modifier for subcutaneous injection of the drug.

ADZYNMA - HCP231220BHN7U

Topic/Issue

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

Applicant's suggested language: JXXXX, “Injection, ADAMTS13, recombinant-krhn, 1 IU”

Summary of Applicant's Submission

Takeda Pharmaceuticals America, Inc. submitted a request to establish a new HCPCS Level II code to identify ADZYNMA (ADAMTS13, recombinant-krhn). ADZYNMA was approved by the Food and Drug Administration (FDA) under the under Biologics License Application (BLA) pathway on November 9, 2023. ADZYNMA is indicated for adult and pediatric patients with congenital thrombotic thrombocytopenic purpura (cTTP) as prophylactic or on-demand enzyme replacement therapy (ERT). ADAMST13 regulates the activity of von Willebrand factor (VWF) by cleaving large and ultra large VWF multimers to smaller units and thereby reducing the platelet binding properties of VWF and its propensity to form microthrombi. The use of ADZYNMA in patients with cTTP is expected to reduce or eliminate the spontaneous formation of VWF platelet microthrombi that leads to platelet consumption and thrombocytopenia, which is a marker of disease activity in patients with cTTP. ADZYNMA administration dose and volume are calculated based on the patient’s body weight using the actual potency (and not the nominal potency) as printed on ADZYNMA vial. It is for intravenous infusion at a rate of 2 to 4 mL per minute. The dosage for prophylactic ERT is 40 IU/kg body weight of ADZYNMA once every other week. Dosing frequency may be adjusted to 40 IU/kg body weight once weekly based on prior prophylactic dosing regimen or clinical response. On-demand ERT with ADZYNMA is used for the treatment of acute TTP events. When used for on demand ERT, ADZYNMA is administered daily until two days after the acute event is resolved. On day 1, 40 IU/kg body weight of ADZYNMA is administered. On day 2, 20 IU/kg body weight of ADZYNMA is administered. And, on day 3 and until two days after the acute event is resolved, 15 IU/kg body weight of ADZYNMA is administered. Each single dose vial of ADZYNMA contains nominally 500 IU or 1500 IU of rADAMTS13 powder.

CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code J7171, “Injection, adamts13, recombinant-krhn, 10 iu”

Ryzneuta™ - HCP231228V2CQ1

Topic/Issue

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

Applicant's suggested language: JXXXX, “Injection, efbemalenograstim alfa-vuxw, 1 mg”

Summary of Applicant's Submission

Acrotech Biopharma submitted a request to establish a new HCPCS Level II code to identify Ryzneuta™ (efbemalenograstim alfa-vuxw). Ryzneuta™ was approved by the Food and Drug Administration (FDA) under the Biological License Application (BLA) pathway on November 16, 2023. Ryzneuta™ is a man-made form of granulocyte colony-stimulating factor (G-CSF). G-CSF is a substance produced by the body. It stimulates the growth of neutrophils, a type of white blood cell important in the body's fight against infection. Ryzneuta™ is a recombinant fusion protein containing human G-CSF and the crystallizable fragment domain of human immunoglobulin G2. It is expressed in and purified from Chinese hamster ovary cell culture. Ryzneuta™ acts on hematopoietic cells by binding to specific cell surface receptors, thereby stimulating proliferation, differentiation, commitment, and end cell functional activation. Ryzneuta™ is indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in adult patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia. Ryzneuta™ is not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation. The recommended dosage of Ryzneuta™ is a single subcutaneous injection of 20 mg administered once per chemotherapy cycle at least 24 hours after cytotoxic chemotherapy. Ryzneuta™ is packaged in a dispensing pack containing one sterile 20 mg/mL clear, colorless, preservative-free solution in a single-dose prefilled syringe.

CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code J9361, “Injection, efbemalenograstim alfa-vuxw, 0.5 mg”

ZYNTEGLO™ - HCP231229C71X3

Topic/Issue

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

Applicant's suggested language: JXXXX, “Betibeglogene autotemcel, per treatment, minimum 5 x 10^6 CD34+ cells/kg”

Summary of Applicant's Submission

bluebird bio, Inc. (bluebird) submitted a request to establish a new HCPCS Level II code to identify ZYNTEGLO™ (betibeglogene autotemcel) suspension, for intravenous (IV) infusion. ZYNTEGLO™ was approved by the Food and Drug Administration (FDA) under the Biological License Application (BLA) pathway on August 17, 2022. ZYNTEGLO™ is an autologous, one-time hematopoietic stem cell-based gene therapy that adds functional copies of a modified β-globin gene, βA-T87Q globin gene, into a beta-thalassemia patient’s own hematopoietic stem cells ex-vivo through transduction of autologous CD34+ cells with BB305 lentiviral vector, to enable the production of a modified functional adult hemoglobin. ZYNTEGLO™ is indicated for the treatment of adult and pediatric patients with beta-thalassemia who require regular red blood cell transfusions. ZYNTEGLO™ is supplied in up to four infusion bags containing a frozen suspension of genetically modified autologous cells, enriched for CD34+ cells. Each bag contains approximately 20 mL. A single dose of ZYNTEGLO™ contains a minimum of 5 x 10^6 CD34+ cells/kg in one to four infusion bags. Each infusion bag is administered via IV infusion over a period of less than 30 minutes.

CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code J3393, “Injection, betibeglogene autotemcel, per treatment”

LYFGENIA™ - HCP231229CVUDD

Topic/Issue

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

Applicant's suggested language: JXXXX, “Lovotibeglogene autotemcel, per treatment, minimum 3 x 10^6 CD34+ cells/kg”

Summary of Applicant's Submission

bluebird bio, Inc. (bluebird) submitted a request to establish a new HCPCS Level II code to identify LYFGENIA™ (lovotibeglogene autotemcel) suspension, for intravenous (IV) infusion. LYFGENIA™ was approved by the Food and Drug Administration (FDA) under the Biological License Application (BLA) pathway on December 8, 2023. LYFGENIA™ is an autologous, one-time hematopoietic stem cell-based gene therapy that adds functional copies of a modified β-globin gene, βA-T87Q globin gene, into patients’ own hematopoietic stem cells ex-vivo through transduction of autologous CD34+ cells with BB305 lentiviral vector, to produce HbAT87Q. LYFGENIA™ is indicated for the treatment of patients 12 years of age or older with sickle cell disease and a history of vaso-occlusive events. LYFGENIA™ is supplied in one to four infusion bags containing a frozen suspension of genetically modified autologous cells, enriched for CD34+ cells. Each bag contains approximately 20 mL. A single dose of LYFGENIA™ contains a minimum of 3 x 10^6 CD34+ cells/kg, in one to four infusion bags. After thawing, each infusion bag is administered via IV infusion over a period of less than 30 minutes.

CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code J3394, “Injection, lovotibeglogene autotemcel, per treatment”

COSENTYX® - HCP23100932U0D

Topic/Issue

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

Applicant's suggested language: JXXXX, “Secukinumab, for intravenous use, per 1 mg”

Summary of Applicant's Submission

Novartis Pharmaceuticals Corporation submitted a request to establish a new HCPCS Level II code to identify COSENTYX® (secukinumab), for intravenous (IV) use. COSENTYX® was approved by the Food and Drug Administration (FDA) under the Biological License Application (BLA) pathway on October 6, 2023. COSENTYX®, is a human interleukin-17A antagonist, and indicated for use in adult patients with active psoriatic arthritis, active ankylosing spondylitis, and active non-radiographic axial spondyloarthritis (nr-axSpA), with objective signs of inflammation. This specific HCPCS Level II request is designed to exclude any possible use associated with the subcutaneous formulations of COSENTYX® that were separately FDA-approved under a unique prior BLA. The recommended IV dosage regimen for COSENTYX® is with a loading dose: 6 mg/kg given at week 0 as a loading dose, followed by 1.75 mg/kg every 4 weeks thereafter (maintenance dosage). COSENTYX® may also be administered without a loading dose: 1.75 mg/kg every 4 weeks. Total doses exceeding 300 mg per infusion are not recommended for the 1.75 mg/kg maintenance dose, with or without a loading dose. COSENTYX® for IV use is supplied in a carton containing one 125 mg/5 mL (25 mg/mL) solution in a single-dose vial for dilution prior to IV infusion. IV administration of COSENTYX® is only for use by a healthcare professional in a healthcare setting.

CMS Final HCPCS Coding Decision

CMS is approving the applicant’s request to establish a new HCPCS Level II code to identify COSENTYX® (secukinumab), for intravenous use, as it is approved under its own unique BLA, 761349, and to distinguish it from COSENTYX® (secukinumab), for subcutaneous use, which also has a unique BLA, 125504.

Establish a new HCPCS Level II code J3247, “Injection, secukinumab, intravenous, 1 mg”

Daptomycin for Injection (room temperature) - HCP240102BF5RA

Topic/Issue

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

Applicant's suggested language: JXXXX, “Injection, daptomycin room temperature (xellia), not therapeutically equivalent to j0878 or j0873, 1 mg”

Summary of Applicant's Submission

Xellia Pharmaceuticals USA, LLC submitted a request to establish a new HCPCS Level II code to identify Daptomycin for Injection (room temperature). Daptomycin for Injection (room temperature) was approved by the Food and Drug Administration (FDA) under a 505(b)(2) New Drug Application (NDA) on January 30, 2023. Daptomycin for Injection (room temperature) contains daptomycin, a lipopeptide antibacterial agent active against gram-positive bacteria. Daptomycin for Injection (room temperature) belongs to the cyclic lipopeptide class of antibacterials. Daptomycin has clinical utility in the treatment of infections caused by aerobic, Gram-positive bacteria. Daptomycin for Injection (room temperature) is indicated in adults and pediatric (1 to 17 years of age) patients for the treatment of complicated skin and skin structure infections; in adults with staphylococcus aureus bloodstream infections (bacteremia) including those with right-sided infective endocarditis; and in pediatric patients (1 to 17 years of age) with staphylococcus aureus bloodstream infections (bacteremia). For adult patients, Daptomycin for Injection (room temperature) is administered by intravenous (IV) injection over a period of 2 minutes, or by IV infusion over a period of 30 minutes. For pediatric patients, Daptomycin for Injection (room temperature) is administered by IV infusion over a period of 30 or 60 minutes. The recommended dosages for Daptomycin for Injection (room temperature) range from 4 mg/kg to 12 mg/kg, depending on the indication and patient population. Daptomycin for Injection (room temperature) is supplied as a sterile, pale yellow to light brown lyophilized powder or cake in a 350 mg or 500 mg single-dose vial for reconstitution.

CMS Final HCPCS Coding Decision

CMS is approving the applicant’s request to establish a new HCPCS Level II code to make clear that this HCPCS Level II code is not therapeutically equivalent to the manufacturer’s refrigerated product. Both products were approved under separate 505(b)(2) NDAs.

Establish a new HCPCS Level II code J0872, “Injection, daptomycin (xellia), unrefrigerated, not therapeutically equivalent to j0878 or j0873, 1 mg”

Daptomycin for Injection (refrigerated) - HCP240102BTFJA

Topic/Issue

Request to revise existing HCPCS Level II code J0873, “Injection, daptomycin (xellia) not therapeutically equivalent to j0878, 1 mg” to identify Daptomycin for Injection (refrigerated).

Applicant's suggested language: J0873, “Injection, daptomycin refrigerated (xellia), not therapeutically equivalent to j0878 or j087X, 1 mg”

Summary of Applicant's Submission

Xellia Pharmaceuticals USA, LLC submitted a request to revise existing HCPCS Level II code J0873 to differentiate Xellia's Daptomycin for Injection (refrigerated) from Xellia's Daptomycin for Injection (room temperature), the latter being the subject of a separate application HCP240102BF5RA. Daptomycin for Injection (refrigerated) was approved by the Food and Drug Administration (FDA) under a 505(b)(2) New Drug Application (NDA) on October 20, 2017. Daptomycin for Injection (refrigerated) and Daptomycin for Injection (room temperature) have their own unique NDAs.

CMS Final HCPCS Coding Decision

CMS is approving the applicant’s request to revise existing HCPCS Level II code J0873, to make clear that this HCPCS Level II code is not therapeutically equivalent to the manufacturer’s new unrefrigerated product. Both products were approved under separate 505(b)(2) NDAs.

Revise existing HCPCS Level II code J0873, “Injection, daptomycin (xellia) not therapeutically equivalent to j0878, 1 mg,” to instead read, “Injection, daptomycin (xellia), not therapeutically equivalent to j0878 or j0872, 1 mg”

PEDMARK® - HCP2401022WL6F

Topic/Issue

Request to revise existing HCPCS Level II code J0208, “Injection, sodium thiosulfate, 100mg” to further identify PEDMARK®.

Applicant's suggested language: J0208, “Injection sodium thiosulfate, (Fennec), not therapeutically equivalent to JXXXX, 100mg”

Summary of Applicant's Submission

Fennec Pharmaceuticals submitted a request to revise existing HCPCS Level II code J0208, “Injection, sodium thiosulfate, 100mg” to further identify PEDMARK®. PEDMARK® was approved by the Food and Drug Administration (FDA) under a 505(b)(2) New Drug Application (NDA) on September 21, 2022. HCPCS Level II code J0208 was assigned to PEDMARK® in April of 2023. The approved orphan indication for PEDMARK® is to reduce the risk of ototoxicity associated with cisplatin in pediatric patients 1 month of age and older with localized, non-metastatic solid tumors. PEDMARK® is delivered via a 15-minute intravenous infusion, following cisplatin infusions that are 1 to 6 hours in duration. The recommended dosage for PEDMARK® is based on surface area according to actual body weight. PEDMARK® is supplied as 12.5 g/100 mL (125 mg/mL) clear, colorless solution in a single-dose vial. The current J0208 code description does not align with CMS modifications as outlined in the “HCPCS Level II Coding for 505(b)(2)-Approved Drugs or Biologicals - Frequently Asked Questions.”

CMS Final HCPCS Coding Decision

CMS revised existing HCPCS Level II code J0208, “Injection, sodium thiosulfate (pedmark), 100 mg,” in the fourth quarter of 2023 with an effective date of 04/01/2024. The current revised language follows CMS’ effort to identify products approved under the 505(b)(2) New Drug Application (NDA) or the Biologics License Application (BLA) pathways after October 2003. At this time, we will not further revise existing HCPCS Level II code J0208.

iDose TR® - HCP231221VCXP9

Topic/Issue

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

Applicant's suggested language: JXXXX, “Injection, travoprost intracameral implant, 1 mcg”

Summary of Applicant's Submission

Glaukos submitted a request to establish a new HCPCS Level II code to identify iDose TR®. iDose TR® was approved by the Food and Drug Administration (FDA) under 505(b)(2) New Drug Application (NDA) on December 13, 2023. iDose TR® is a sustained release micro-invasive intracameral implant inserted through the anatomical drain of the eye and anchored in the sclera at the iridocorneal angle. iDose TR® is indicated for the reduction of intraocular pressure (IOP) in patients with open angle glaucoma or ocular hypertension. iDose TR is designed to continuously deliver therapeutic levels of a proprietary preservative-free formulation of travoprost, a prostaglandin analog used to lower intraocular pressure, from within the eye for extended periods of time. It is believed to reduce IOP by increasing uveoscleral outflow. The dosage of iDose TR® is 75 mcg and it is administered intracamerally through a small corneal incision. iDose TR® is supplied as a single implant preloaded in a sterile, single-use inserter.

CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code J7355, “Injection, travoprost, intracameral implant, 1 microgram”

DEFENCATH® - HCP231208YYVY7

Topic/Issue

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

Applicant's suggested language: JXXXX, “Taurolidine and heparin catheter lock solution, 1mL”

Summary of Applicant's Submission

CorMedix submitted a request to establish a new HCPCS Level II code to identify DEFENCATH®. DEFENCATH® was approved by the Food and Drug Administration (FDA) under 505(b) New Drug Application (NDA) on November 15, 2023. DEFENCATH® is a combination of taurolidine, an antimicrobial and heparin, an anti-coagulant. DEFENCATH® is indicated to reduce the incidence of catheter-related bloodstream infections in adult patients with kidney failure receiving chronic hemodialysis. DEFENCATH® is administered through a central venous catheter only, it is not intended for systemic administration. DEFENCATH® is available in 3 or 5 milliliters (mL) single dose vial containing taurolidine 13.5 mg and heparin 1,000 units/mL.

CMS Final HCPCS Coding Decision[2]

Establish a new HCPCS Level II code J0911, “Instillation, taurolidine 1.35 mg and heparin sodium 100 units (central venous catheter lock for adult patients receiving chronic hemodialysis)”

[2] Revised on April 19, 2024 to update the long descriptor for J0911.

Palonosetron Hydrochloride Injection - HCP2401024BNEN

Topic/Issue

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

Applicant's suggested language: JXXXX, “Injection, palonosetron hcl (Avyxa) not therapeutically equivalent to J2469, 25 mcg”

Summary of Applicant's Submission

Avyxa Pharma submitted a request to establish a new HCPCS Level II code to identify Palonosetron Hydrochloride Injection. Palonosetron Hydrochloride Injection was approved by the Food and Drug Administration (FDA) under a 505(b)(2) New Drug Application (NDA) on March 1, 2016. Palonosetron Hydrochloride Injection is used as an antiemetic and antinauseant agent. It is indicated for use in adults for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of moderately and highly emetogenic cancer chemotherapy, as well as for the prevention of postoperative nausea and vomiting for up to 24 hours following surgery. For chemotherapy-induced nausea and vomiting, the recommended adult dosage is 0.25 mg as a single intravenous dose administered over 30 seconds, and dosing should occur approximately 30 minutes before the start of chemotherapy. For postoperative nausea and vomiting, the recommended adult dosage is 0.075 mg as a single intravenous dose administered over 10 seconds immediately before the induction of anesthesia. Palonosetron Hydrochloride Injection is available as single dose vials containing either 0.25 mg palonosetron in 5 mL (0.05 mg/mL) or 0.075 mg palonosetron in 1.5 mL (0.05 mg/mL).

CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code J2468, “Injection, palonosetron hydrochloride (avyxa), not therapeutically equivalent to J2469, 25 micrograms”

Baxter's Micafungin in Sodium Chloride Injection - HCP231231GFA9X

Topic/Issue

Request to establish a new HCPCS Level II code to identify Baxter's Micafungin in Sodium Chloride Injection.

Applicant's suggested language: JXXXX, “Injection, Micafungin in Sodium Chloride (Baxter)”

Summary of Applicant's Submission

Baxter Healthcare Corporation (Baxter) submitted a request to establish a new HCPCS Level II code identify Micafungin in Sodium Chloride Injection. Baxter's Micafungin in Sodium Chloride Injection was approved by the Food and Drug Administration (FDA) under a 505(b)(2) New Drug Application (NDA) on September 29, 2023. Baxter's Micafungin in Sodium Chloride Injection was approved for treating various candida infections. Baxter’s Micafungin in Sodium Chloride Injection is a premixed, iso-osmotic, sterile, nonpyrogenic solution for intravenous (IV) infusion that contains micafungin sodium. Micafungin sodium is a semisynthetic lipopeptide (echinocandin). Baxter's Micafungin in Sodium Chloride Injection is indicated for the treatment of adult and pediatric patients four months of age and older with candidemia, acute disseminated candidiasis, candida peritonitis and abscesses; treating pediatric patients younger than four months of age with candidemia, acute disseminated candidiasis, candida peritonitis and abscesses without meningoencephalitis and/or ocular dissemination; treating adult and pediatric patients four months of age and older with esophageal candidiasis; treating adult and pediatric patients four months of age and older prophylaxis of candida undergoing hematopoietic stem cell transplantation. Baxter’s Micafungin in Sodium Chloride Injection is supplied as a clear, colorless, refrigerated, premixed, isosmotic, sterile, nonpyrogenic solution for IV infusion. It is available in the following packaging configurations: a single-dose frozen, premixed, iso-osmotic, sterile, nonpyrogenic solution containing either 50 milligrams of micafungin per 50 mL container or 100 milligrams of micafungin per 100 mL container, or 150 milligrams of micafungin per 150 mL container. Baxter’s Micafungin in Sodium Chloride Injection is supplied in 12 bags per carton for the 50 mL and 100 mL containers and ten bags per carton for the 150 mL containers.

CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code J2246, “Injection, micafungin in sodium (baxter), not therapeutically equivalent to j2248, 1 mg”

Neuraceq®, Florbetaben F18 - HCP2311200W2TT

Topic/Issue

Request to discontinue existing HCPCS Level II code Q9983, “Florbetaben f18, diagnostic, per study dose, up to 8.1 millicuries”, and establish a new HCPCS Level II code to identify Nueraceq®.

Applicant's suggested language: AXXXX, “Florbetaben F18 (Trade Name Neuraceq®, diagnostic, per study dose, up to 8.1 millicuries”

Summary of Applicant's Submission

Life Molecular Imaging submitted a request to discontinue existing HCPCS Level II code Q9983, “Florbetaben f18, diagnostic, per study dose, up to 8.1 millicuries”, and establish a new A-code to identify Neuraceq®. Neuraceq® was approved by the Food and Drug Administration (FDA) under the under New Drug Application (NDA) pathway on March 20, 2014. Neuraceq® is a diagnostic radiopharmaceutical used with Positron Emission Tomography (PET) imaging of the brain to estimate beta-amyloid neuritic plaque density in adult patients with cognitive impairment who are being evaluated for Alzheimer’s disease and other causes of cognitive decline. CMS established Q9983 in 2016 and it has been used since then, but some providers who purchase Neuraceq® and submit claims have suggested an A-code would be consistent with all other radiopharmaceutical agents, more specifically PET agents.

CMS Final HCPCS Coding Decision

CMS is denying the request to discontinue the existing HCPCS Level II code Q9983, “Florbetaben f18, diagnostic, per study dose, up to 8.1 millicuries”, and establish a new A-code.

In general, Q-codes are no longer considered temporary and are instead considered permanent similar to other HCPCS Level II codes (e.g., A-codes, G-codes, and J-codes). We believe the requested change is not needed because this and other Q-codes and A-codes pertaining to PET are currently referenced in the Medicare Claims Processing Manual.

ABILIFY MAINTENA® - HCP23122998J1Q

Topic/Issue

Request to revise existing HCPCS Level II code J0401, “Injection, aripiprazole, extended release, 1 mg” to identify ABILIFY MAINTENA®.

Applicant's suggested language: J0401, “Injection, aripiprazole (abilify maintena), 1 mg”

Summary of Applicant's Submission

Otsuka America Pharmaceutical, Inc. submitted a request to revise existing HCPCS Level II code, J0401, to identify ABILIFY MAINTENA® (aripiprazole). ABILIFY MAINTENA® was approved by the Food and Drug Administration (FDA) under the New Drug Application (NDA) pathway on February 28, 2013. It is indicated for the treatment of adults with schizophrenia, or for maintenance monotherapy treatment of adults with bipolar I disorder. The recommended starting and maintenance dosage of ABILIFY MAINTENA® is 400 mg administered monthly as a single injection. The dose can be reduced to 300 mg in patients with adverse reactions. ABILIFY MAINTENA® is supplied in two types of kits: (1) pre-filled dual chamber syringe available in 300 mg or 400 mg strength syringes and (2) single-use vials available in 300 mg or 400 mg strength vials. The HCPCS Level II code J0401 was established and effective on January 1, 2014, with the long description, “Injection, aripiprazole, extended release, 1 mg.” Revising the description of J0401 to reflect the brand name ABILIFY MAINTENA® would reduce coding confusion and potential miscoding, given “injection, aripiprazole” is included in the description of other active codes (e.g., J0400 and J0402). Reflecting the brand name in the coding description is consistent with recent coding changes for products that contain the same active ingredient but are not rated by the FDA as therapeutically equivalent in formulation, dose, dosing duration, and presentation.

CMS Final HCPCS Coding Decision

Revise existing HCPCS Level II code J0401, “Injection, aripiprazole, extended release, 1 mg” to instead read, “Injection, aripiprazole (abilify maintena), 1 mg”

Ranitidine - IHC240125QF8N0

Topic/Issue

Request to discontinue an existing HCPCS Level II code J2780, “Injection, ranitidine hydrochloride, 25 mg.”

Summary of Applicant's Submission

CMS has reviewed the deletion of an existing HCPCS Level II code J2780, “Injection, ranitidine hydrochloride, 25 mg.” HCPCS Level II code J2780 is no longer used because on April 1, 2020, the Food and Drug Administration (FDA) requested all manufacturers to withdraw all products containing ranitidine from the market. The FDA’s Orange Book currently lists all injectable formulations of ranitidine as discontinued from the market.

CMS Final HCPCS Coding Decision

Discontinue existing HCPCS Level II code J2780, “Injection, ranitidine hydrochloride, 25 mg”

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

ACApatch™ - HCP2312215U9G1

Topic/Issue

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

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

Summary of Applicant's Submission

RegenTX Partners LLC submitted a request to establish a new Level II code to identify ACApatch™. ACApatch™ is a dehydrated allograft composed of three-layers: two (2) amnion layers and one (1) chorion layer. ACApatch™ is intended as a barrier and provides protective coverage from the surrounding environment to acute and chronic wounds. ACApatch™ is supplied in various sizes.

CMS Final HCPCS Coding Decision

After review of the Food and Drug Administration’s (FDA’s) Tissue Reference Group (TRG) letter submitted by the applicant, “ACAPatch™, when intended as a barrier and to provide protective coverage, 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 Q4325, “Acapatch, per square centimeter”

This coding decision applies to the ACApatch™ product described in the application and accompanying FDA TRG Letter dated August 28, 2023, when intended as a “barrier and to provide protective coverage.”

AmnioTX™ - HCP231221UR624

Topic/Issue

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

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

Summary of Applicant's Submission

RegenTX Partners LLC submitted a request to establish a new HCPCS Level II code to identify Amnio TX™. AmnioTX™ is a dehydrated dual layer amniotic membrane protective wound covering. AmnioTX™ is intended to be used as a barrier that protect wounds. AmnioTX™ is available in various sizes.

CMS Final HCPCS Coding Decision

After review of the Food and Drug Administration’s (FDA’s) Tissue Reference Group (TRG) letter submitted by the applicant, “AmnioTX™, when intended for use as a barrier that protects 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 Q4324, “Amniotx, per square centimeter”

This coding decision applies to the AmnioTX™ product described in the application and accompanying FDA TRG Letter dated August 23, 2022, when intended for use as a “barrier that protects wounds.”

alloPLY™ - HCP2312210QKXM

Topic/Issue

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

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

Summary of Applicant's Submission

RegenTX Partners LLC submitted a request to establish a new HCPCS Level II code to identify alloPLY™. alloPLY™ is a dehydrated dual-layer epithelium/basement membrane allograft that retains the amniotic membrane’s key structural components related to its utility to serve as a barrier. alloPLY™ is intended to be used as a wound cover and barrier. alloPLY™ is supplied in varies sizes.

CMS Final HCPCS Coding Decision

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

Establish a new HCPCS Level II code Q4323, Alloply, per square centimeter”

This coding decision applies to the alloPLY™ product described in the application and accompanying FDA TRG Letter dated November 3, 2023, when intended as a “wound cover and barrier.”

CaregraFT™ - HCP231221V46MG

Topic/Issue

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

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

Summary of Applicant's Submission

RegenTX Partners LLC submitted a request to establish a new HCPCS Level II code to identify CaregraFT™. CaregraFT™ is a dehydrated amnion and chorion membrane allograft. CaregraFT™ is intended as a barrier and provides protective coverage from the surrounding environment to acute and chronic wounds. Human amniotic membrane is a thin collagenous membrane derived from the submucosa of the placenta, the area in which the human fetus grows and develops within the mother’s uterus. Human amniotic membrane is a basement membrane comprised of collagen layers and extracellular stromal matrix. CaregraFT™ is supplied in varies sizes.

CMS Final HCPCS Coding Decision

After review of the Food and Drug Administration’s (FDA’s) Tissue Reference Group (TRG) letter submitted by the applicant, “CaregraFT™, when intended as a barrier and to provide protective coverage, 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 Q4322, “Caregraft, per square centimeter”

This coding decision applies to the CaregraFT™ product described in the application and accompanying FDA TRG Letter dated November 3, 2023, when intended as a “barrier and to provide protective coverage.”

Axolotl DualGraft™ & Axolotl Graft™ - HCP231227MB9N6

Topic/Issue

Request to revise existing HCPCS Level II code Q4210, “Axolotl graft or axolotl dualgraft, per square centimeter” to only distinguish Axolotl DualGraft and establish a new code to describe Axolotl Graft™.

Applicant's suggested language:

1. Q4210, “Axolotl DualGraft, per square centimeter”

2. XXXXX, “Axoltol Graft, per square centimeter”

Summary of Applicant's Submiss.ion

Axolotl Biologix submitted a request to revise existing HCPCS Level II code Q4210 to only identify Axolotl Graft™ and establish a new HCPCS Level II code to describe Axolotl Graft™. Currently, HCPCS Level II code Q4210 describes both Axolotl DualGraft™ (ADG) and Axolotl Graft™ (AG). ADG and AG are indicated as a resorbable, chorion free human amnion allografts derived from donated human birth tissue. These allografts are intended for homologous use as a wound covering.

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, “Axolotl Graft™ and Axolotl DualGraft™, when intended to be used as a wound covering and to act as a barrier, appear to meet the criteria for regulation solely under section 361 of the Public Health Service (PHS) Act and the regulations in 21 CFR part 1271.” As a result of our review of the TRG’s feedback, CMS has decided to:

1. Discontinue existing HCPCS Level II code Q4210, “Axolotl graft or Axolotl dualgraft, per square centimeter”

   Effective June 30, 2024

2. Establish a new HCPCS Level II code Q4331, “Axolotl graft, per square centimeter”

   Effective July 1, 2024

3. Establish a new HCPCS Level II code Q4332, “Axolotl dualgraft, per square centimeter”

   Effective July 1, 2024

This coding decision applies to the Axolotl Graft™ and Axolotl DualGraft™ products described in the application and accompanying FDA TRG Letter dated August 3, 2023, when intended as a “wound covering” and to act as a “barrier.”

Reeva FT - HCP231213NRWKA

Topic/Issue

Request to establish a new HCPCS Level II code to identify Reeva FT.

The applicant did not submit any suggested language.

Summary of Applicant's Submission

Legacy Medical Consultants submitted a request to establish a new HCPCS Level II code to identify Reeva FT. Reeva FT is a sterile, single use, dehydrated resorbable allograft derived from donated human placental birth tissue. Reeva FT is applied over the wound and serves as a barrier and protective covering 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, "Reeva FT amniotic membrane allograft, when intended for use as a barrier and provides protective coverage … to acute and chronic wounds, appears to meet the criteria for regulation solely under section 361 of the Public Health Service (PHS) Act and the regulations in 21 CFR part 1271." As a result of our review of the TRG's feedback, CMS has decided to:

Establish a new HCPCS Level II code Q4314, "Reeva ft, per square centimeter"

This coding decision applies to the Reeva FT product described in the application and accompanying FDA TRG Letter dated October 23, 2023, when intended as a "barrier and provides protective coverage … to acute and chronic wounds."

Acesso AC - HCP231213ML6QE

Topic/Issue

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

The applicant did not submit any suggested language.

Summary of Applicant's Submission

Dynamic Medical Services LLC submitted a request to establish a new Level II code to identify Acesso AC. Acesso AC Allograft is a dual layer human amnion/chorion membrane. Acesso AC Allograft membrane is intended to serve as a protective covering or barrier for acute and chronic wounds. Acesso AC is only to be used in one patient on a single occasion and applied by a licensed healthcare professional. Multiple sizes are available for optimizing graft sizes to wound sizes.

CMS Final HCPCS Coding Decision

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

Establish a new HCPCS Level II code Q4312, "Acesso ac, per square centimeter"

This coding decision applies to the Acesso AC product described in the application and accompanying FDA TRG Letter dated September 29, 2023, when intended as a "barrier and provides protective coverage … to acute and chronic wounds."

Acesso - HCP231213JV828

Topic/Issue

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

The applicant did not submit any suggested language.

Summary of Applicant's Submission

Dynamic Medical Services LLC submitted a request to establish a new HCPCS Level II code to identify Acesso. Acesso membrane is a sterile single layered human amniotic membrane intended to serve as a wound barrier or protective covering for acute and chronic wounds. The membrane is only to be used in one patient on a single occasion. Multiple sizes are available.

CMS Final HCPCS Coding Decision

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

Establish a new HCPCS Level II code Q4311, "Acesso, per square centimeter"

This coding decision applies to the Acesso product described in the application and accompanying FDA TRG Letter dated November 30, 2022, when intended "as a barrier" or "protective coverage…to acute and chronic wounds."

DermaBind FM™ - HCP231109TJY0Y

Topic/Issue

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

Applicant's suggested language: XXXXX, DermaBind FM™ per sq cm”

Summary of Applicant's Submission

HealthTech WC submitted a request to establish a new HCPCS Level II code to identify DermaBind FM™. DermaBind FM™ is a dehydrated human placental membrane allograft comprised of an extracellular matrix that is rich in collagen, fibrin, and elastin fibers native to the tissue. DermaBind FM™ membrane is intended for use as a wound covering. DermaBind FM™ is packaged in Tyvek® pouches and terminally sterilized.

CMS Final HCPCS Coding Decision

After review of the Food and Drug Administration’s (FDA’s) Tissue Reference Group (TRG) letter submitted by the applicant, “DermaBind FM™, when intended for use as a wound covering and to protect those wounds from the environment, 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 Q4313, “Dermabind fm, per square centimeter”

This coding decision applies to the DermaBind FM™, product described in the application and accompanying FDA TRG Letter dated November 3, 2023, when intended as a “wound covering” and “to protect those wounds from the environment.”

RegeneLink Amniotic Membrane Allograft - HCP231213GA7B0

Topic/Issue

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

Applicant's suggested language: XXXXX, “Regenelink amniotic membrane allograft, per square centimeter”

Summary of Applicant's Submission

LifeLink Foundation, Inc. submitted a request to establish a new HCPCS Level II code to identify RegeneLink Amniotic Membrane Allograft. RegeneLink Amniotic Membrane Allograft is a single use, sterile, lyophilized, gamma irradiated, full thickness allograft which includes amnion and chorion. RegeneLink Amniotic Membrane Allograft is derived from donated human placenta. RegeneLink Amniotic Membrane Allograft is intended for use as a protective covering or barrier for internal and external tissue defects at the direction of a physician or other qualified healthcare professional. The RegeneLink Amniotic Membrane Allograft sheet is available in a variety of sizes. RegeneLink Amniotic Membrane is packaged in a single-use double peel pouch configuration (inner peel pouch sealed in an outer peel pouch).

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

Establish a new HCPCS Level II code Q4315, “Regenelink amniotic membrane allograft, per square centimeter”

This coding decision applies to the RegeneLink Amniotic Membrane Allografts product described in the application and accompanying FDA TRG Letter dated November 30, 2023, when intended as a “protective covering or barrier.”

AmchoPlast® - HCP231222KT82E

Topic/Issue

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

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

Summary of Applicant's Submission

RMBB Health submitted a request to establish a new HCPCS Level II code to identify AmchoPlast®. AmchoPlast® is a minimally manipulated, dehydrated, human amnion/chorion membrane allograft intended for use as a protective barrier and cover that offers protection from the surrounding environment in repair and reconstruction procedures. It consists of a basement membrane and stromal matrix collagen layer. The allograft is processed using aseptic techniques and terminally sterilized by gamma radiation to achieve a Sterility Assurance Level (SAL) of 10-6. A single sterile allograft is packaged in a primary aluminum polyester pouch and a secondary aluminum pouch and sterilized by gamma radiation to a SAL of 10-6. Allograft must be stored in a clean and dry environment at ambient room temperature prior to patient application. AmchoPlast® comes in various sizes.

CMS Final HCPCS Coding Decision

After review of the Food and Drug Administration’s (FDA’s) Tissue Reference Group (TRG) letter submitted by the applicant, “AmchoPlast®, when intended for use as a barrier and cover 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 Q4316, “Amchoplast, per square centimeter”

This coding decision applies to the AmchoPlast® product described in the application and accompanying FDA TRG Letter dated September 29, 2023, when intended as a “barrier” and “cover”.

MOST™ - HCP2310300G0L6

Topic/Issue

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

Applicant's suggested language: XXXXX, “MOST™, per sq. cm.”

Summary of Applicant's Submission

Samaritan Biologics LLC submitted a request to establish a HCPCS new Level II code to identify MOST™. MOST™ a perforated three-layer amnion-chorion-amnion derived allograft to serve as a barrier and provide protective coverage from the surrounding environment to acute and chronic wounds. MOST™ is a sterile, single use, perforated and dehydrated allograft derived from donated human amnion chorion membrane. MOST™ graft can be reapplied as needed. MOST™ is intended for external application. MOST™ is applied directly to the wound. MOST™ adheres to the wound bed with or without fixation. MOST™ does not have to be removed from the wound bed. MOST™ is supplied sterile, in a single use package in a variety of sizes.

CMS Final HCPCS Coding Decision

After review of the Food and Drug Administration’s (FDA’s) Tissue Reference Group (TRG) letter submitted by the applicant, “MOST™ product, when intended for use as a barrier or cover for acute and chronic wounds, it 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 Q4328, “Most, per square centimeter”

This coding decision applies to the MOST™ product described in the application and accompanying FDA TRG Letter dated September 29, 2023, when intended as a “barrier or cover for acute and chronic wounds.”

TOTAL™ - HCP231030UNMF4

Topic/Issue

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

Applicant's suggested language: XXXXX, “TOTAL™, per sq. cm.”

Summary of Applicant's Submission

Samaritan Biologics LLC submitted a request to establish a new HCPCS Level II code to identify TOTAL™. TOTAL™ is a perforated amnion-chorion derived allograft to serve as a barrier and provide protective coverage from the surrounding environment to acute and chronic wounds. TOTAL™ is a sterile, single use, perforated and dehydrated allograft derived from donated human amnion chorion membrane. TOTAL™ graft can be reapplied as needed. TOTAL™ is intended for external application. TOTAL™ is applied directly to the wound. TOTAL™ adheres to the wound bed with or without fixation. TOTAL™ does not have to be removed from the wound bed. TOTAL™ is supplied sterile, in a single use package in a variety of sizes.

CMS Final HCPCS Coding Decision

After review of the Food and Drug Administration’s (FDA’s) Tissue Reference Group (TRG) letter submitted by the applicant, “TOTAL™ product, when intended for use as a barrier or cover for acute and chronic wounds, it 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 Q4330, “Total, per square centimeter”

This coding decision applies to the TOTAL™ product described in the application and accompanying FDA TRG Letter dated September 29, 2023, when intended as a “barrier or cover for acute and chronic wounds.”

Singlay™ - HCP231030FJC8A

Topic/Issue

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

Applicant's suggested language: XXXXX, “Singlay™, per sq. cm.”

Summary of Applicant's Submission

Samaritan Biologics LLC submitted a request to establish a new HCPCS Level II code to identify Singlay™. Singlay™ is a perforated single layer amnion derived allograft to serve as a barrier and provide protective coverage from the surrounding environment to acute and chronic wounds. Singlay™ is a sterile, single use, perforated and dehydrated allograft derived from donated human amnion membrane. Singlay™ is an allograft that acts by providing a physical barrier to the wound. Singlay™ graft can be reapplied as needed. Singlay™ is intended for external application. Singlay™ is applied directly to the wound. Singlay™ adheres to the wound bed with or without fixation. Singlay™ does not have to be removed from the wound bed. Singlay™ is supplied sterile, in a single use package in a variety of sizes.

CMS Final HCPCS Coding Decision

After review of the Food and Drug Administration’s (FDA’s) Tissue Reference Group (TRG) letter submitted by the applicant, “SINGLAY™ product, when intended for use as a barrier or cover for acute and chronic wounds, it 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 Q4329, “Singlay, per square centimeter”

This coding decision applies to the Singlay™ product described in the application and accompanying FDA TRG Letter dated September 29, 2023, when intended use as a “barrier or cover for acute and chronic wounds.”

DuoAmnion™ - HCP231030TFQYQ

Topic/Issue

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

Applicant's suggested language: XXXXX, “DuoAmnion™, per sq. cm.”

Summary of Applicant's Submission

Samaritan Biologics LLC submitted a request to establish a new HCPCS Level II code to identify DuoAmnion™. DuoAmnion™ is a sterile, single use, dehydrated allograft derived from donated human amniotic membrane. DuoAmnion™ serves as a barrier and provides protective coverage from the surrounding environment to acute and chronic wounds. DuoAmnion™ is a fully resorbable graft that acts by providing a physical barrier to the wound. DuoAmnion™ graft can be reapplied as needed. DuoAmnion™ is intended for external application. DuoAmnion™ is applied directly to the wound. DuoAmnion™ adheres to the wound bed with or without fixation. DuoAmnion™ is fully resorbable and does not have to be removed from the wound bed. DuoAmnion™ is supplied sterile, in a single use package in a variety of sizes.

CMS Final HCPCS Coding Decision

After review of the Food and Drug Administration’s (FDA’s) Tissue Reference Group (TRG) letter submitted by the applicant, “DUOAMNION™ product, when intended for use as a barrier or cover for acute and chronic wounds, it 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 Q4327, “Duoamnion, per square centimeter”

This coding decision applies to the DuoAmnion™ product described in the application and accompanying FDA TRG Letter dated September 29, 2023, when intended as a “barrier or cover for acute and chronic wounds.”

WoundPlus™ - HCP24010208QY0

Topic/Issue

Request to revise existing HCPCS Level II code to identify Q4277, “Woundplus membrane or e-graft, per square centimeter” to only identify WoundPlus™. (another application has been submitted to establish a new HCPCS Level II code for E-Graft).

Applicant's suggested language: Q4277, “WoundPlus™ membrane, per square centimeter”

Summary of Applicant's Submission

Skye Biologics Holdings submitted a request to revise existing HCPCS Level II code Q4277, “Woundplus membrane or egraft, per square centimeter” to only identify WoundPlus™. WoundPlus™ Membrane consists of dehydrated and devitalized human derived amniotic membrane that has been processed with proprietary HydraTek™ technology. WoundPlus™ is a single layer amnion-only membrane allograft intended for use as a barrier, wrap or cover for acute and chronic wounds. WoundPlus™ may be applied topically to the wound and should only be used in one patient. Additional WoundPlus™ may be applied for the duration of the wound, weekly, or at the discretion of the health care practitioner. Healthcare practitioners use sterile forceps to topically apply the allograft over the intended site. The forceps used are selected by the healthcare practitioner and are not provided with the product. WoundPlus™ Membrane is processed in a sterile clean room environment, sterilized post-packaging, and supplied in single one-time-use sterile packaging. WoundPlus™ Membrane is provided in a variety of sizes. Dosing or sizing is dependent on the size of the wound. WoundPlus™ Membrane is stored at ambient temperature, with a 5-year shelf life.

CMS Final HCPCS Coding Decision

After review of the Food and Drug Administration’s (FDA’s) Tissue Reference Group (TRG) letter submitted by the applicant, “WoundPlus and E-Graft, when intended for use as a barrier, wrap or cover, 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:

1. Discontinue existing HCPCS Level II code Q4277, “Woundplus or e-graft, per square centimeter”

   Effective June 30, 2024

2. Establish new HCPCS Level II code Q4326, “Woundplus, per square centimeter”

   Effective July 1, 2024

This coding decision applies to the WoundPlus™ product described in the application and accompanying FDA TRG Letter dated December 16, 2022, when intended as a “barrier, wrap or cover.” E-Graft™ is the subject of a separate HCPCS Level II code application.

E-Graft™ - HCP240102WKMWX

Topic/Issue

Request to establish a new HCPCS Level II code to identify E-Graft™.

Applicant's suggested language: XXXXX, “E-Graft™ per square centimeter”

Summary of Applicant's Submission

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

CMS Final HCPCS Coding Decision

After review of the Food and Drug Administration’s (FDA’s) Tissue Reference Group (TRG) letter submitted by the applicant, “WoundPlus and E-Graft, when intended for use as a barrier, wrap or cover, 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 new HCPCS Level II code Q4318, "E-graft, per square centimeter"

This coding decision applies to the E-Graft™ product described in the application and accompanying FDA TRG Letter dated December 16, 2022, when intended as a “barrier, wrap or cover.” WoundPlus™ is the subject of a separate HCPCS Level II code application.

VitoGraft - HCP23122244A1R

Topic/Issue

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

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

Summary of Applicant's Submission

Surgenex submitted a request to establish a new HCPCS Level II code to identify VitoGraft. VitoGraft is a sterile, dehydrated, dual layer amnion membrane allograft. VitoGraft functions as a barrier and provides protective coverage to acute and chronic wounds. VitoGraft is applied directly to the wound and is for single use only on one patient during one patient encounter. VitoGraft is packages in a primary foil pouch and a secondary Tyvek® pouch and sterilized by e-beam, meeting sterility assurance level of 10-6. VitoGraft amnion dual layer allograft membrane is available in multiple sizes.

CMS Final HCPCS Coding Decision

After review of the Food and Drug Administration’s (FDA’s) Tissue Reference Group (TRG) letter submitted by the applicant, “VitoGraft, when intended for use as a barrier and provides protective coverage … to acute and chronic wounds, appears to meet the criteria for regulation solely under section 361 of the Public Health Service (PHS) Act and the regulations in 21 CFR part 1271.” As a result of our review of the TRG’s feedback, CMS has decided to:

Establish a new HCPCS Level II code Q4317, “Vitograft, per square centimeter”

This coding decision applies to the VitoGraft product described in the application and accompanying FDA TRG Letter dated November 3, 2023, when intended as a “barrier and provides protective coverage … to acute and chronic wounds.”

SanoGraft - HCP231222K4YP0

Topic/Issue

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

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

Summary of Applicant's Submission

Surgenex submitted a request to establish a new HCPCS Level II code to identify SanoGraft. SanoGraft is a sterile, dehydrated single layer amnion membrane allograft. SanoGraft functions as a barrier and provides protective coverage 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, “SanoGraft, when intended for use as a barrier and provides protective coverage … to acute and chronic wounds, appears to meet the criteria for regulation solely under section 361 of the Public Health Service (PHS) Act and the regulations in 21 CFR part 1271.” As a result of our review of the TRG’s feedback, CMS has decided to:

Establish a new HCPCS Level code II Q4319, “Sanograft, per square centimeter”

This coding decision applies to the SanoGraft product described in the application and accompanying FDA TRG Letter dated November 3, 2023, when intended as a “barrier and provides protective coverage … to acute and chronic wounds.”

PelloGraft - HCP2312229B7HE

Topic/Issue

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

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

Summary of Applicant's Submission

Surgenex submitted a request to establish a new HCPCS Level II code to identify PelloGraft. PelloGraft is a dual layer amniotic/chorionic membrane allograft. PelloGraft functions as a barrier and provides protective coverage to acute and chronic wounds. PelloGraft is applied directly to the wound and is for single use only on one patient during one patient encounter. PelloGraft is packaged in a primary foil pouch and a secondary Tyvek® pouch and sterilized by e-beam, meeting sterility assurance level of 10-6. PelloGraft amniotic/chorionic membrane is available in multiple sizes.

CMS Final HCPCS Coding Decision

After review of the Food and Drug Administration’s (FDA’s) Tissue Reference Group (TRG) letter submitted by the applicant, “PelloGraft, when intended for use as a barrier and provides protective coverage … to acute and chronic wounds, appears to meet the criteria for regulation solely under section 361 of the Public Health Service (PHS) Act and the regulations in 21 CFR part 1271.” As a result of our review of the TRG’s feedback, CMS has decided to:

Establish a new HCPCS Level II code Q4320, “Pellograft, per square centimeter”

This coding decision applies to the PelloGraft product described in the application and accompanying FDA TRG Letter dated November 3, 2023, when intended as a “barrier and provides protective coverage … to acute and chronic wounds.”

ArdeoGraft - HCP231220NDJ9G

Topic/Issue

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

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

Summary of Applicant's Submission

Surgenex submitted a request to establish a new HCPCS Level II code to identify ArdeoGraft. ArdeoGraft is a sterile, dehydrated dual layer human chorionic membrane allograft. ArdeoGraft functions as a barrier and provides protective coverage 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, “ArdeoGraft, when intended for use as a barrier and provides protective coverage … to acute and chronic wounds, appears to meet the criteria for regulation solely under section 361 of the Public Health Service (PHS) Act and the regulations in 21 CFR part 1271.” As a result of our review of the TRG’s feedback, CMS has decided to:

Establish a new HCPCS Level II code Q4333, “Ardeograft, per square centimeter”

This coding decision applies to the Ardeograft product described in the application and accompanying FDA TRG Letter dated November 3, 2023, when intended as a “barrier and provides protective coverage … to acute and chronic wounds.”
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RenoGraft - HCP231228W1X6B

Topic/Issue

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

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

Summary of Applicant's Submission

Surgenex submitted a request to establish a new HCPCS Level II code to identify RenoGraft. RenoGraft is a sterile, dehydrated, triple layer amniotic/chorionic membrane allograft. RenoGraft functions as a barrier and provides protective coverage to acute and chronic wounds. RenoGraft is applied directly to the wound and is for single use only for one patient during the patient encounter. RenoGraft is packaged in a primary foil pouch and a secondary Tyvek® pouch and sterilized by e-beam, meeting sterility assurance level of 10-6. RenoGraft triple layer amniotic/chorionic membrane allograft is available in multiple sizes.

CMS Final HCPCS Coding Decision

After review of the Food and Drug Administration’s (FDA’s) Tissue Reference Group (TRG) letter submitted by the applicant, “RenoGraft, when intended for use as a barrier and provides protective coverage … to acute and chronic wounds, appears to meet the criteria for regulation solely under section 361 of the Public Health Service (PHS) Act and the regulations in 21 CFR part 1271.” As a result of our review of the TRG’s feedback, CMS has decided to:

Establish a new HCPCS Level II code Q4321, “Renograft, per square centimeter”

This coding decision applies to the RenoGraft product described in the application and accompanying FDA TRG Letter dated November 3, 2023, when intended as a “barrier and provides protective coverage … 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[3], 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 Level II codes as described at the following CMS link: https://www.cms.gov/files/document/frequently-asked-questions-single-source-drugs-and-biologicals.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 Level II 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[4] to identify the correct billing and payment code for each applicable product.

CMS Final HCPCS Coding Decision

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

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

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

[3] 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.

[4] 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.

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
C9113*	Delete	Injection, pantoprazole sodium, per vial
J2470	Add	Injection, pantoprazole sodium, 40 mg
J2471	Add	Injection, pantoprazole (hikma), not therapeutically equivalent to J2470, 40 mg
S0164*	Delete	Injection, pantoprazole sodium, 40 mg
J0211	Add	Injection, sodium nitrite 3 mg and sodium thiosulfate 25 mg (nithiodote)
J0687	Add	Injection, cefazolin sodium (wg critical care), not therapeutically equivalent to j0690, 500 mg
J1597	Add	Injection, glycopyrrolate (glyrx-pf), 0.1 mg
J1598	Add	Injection, glycopyrrolate (fresenius kabi), not therapeutically equivalent to J1596, 0.1 mg
J2183	Add	Injection, meropenem (wg critical care), not therapeutically equivalent to j2185, 100 mg
J2373	Add	Injection, phenylephrine hydrochloride (immphentiv), 20 micrograms
J8611	Add	Methotrexate (jylamvo), oral, 2.5 mg
J8612	Add	Methotrexate (xatmep), oral, 2.5 mg
J9371*	Delete	Injection, vincristine sulfate liposome, 1 mg

* The effective date for the discontinuation of this code is June 30, 2024.