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, 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' Fourth 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 Level II coding decision. All new coding actions will be effective April 1, 2025, unless otherwise indicated.

The HCPCS Level II coding decisions below will also be included in the April 2025 HCPCS Quarterly Update, pending publication by CMS in the coming weeks at: https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update.

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

CMS has a long-standing convention to assign dose descriptors in the smallest amount that could be billed in multiple units to accommodate a variety of doses and support streamlined billing. This long-standing policy makes coding more robust and facilitates accurate payment and reporting of the exact dose administered, as only 999 units can appear on a claim line for Medicare fee-for-service using the CMS-1500 form. In addition, CMS will use the generic or chemical name if there are no other similar chemical products on the market. If there are multiple products on the market with the same generic or chemical name, CMS will further distinguish a new code by using the brand 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.

# Table of Contents

Final Determinations for the Fourth Quarter 2024 Drug and Biological HCPCS Level II Applications.

# AZMIRO™ - HCP24092736VXF

## Topic/Issue

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

Applicant's suggested language: JXXXX, “Injection, testosterone cypionate (AZMIRO), 1 mg”

## Summary of Applicant's Submission

Azurity Pharmaceuticals, Inc. submitted a request to establish a new HCPCS Level II code to identify AZMIRO™ (testosterone cypionate). AZMIRO™ (testosterone cypionate) was approved by the Food and Drug Administration (FDA) under a 505(b)(2) New Drug Application (NDA) on June 2, 2022. AZMIRO™ is indicated for testosterone replacement therapy in individuals for conditions associated with a deficiency or absence of endogenous testosterone. The active ingredient in AZMIRO™ is testosterone cypionate. AZMIRO™ treats individuals with congenital or acquired primary hypogonadism. Congenital hypogonadism could be due to conditions such as cryptorchidism, bilateral torsion, orchitis, or vanishing testis syndrome; and acquired hypogonadism can be due to orchiectomy, Klinefelter’s syndrome, or toxic damage from alcohol, heavy metals, or chemotherapy. These individuals usually have low serum testosterone concentrations and gonadotropins follicle stimulating hormone, luteinizing hormone above the normal range. AZMIRO™ also treats individuals with hypogonadotropic hypogonadism (congenital or acquired): gonadotropin or luteinizing hormone-releasing hormone deficiency, or pituitary-hypothalamic injury from tumors, trauma, or radiation. These individuals have low testosterone serum concentrations but have gonadotropins in the normal or low range. AZMIRO™ is a clear, colorless to pale yellow solution for intramuscular use.  AZMIRO™ is supplied in either a 1 mL single-dose glass vial or pre-filled syringe containing 200 mg per 1 mL.

## CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code J1072, “Injection, testosterone cypionate (azmiro), 1 mg”

# CERIANNA™ - HCP240925CMCLW

## Topic/Issue

Request to revise existing HCPCS Level II code A9591, “Fluoroestradiol f 18, diagnostic, 1 millicurie” so the unit descriptor instead reads “per study dose up to 6 millicuries” to further describe CERIANNA™.

Applicant's suggested language: A9591, “Fluoroestradiol f 18, diagnostic, per study dose up to 6 millicuries”

## Summary of Applicant's Submission

GE Healthcare submitted a request to revise existing HCPCS Level II code A9591 to further define the unit descriptor for CERIANNA™ (fluoroestradiol f 18). CERIANNA™ (fluoroestradiol F 18) was approved by the Food and Drug Administration (FDA) under a 505(b)(2) New Drug Application (NDA) on May 20, 2020. CERIANNA™ is a radioactive diagnostic agent indicated for use with positron emission tomography (PET) imaging for the detection of estrogen receptor positive lesions as an adjunct to biopsy in individuals with recurrent or metastatic breast cancer. The recommended amount of radioactivity to be administered for PET imaging is 222 megabecquerels (MBq) or 6 millicuries (mCi), with a range of 111 MBq to 222 MBq (3 mCi to 6 mCi), administered as a single intravenous injection of 10 mL or less over 1 to 2 minutes. CERIANNA™ is supplied as a sterile, clear, colorless solution in a 50 mL multiple-dose glass vial at a strength of 148 MBq/mL to 3,700 MBq/mL (4 mCi/mL to 100 mCi/mL) fluoroestradiol F 18 at the end of synthesis. Each vial contains multiple doses and is enclosed in a shield container to minimize external radiation exposure. The current HCPCS Level II code A9591 requires that utilization be reported by the number of single millicuries administered. However, the recommended dose is a range from 3 millicuries up to 6 millicuries based on a half-life of 109.8 minutes. Dosage is not affected by the individual's weight or other characteristics. It is not necessary to determine the specific amount administered within the range other than for billing purposes. Many other diagnostic radiopharmaceuticals have a “per study dose” unit descriptor that simplifies coding and billing.

## CMS Final HCPCS Coding Decision

CMS is denying the applicant’s request as there is no claims processing need to modify existing HCPCS Level II code A9591, “Fluoroestradiol f 18, diagnostic, 1 millicurie”.

CMS acknowledges that many radiopharmaceutical products, such as CERIANNA™, are supplied from the manufacturer in a multiple-dose vial to the nuclear pharmacy, requiring the clinician to accurately measure, calibrate, and adjust each patient-specific dose while accommodating delays such as anticipated radioactive decay as well as transport time from the lab to the imaging center for administration to each patient. In considering that CERIANNA™ has a half-life of 109.8 minutes, and multiple doses are intended to be drawn from a single 50 mL vial, CMS believes the “1 millicurie” unit descriptor is most appropriate to maximize efficiency and accuracy.

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.

# FLYRCADO™ - HCP240930FT1Y8

## Topic/Issue

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

Applicant's suggested language: AXXXX, “Flurpiridaz F 18, diagnostic, per study dose up to 10 millicuries”

## Summary of Applicant's Submission

GE Healthcare submitted a request to establish a new HCPCS Level II code to identify FLYRCADO™ (flurpiridaz F 18). FLYRCADO™ (flurpiridaz F 18) was approved by the Food and Drug Administration (FDA) under a New Drug Application (NDA) on May 20, 2020. FLYRCADO™ is a radioactive diagnostic drug indicated for positron emission tomography myocardial perfusion imaging under rest or stress (pharmacologic or exercise) in adult individuals with known or suspected coronary artery disease to evaluate for myocardial ischemia and infarction. FLYRCADO™ is an analog of the mitochondrial complex 1 inhibitor, pyridaben. FLYRCADO™ is extracted by the myocardium proportional to the blood flow and binds to heart tissue that has biologically active mitochondria. Therefore, radioactivity in viable myocardium is higher than in infarcted tissue. FLYRCADO™ is administered by intravenous injection and is supplied as a clear, colorless to yellow solution containing 190 MBq/mL to 2,050 MBq/mL (5 mCi/mL to 55 mCi/mL) of flurpiridaz F 18 at the end of synthesis in a shielded multiple-dose vial with up to 30 mL fill volume. Dosage depends on the testing protocol. When rest and stress imaging are conducted on the same day, the recommended dosages are as follows: 93 to 111 megabecquerels (MBq) or 2.5 to 3 millicuries (mCi) for rest imaging, 222 to 241 MBq (6 to 6.5 mCi) for pharmacologic stress imaging, and 333 to 352 MBq (9 to 9.5 mCi) for exercise stress imaging. When rest and stress imaging are conducted over two separate days, the recommended dosages for rest imaging as well as both pharmacologic and exercise stress imaging are 93 to 111 MBq (2.5 to 3 mCi). The recommended dose is a range from 2.5 up to 9.5 mCi based on a half-life of 109.8 minutes and the testing protocol. Dosage is not affected by the individual's weight or other characteristics and is not specific to exact radioactive content (measured in mCi). Radiopharmaceuticals have a limited half-life and the radioactivity dose (number of mCi) available for administration is constantly being reduced. The request emphasizes that a new HCPCS Level II code for FLYRCADO™ also have a “per study dose” unit descriptor. Billing per mCi creates challenges in accounting for this decay and leads to variation in the number of units reported based solely on the timing of administration. The price of FLYRCADO™ is a fixed amount per dose and does not vary based on the number of mCi furnished. Billing by study dose avoids potential confusion and inappropriate variability in payment. Many other diagnostic radiopharmaceuticals have a “per study dose” unit descriptor that simplifies coding and billing and aligns with clinical protocols and product labeling.

## CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code A9611, “Flurpiridaz f 18, diagnostic, 1 millicurie”

CMS acknowledges that many radiopharmaceutical products, such as FLYRCADO™, are supplied from the manufacturer in a multiple-dose vial to the nuclear pharmacy, requiring the clinician to accurately measure, calibrate, and adjust each patient-specific dose while

accommodating delays such as anticipated radioactive decay as well as transport time from the lab to the imaging center for administration to each patient. In considering that FLYRCADO™ has a half-life of 109.8 minutes and multiple doses are intended to be drawn from a single 30 mL vial, CMS believes the "1 millicurie" unit descriptor is most appropriate to maximize efficiency and accuracy.

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.

# ERZOFRI® - HCP240906CK4YT

## Topic/Issue

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

Applicant's suggested language: JXXXX, “Injection, paliperidone palmitate”

## Summary of Applicant's Submission

Luye Pharma USA Ltd. submitted a request to establish a new HCPCS Level II code to identify ERZOFRI® (paliperidone palmitate). ERZOFRI® (paliperidone palmitate) extended-release injectable suspension was approved by the Food and Drug Administration (FDA) under a 505(b)(2) New Drug Application (NDA) on July 26, 2024. ERZOFRI® is indicated for adults for the treatment of schizophrenia, as monotherapy for schizoaffective disorder, and as an adjunct to mood stabilizers or antidepressants. ERZOFRI® is administered monthly by intramuscular injection by a healthcare provider, with the initial injection in the deltoid, and the subsequent monthly doses in either the gluteal or deltoid muscle. ERZOFRI® is available as a white to off-white sterile aqueous extended-release suspension for intramuscular injection in the following dose strengths of paliperidone palmitate (deliverable volume) in single-dose prefilled syringes: 39 mg (0.25 mL), 78 mg (0.5 mL), 117 mg (0.75 mL), 156 mg (1 mL), 234 mg (1.5 mL), and 351 mg (2.25 mL). The drug product hydrolyzes in vivo to the active moiety, paliperidone, resulting in dose strengths of 25 mg, 50 mg, 75 mg, 100 mg, 150 mg, and 225 mg of paliperidone, respectively. Each strength of ERZOFRI® is provided as a single-use kit containing a single-dose prefilled syringe with a plunger stopper and tip cap along with a 1 ½-inch 22 gauge safety needle and a 1-inch 23 gauge safety needle.

## CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code J2428, “Injection, paliperidone palmitate extended release (erzofri), 1 mg”

# NYPOZI™ - HCP240827LLE4Q

## Topic/Issue

Request to establish a HCPCS Level II code to identify NYPOZI™.

Applicant's suggested language: QXXXX, “Injection, filgrastim-txid, biosimilar, (Nypozi), 1 microgram”

## Summary of Applicant's Submission

Tanvex BioPharma USA, Inc. submitted a request to establish a new HCPCS Level II code to identify NYPOZI™ (filgrastim-txid). NYPOZI™ (filgrastim-txid) for subcutaneous (SQ) injection and intravenous (IV) infusion was approved by the Food and Drug Administration (FDA) under the 351(k) Biologics License Application (BLA) pathway on June 28, 2024. NYPOZI™ leukocyte growth factor is a biosimilar to NEUPOGEN® (filgrastim). NYPOZI™ is indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in individuals with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever; to reduce the time to neutrophil recovery and the duration of fever following induction or consolidation chemotherapy treatment of individuals with acute myeloid leukemia; to reduce the duration of neutropenia and neutropenia-related clinical sequelae (e.g., febrile neutropenia) in individuals with nonmyeloid malignancies undergoing myeloablative chemotherapy followed by bone marrow transplantation; to mobilize autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis, to reduce the incidence and duration of sequelae of severe neutropenia (e.g., fever, infections, oropharyngeal ulcers) in symptomatic individuals with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia, and to increase survival in individuals acutely exposed to myelosuppressive doses of radiation (Hematopoietic Syndrome of Acute Radiation Syndrome). NYPOZI™ is administered via SQ injection or IV infusion by a healthcare professional and is dosed based on body weight and indication. NYPOZI™ injection is available as a sterile, clear, colorless to slightly yellowish, preservative-free liquid in single-dose prefilled syringes containing either 300 mcg/0.5 mL or 480 mcg/0.8 mL of filgrastim-txid.

## CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code Q5148, “Injection, filgrastim-txid (nypozi), biosimilar, 1 microgram”

# PAVBLU™ - HCP241001KRXXH

## Topic/Issue

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

Applicant's suggested language: QXXXX, “Injection, aflibercept-ayyh (pavblu), biosimilar, 1 mg”

## Summary of Applicant's Submission

Amgen Inc. submitted a request to establish a new HCPCS Level II code to identify PAVBLU™ (aflibercept-ayyh) injection for intravitreal use. PAVBLU™ was approved by the Food and Drug Administration (FDA) under the 351(k) Biologics License Application (BLA) pathway on August 23, 2024. PAVBLU™ is a vascular endothelial growth factor (VEGF) inhibitor. VEGF-A and placental growth factor (PlGF) are members of the VEGF family of angiogenic factors that can act as mitogenic, chemotactic, and vascular permeability factors for endothelial cells. VEGF acts via two receptor tyrosine kinases, VEGFR-1 and VEGFR-2, present on the surface of endothelial cells. PlGF binds only to VEGFR-1, which is also present on the surface of leucocytes. Activation of these receptors by VEGF-A can result in neovascularization and vascular permeability. The FDA approved PAVBLU™ as a biosimilar to Eylea (aflibercept) for the treatment of individuals with neovascular (wet) age-related macular degeneration (AMD), macular edema following retinal vein occlusion (RVO), diabetic macular edema (DME), and diabetic retinopathy. Aflibercept acts as a soluble decoy receptor that binds VEGF-A and PlGF, and thereby can inhibit the binding and activation of these cognate VEGF receptors. For individuals with wet AMD, the recommended dose is 2 mg every 4 weeks for the first 3 months, followed by 2 mg once every 8 weeks. Some individuals with wet AMD may need dosing every 4 weeks after the first 12 weeks, instead of once every 8 weeks. After one year of effective therapy, some individuals with wet AMD may also be treated with one dose every 12 weeks, instead of every 8 weeks. For individuals with macular edema following RVO, the recommended dose is 2 mg once every 4 weeks. For individuals with DME or diabetic retinopathy, the recommended dose is 2 mg every 4 weeks for the first 5 injections, followed by 2 mg once every 8 weeks. Some individuals with DME or diabetic retinopathy may need dosing every 4 weeks after the first 20 weeks, instead of once every 8 weeks. PAVBLU™ must be administered by ophthalmic intravitreal injection. PAVBLU™ must only be administered by a qualified physician. PAVBLU™ is a clear to opalescent and colorless to slightly yellow solution that is supplied as 2 mg (0.05 mL of 40 mg/mL solution) in a single-dose prefilled plastic syringe, and 2 mg (0.05 mL of 40 mg/mL solution) in a single-dose glass vial.

## CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code Q5147, “Injection, aflibercept-ayyh (pavblu), biosimilar, 1 mg”

## AHZANTIVE® - HCP2410012H251

### Topic/Issue

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

Applicant's suggested language: QXXXX, “aflibercept-mrbb injection, for intravitreal use (AHZANTIVE)”

### Summary of Applicant's Submission

Valorum Bio submitted a request to establish a new HCPCS Level II code to identify AZHANTIVE® (aflibercept-mrbb) injection for intravitreal use. AZHANTIVE® was approved by the Food and Drug Administration (FDA) under the 351(k) Biologics License Application (BLA) pathway on June 28, 2024. AHZANTIVE® is a vascular endothelial growth factor (VEGF) inhibitor indicated for the treatment of individuals with neovascular (wet) age-related macular degeneration, macular edema following retinal vein occlusion, diabetic macular edema, and diabetic retinopathy. Aflibercept-mrbb is a recombinant fusion protein consisting of portions of human VEGF receptors 1 and 2 extracellular domains fused to the Fc portion of human IgG1 formulated as an iso-osmotic solution for intravitreal administration. Aflibercept-mrbb is a dimeric glycoprotein with a protein molecular weight of 97 kilodaltons (kDa) and contains glycosylation, constituting an additional 15% of the total molecular mass, resulting in a total molecular weight of 115 kDa. Aflibercept-mrbb is produced in recombinant Chinese hamster ovary cells. Vascular endothelial growth factor-A (VEGF-A) and placental growth factor (PlGF) are members of the VEGF family of angiogenic factors that can act as mitogenic, chemotactic, and vascular permeability factors for endothelial cells. VEGF acts via two receptor tyrosine kinases, VEGFR-1 and VEGFR-2, present on the surface of endothelial cells. PlGF binds only to VEGFR-1, which is also present on the surface of leucocytes. Activation of these receptors by VEGF-A can result in neovascularization and vascular permeability. Aflibercept products act as soluble decoy receptors that bind VEGF-A and PlGF, and thereby can inhibit the binding and activation of these cognate VEGF receptors. Its dosage form is and injection, 2 mg (0.05 mL of 40 mg/mL) solution in a single-dose vial. AHZANTIVE® (aflibercept-mrbb) injection is a sterile, clear, and colorless to pale yellow solution. AHZANTIVE® does not contain anti-microbial preservative and is supplied as a sterile, aqueous solution for intravitreal injection in a single-dose glass vial designed to deliver 0.05 mL (50 microliters) of solution containing 2 mg of aflibercept-mrbb in histidine (0.046 mg), L-histidine hydrochloride monohydrate (0.043 mg), polysorbate 20 (0.015 mg), sodium chloride (0.117 mg), sucrose (2.5 mg) and water for injection with a pH of 6.2. AHZANTIVE® is administered via intravitreal injection and dosing frequency varies by indication.

### CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code Q5150, “Injection, aflibercept-mrbb (ahzantive), biosimilar, 1 mg”

## ENZEEVU™ - HCP240930PGYG6

**Topic/Issue**

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

Applicant's suggested language: JXXXX, “Injection, aflibercept-abzv (ENZEEVU), biosimilar, 1 mg”

**Summary of Applicant's Submission**

Sandoz Inc. submitted a request to establish a new HCPCS Level II code to identify ENZEEVU™ (aflibercept-abzv) injection for intravitreal use. ENZEEVU™ was approved by the Food and Drug Administration (FDA) under the 351(k) Biologics License Application (BLA) pathway on August 9, 2024, as a biosimilar to EYLEA® (aflibercept). ENZEEVU™ is a vascular endothelial growth factor inhibitor indicated for the treatment of adult individuals with neovascular (“wet”) age-related macular degeneration. ENZEEVU™ injection is a sterile, clear, and colorless to slightly brownish-yellow solution supplied as a sterile, aqueous solution for intravitreal injection in a single-dose pre-filled glass syringe or a single-dose glass vial containing 2 mg (0.05 mL of a 40 mg/mL solution). The recommended dosage of ENZEEVU™ is 2 mg (0.05 mL of 40 mg/mL solution) administered by intravitreal injection every 4 weeks (approximately every 28 days) for the first 12 weeks (3 months), followed by 2 mg (0.05 mL of 40 mg/mL solution) via intravitreal injection once every 8 weeks (2 months). After the first 12 weeks (3 months), some individuals may need dosing every 4 weeks (monthly). ENZEEVU™ may be dosed as frequently as 2 mg every 4 weeks (approximately every 25 days). After 1 year of effective therapy, individuals may be treated with one dose of ENZEEVU™ every 12 weeks.

**CMS Final HCPCS Coding Decision**

Establish a new HCPCS Level II code Q5149, “Injection, aflibercept-abzv (enzeevu), biosimilar, 1 mg”

# EPYSQLI® - HCP240927Y0VWM

## Topic/Issue

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

Applicant's suggested language: JXXXX, “Injection, eculizumab-aagh, 1mg”

## Summary of Applicant's Submission

Samsung Bioeps submitted a request to establish a new HCPCS Level II code to identify EPYSQLI® (eculizumab-aagh) injection for intravenous (IV) use. EPYSQLI® was approved by the Food and Drug Administration (FDA) under the 351(k) Biologics License Application (BLA) pathway on July 19, 2024, as a biosimilar to SOLIRIS® (eculizumab). EPYSQLI® is a complement inhibitor indicated for the treatment of individuals with paroxysmal nocturnal hemoglobinuria (PNH) to reduce hemolysis. EPYSQLI® is also indicated for the treatment of individuals with atypical hemolytic uremic syndrome (aHUS), to inhibit complement-mediated thrombotic microangiopathy. EPYSQLI® is administered intravenously. For individuals with PNH that are 18 years of age and older, EPYSQLI® therapy consists of 600 mg IV infused weekly for the first 4 weeks, followed by 900 mg for the fifth dose 1 week later, and then 900 mg every 2 weeks thereafter. EPYSQLI® is administered at the recommended dosage regimen time points, or within two days of these time points. For individuals with aHUS that are 18 years of age and older, EPYSQLI® therapy consists of 900 mg IV infused weekly for the first 4 weeks, followed by 1200 mg for the fifth dose 1 week later, and then 1200 mg every 2 weeks thereafter. Eculizumab-aagh, the active ingredient in EPYSQLI®, is a monoclonal antibody that specifically binds to the complement protein C5 with high affinity, thereby inhibiting its cleavage to C5a and C5b and preventing the generation of the terminal complement complex C5b-9. Again, eculizumab products inhibit terminal complement-mediated intravascular hemolysis in individuals with PNH and complement-mediated thrombotic microangiopathy in individuals with aHUS. A phase 1, randomized, double-blind, 3-arm, parallel-group, single-dose study in healthy volunteers (NCT03722329) demonstrated pharmacokinetic (PK) equivalence and comparable pharmacodynamic safety, tolerability, and immunogenicity profiles between EPYSQLI® and the SOLIRIS® reference product. Additionally, a phase 3, randomized, double-blind, multicenter, cross-over study in individuals with PNH (NCT04058158) showed clinical equivalence in efficacy, safety, PK, and immunogenicity between the two drugs.

## CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code Q5151, “Injection, eculizumab-aagh (epysqli), biosimilar, 2 mg”

# TECELRA® - HCP240930YQT93

## Topic/Issue

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

Applicant's suggested language: JXXXX, “Afamitresgene autoleucel up to 10 x 10^9 MAGE-A4 TCR positive T-cells, per therapeutic dose”

## Summary of Applicant's Submission

Adaptimmune LLC submitted a request to establish a new HCPCS Level II code to identify TECELRA® (afamitresgene autoleucel). TECELRA® was approved by the Food and Drug Administration (FDA) under the 351(a) Biologics License Application (BLA) pathway on August 1, 2024. TECELRA® is a melanoma-associated antigen A4 (MAGE-A4)-directed genetically modified autologous T-cell immunotherapy indicated for the treatment of adult individuals with unresectable or metastatic synovial sarcoma (SyS) who have received prior chemotherapy, are HLA-A*02:01P, -A*02:02P, -A*02:03P, or -A*02:06P positive, and whose tumor expresses the MAGE-A4 antigen as determined by FDA-approved or -cleared companion diagnostic device. As an autologous TCR T-cell therapy, TECELRA® uses the individual’s own immune system to eliminate their cancer, by engineering TCRs within T-cells to target specific cancer proteins, while minimizing non-cancer cell reactions. Specifically, the affinity enhanced TCR of TECELRA® recognizes a specific HLA-A*02 restricted MAGE-A4 peptide. By specifically recognizing the cancer cell’s HLA-peptide complex, TECELRA® can target SyS cancer cells expressing MAGE-A4/HLA-A*02 and eliminate them. TECELRA® is provided as a single, one-time individual specific treatment. TECELRA® is provided as a cell suspension for intravenous infusion. The TECELRA® dose contains 2.68 x 10^9 to 10 x 10^9 MAGE-A4 TCR positive T-cells, in one or more infusion bag(s).

## CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code Q2057, “Afamitresgene autoleucel, including leukapheresis and dose preparation procedures, per therapeutic dose”

# BORUZU® - HCP240930X3K6K

## Topic/Issue

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

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

## Summary of Applicant's Submission

Amneal Pharmaceuticals, Inc. submitted a request to establish a new HCPCS Level II code to identify BORUZU® (Bortezomib injection). BORUZU® was approved by the Food and Drug Administration (FDA) under a 505(b)(2) New Drug Application (NDA) on August 26, 2024. BORUZU® has been developed against the lyophilized powder formulation of the reference product VELCADE. BORUZU® is a proteasome inhibitor indicated for the treatment of adults with multiple myeloma and mantle cell lymphoma. Bortezomib is a reversible inhibitor of the chymotrypsin-like activity of the 26S proteasome in mammalian cells. BORUZU® is ready to use at a concentration of 2.5 mg/mL subcutaneously and can be further diluted by adding 0.9% sodium chloride at a concentration of 1 mg/mL intravenously. The recommended starting dose of BORUZU® is 1.3 $mg/m^2$ administered either as a 3 to 5 second bolus intravenously. In previously untreated multiple myeloma, BORUZU® is administered in combination with oral melphalan and oral prednisone. Additionally, in previously untreated mantle cell lymphoma, BORUZU® is administered intravenously in combination with intravenous rituximab, cyclophosphamide, doxorubicin and oral prednisone. Allow at least 72 hours between consecutive doses of BORUZU®. BORUZU® retreatment may be considered for individuals who had previously responded to treatment with BORUZU® and who have relapsed at least six months after completing prior BORUZU® treatment. Treatment may be started at the last tolerated BORUZU® dose. BORUZU® is a sterile, clear to light yellow solution supplied as a carton containing one single-dose vial.

## CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code J9054, “Injection, bortezomib (boruzu), 0.1 mg”

# Cyclophosphamide - HCP2409206P9GG

## Topic/Issue

Request to revise existing HCPCS Level II code J9073, “Injection, cyclophosphamide (ingenus), 5 mg” to change the manufacturer from Ingenus to Dr. Reddy’s.

Applicant's suggested language: J9073, “Injection, Cyclophosphamide (Dr. Reddys), 5mg”

## Summary of Applicant's Submission

Dr. Reddy’s Laboratories Inc. submitted a request to revise existing HCPCS Level II code J9073 that describes Cyclophosphamide injection. Cyclophosphamide was approved by the Food and Drug Administration (FDA) under a 505(b)(2) New Drug Application (NDA) on July 30, 2020. Cyclophosphamide was assigned the HCPCS Level II code, J9073, and descriptor, “Injection cyclophosphamide, (ingenus), 5 mg,” effective April 1, 2024. In June 2024, Ingenus transferred the NDA for Cyclophosphamide to Dr. Reddy’s Laboratories and therefore is requesting a code descriptor change to account for the product transfer.

## CMS Final HCPCS Coding Decision

Revise existing HCPCS Level II code J9073, “Injection, cyclophosphamide (ingenus), 5 mg” to instead read “Injection, cyclophosphamide (dr. reddy's), 5 mg”

# LYMPHIR - HCP2410013HQ3M

## Topic/Issue

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

Applicant's suggested language: XXXXX, “Injection, denileukin diftitox-cxdl, 1 mcg”

## Summary of Applicant's Submission

Citius Pharmaceuticals Inc. submitted a request to establish a new HCPCS Level II code to identify LYMPHIR (denileukin diftitox-cxdl). LYMPHIR was approved by the Food and Drug Administration (FDA) under the 351(a) Biologics License Application (BLA) pathway on August 7, 2024. LYMPHIR is indicated for the treatment of adult individuals with relapsed or refractory stage I-III cutaneous T-cell lymphoma after at least one prior systemic therapy. LYMPHIR is a fusion protein designed to direct the cytocidal action of diphtheria toxin to cells which express the IL-2 receptor. LYMPHIR demonstrated the ability to deplete immunosuppressive regulatory T lymphocytes and antitumor activity through a direct cytocidal action on IL-2R-expressing tumors. The recommended dosage of LYMPHIR is 9 mcg/kg/day administered as an intravenous infusion. LYMPHIR is administered over 60 minutes through an intravenous line using a syringe pump or intravenous infusion bag. LYMPHIR is supplied as a sterile, white, lyophilized cake for reconstitution in a single-dose vial containing 300 mcg of LYMPHIR.

## CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code J9161, “Injection, denileukin diftitox-cxdl, 1 mcg”

# NIKTIMVO™ - HCP240927295Q7

## Topic/Issue

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

Applicant's suggested language: XXXXX, “Niktimvo (axatilimab-csfr) injection, for intravenous use, 0.1mg”

## Summary of Applicant's Submission

Incyte Corporation submitted a request to establish a new HCPCS Level II code to identify NIKTIMVO™ (axatilimab-csfr). NIKTIMVO™ was approved by the Food and Drug Administration (FDA) under the 351(a) Biologics License Application (BLA) pathway on August 14, 2024. NIKTIMVO™ is indicated for the treatment of individuals with chronic graft-versus-host disease after failure of at least two prior lines of systemic therapy. NIKTIMVO™ is expressed on monocytes and macrophages. Blocking CSF-1R with NIKTIMVO™ reduces the levels of circulating proinflammatory and profibrotic monocytes and monocyte-derived macrophages, as demonstrated by a reduction of nonclassical monocyte counts in nonclinical studies with a NIKTIMVO™ and inhibits the activity of pathogenic macrophages in tissues. For individuals weighing at least 40 kg, NIKTIMVO™ is administered at a dose of 0.3 mg/kg (up to a maximum dose of 35 mg) as an intravenous infusion over 30 minutes, every 2 weeks, until progression or unacceptable toxicity. Each single-dose vial contains 50 mg of NIKTIMVO™.

## CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code J9038, “Injection, axatilimab-csfr, 0.1 mg”

# TECENTRIQ HYBREZA - HCP240930CRY78

## Topic/Issue

Request to establish a new HCPCS Level II code to identify TECENTRIQ HYBREZA.

Applicant's suggested language: JXXXX, “Injection, atezolizumab and hyaluronidase-tqjs, 1 mgs”

## Summary of Applicant's Submission

Genentech Inc. submitted a request to establish a new HCPCS Level II code to identify TECENTRIQ HYBREZA (atezolizumab and hyaluronidase-tqjs). TECENTRIQ HYBREZA was approved by the Food and Drug Administration (FDA) under the 351(a) Biologics License Application (BLA) pathway on September 12, 2024. TECENTRIQ HYBREZA is a combination of atezolizumab, a programmed death-ligand 1 (PD-L1) blocking antibody, and hyaluronidase, an endoglycosidase indicated for the treatment of a variety of tumor types, including non-small cell lung cancer, small cell lung cancer, hepatocellular carcinoma, melanoma, and alveolar soft part sarcoma. TECENTRIQ HYBREZA is a humanized IgG1 monoclonal antibody that targets PD-L1 and inhibits the interaction between PD-L1 and its receptors, PD-1 and B7-1 (also known as CD80), both of which function as inhibitory receptors expressed on T-cells. Atezolizumab acts by binding PD-L1; creating a therapeutic blockage that influences the magnitude and quality of tumor-specific T-cell responses, resulting in improved anti-tumor activity. Additionally, hyaluronidase transiently hydrolyses hyaluronan, a component of the subcutaneous tissue matrix, leading to reduced viscosity of the extracellular matrix of the hypodermis, thus improving the delivery of subcutaneously administered drugs to the systemic circulation. The recommended dosage of TECENTRIQ HYBREZA is 125 mg/2,000 units per mL (1,875 mg atezolizumab and 30,000 units hyaluronidase per 15 mL) administered subcutaneously by a healthcare provider, into the thigh over approximately 7 minutes every 3 weeks. Therapy duration varies based on the type of tumor. TECENTRIQ HYBREZA (atezolizumab and hyaluronidase-tqjs) injection is supplied as a sterile, preservative-free, and colorless to slightly yellow solution packaged in a single dose vial.

## CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code J9024, “Injection, atezolizumab, 5 mg and hyaluronidase-tqjs”

# OCREVUS ZUNOVO - HCP240930L5HXF

## Topic/Issue

Request to establish a new HCPCS Level II code to identify OCREVUS ZUNOVO.

Applicant's suggested language: JXXXX, “Injection, ocrelizumab 1 mg and hyaluronidase-ocsq”

## Summary of Applicant's Submission

Genentech Inc. submitted a request to establish a new HCPCS Level II code to identify OCREVUS ZUNOVO (ocrelizumab and hyaluronidase-ocsq). OCREVUS ZUNOVO was approved the Food and Drug Administration (FDA) under the 351(a) Biologics License Application (BLA) pathway on September 13, 2024. OCREVUS ZUNOVO is a combination of ocrelizumab and hyaluronidase-ocsq. Ocrelizumab is a CD20-directed cytolytic antibody indicated for the treatment of relapsing forms of multiple sclerosis (MS), including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease; and primary progressive MS. Hyaluronidase-ocsq increases the permeability of the tissue under the skin to allow ocrelizumab to be dispersed and absorbed into the bloodstream. The recommended dosage of OCREVUS ZUNOVO is 920 mg/23,000 units (920 mg ocrelizumab and 23,000 units of hyaluronidase) administered subcutaneously by a health care provider in the abdomen over approximately 10 minutes every 6 months. OCREVUS ZUNOVO is supplied in a carton containing one single-dose vial of 920 mg ocrelizumab and 23,000 units/mL hyaluronidase per 23 mL (40 mg and 1,000 units/mL). OCREVUS ZUNOVO injection for subcutaneous use is a preservative-free, sterile, clear to slightly opalescent, and colorless to pale brown solution.

## CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code J2351, “Injection, ocrelizumab, 1 mg and hyaluronidase-ocsq”

# ExEm® Foam - HCP241001H1RHV

## Topic/Issue

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

Applicant's suggested language: SXXXX, “ExEm® Foam, Intrauterine Foam, single-dose”

## Summary of Applicant's Submission

ExEm® Foam Inc. submitted a request to establish a new HCPCS Level II code to identify ExEm® Foam (air polymer-type A intrauterine foam). ExEm® Foam was approved by the Food and Drug Administration (FDA) under a New Drug Application (NDA) on November 7, 2019. ExEm® Foam is a low-invasiveness and clinically effective drug used for assessing tubal patency. ExEm® Foam is formed by mixing the clear gel polymer-type A (hydroxyethyl cellulose), glycerin, and purified water with air and sterile purified water, creating an echogenic contrast agent for ultrasound. ExEm® Foam is indicated for sonohysterosalpingography to assess fallopian tube patency in individuals with known or suspected infertility. Assessment of fallopian tube patency is a fundamental test in a fertility work-up; occluded (non-patent) tubes could prevent sperm from reaching the ova. Before administering ExEm® Foam, healthcare professionals should confirm that the individual has a negative pregnancy test within 24 hours before ExEm® Foam administration and confirm that the individual is in the pre-ovulatory phase of the menstrual cycle (cycle days 6 through 11). The recommended dose is 2 mL to 3 mL of ExEm® Foam intrauterine infusion using a 5-Fr or larger catheter. The dose may be repeated in 2 mL to 3 mL increments, as needed, to achieve visualization of the fallopian tubes.

## CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code S4024, “Air polymer-type a intrauterine foam, per study dose”

# OTULFI® - HCP240930VTJN9

## Topic/Issue

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

Applicant's suggested language: QXXXX, “Injection, for subcutaneous use or intravenous use, ustekinumab-(aauz) (OTULFI), biosimilar per 1.0 mg”

## Summary of Applicant's Submission

Fresenius Kabi USA, LLC submitted a request to establish a new HCPCS Level II code to identify Otulfi® (ustekinumab-aauz). Otulfi® was approved by the Food and Drug Administration (FDA) under the 351(k) Biologics License Application (BLA) pathway on September 27, 2024. Otulfi® is a biosimilar approved for the treatment of Crohn’s disease, ulcerative colitis, moderate to severe plaque psoriasis, and active psoriatic arthritis. Otulfi® is intended for use under the guidance and supervision of a healthcare provider and should only be administered to individuals who will be closely monitored and have regular follow-up visits with a healthcare provider. A healthcare provider should determine the appropriate dose using the individual’s current weight at the time of dosing. Otulfi® injection is a sterile, preservative-free, clear to slightly opalescent, and colorless to slightly brown-yellow solution. It is supplied as individually packaged, single-dose prefilled syringes or single-dose vials.

## CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code Q9999, “Injection, ustekinumab-aauz (otulfi), biosimilar, 1 mg”

# BLENREP - HCP241001B4W85

## Topic/Issue

Request to discontinue existing HCPCS Level II code J9037, “Injection, belantamab mafodotin-blmf, 0.5 mg.”

## Summary of Applicant's Submission

GSK PLC submitted a request to discontinue existing HCPCS Level II code J9037, which identifies BLENREP (belantamab mafodontin-blmf). BLENREP received accelerated approval by the Food and Drug Administration (FDA) under a Biologics License Pathway (BLA) on August 5, 2020. The FDA revoked the biologic license for BLENREP on February 6, 2023 because the confirmatory DREAMM–3 trial did not meet its primary endpoint to demonstrate superior progression-free survival. In addition, there are no third-party payers currently reimbursing for BLENREP and no product is in the commercial market.

## CMS Final HCPCS Coding Decision

Discontinue existing HCPCS Level II code J9037, “Injection, belantamab mafodotin-blmf, 0.5 mg”

**Pepaxto - IHC241007423MY**

## Topic/Issue

Request to discontinue existing HCPCS Level II code J9247, "Injection, melphalan flufenamide, 1mg."

## Summary of Applicant's Submission

An internal request was received to discontinue existing HCPCS Level II code J9247, "Injection, melphalan flufenamide, 1mg" that identifies Pepaxto (melphalan flufenamide). On February 23, 2024, the Food and Drug Administration announced its final decision[1] to withdraw approval of Pepaxto (melphalan flufenamide), which was approved for use in combination with dexamethasone to treat certain individuals with multiple myeloma. As such, existing HCPCS Level II code J9247 is no longer being utilized. It is also CMS' understanding that the manufacturing company, Oncopeptides, does not currently market Pepaxto in the United States.

## CMS Final HCPCS Coding Decision

Discontinue existing HCPCS Level II code J9247, "Injection, melphalan flufenamide, 1mg"

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

[1] Final Decision on the Proposal to Withdraw Approval of Pepaxto (melphalan flufenamide) for Injection, Docket No. FDA-2023-N-3167 February 23, 2024. https://www.fda.gov/media/176510/download?attachment

## Innovar - IHC241119D6A67

### Topic/Issue

Request to discontinue existing HCPCS Level II code J1810, "Injection, droperidol and fentanyl citrate, up to 2 ml ampule."

### Summary of Applicant's Submission

An internal request was received to discontinue existing HCPCS Level II code J1810, "Injection, droperidol and fentanyl citrate, up to 2 ml ampule" that identifies Innovar (droperidol and fentanyl citrate). Prior to January 1, 1982, the Food and Drug Administration (FDA) approved Innovar (droperidol and fentanyl citrate) under a New Drug Application (NDA) pathway for the perioperative prevention or treatment of nausea, as an antipsychotic, and as a rapid sedative. However, the FDA's Orange Book[2] currently lists Innovar (droperidol and fentanyl citrate) as discontinued from marketing in the United States. As such, existing HCPCS Level II code J1810 is no longer being utilized.

### CMS Final HCPCS Coding Decision

Discontinue existing HCPCS Level II code J1810, "Injection, droperidol and fentanyl citrate, up to 2 ml ampule"

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

## Keflin - IHC241119JAGPA

[2] Product Details for NDA 016049. FDA Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. https://www.accessdata.fda.gov/scripts/cder/ob/results_product.cfm?Appl_Type=N&Appl_No=016049

**Topic/Issue**

Request to discontinue existing HCPCS Level II code J1890, "Injection, cephalothin sodium, up to 1 gram."

**Summary of Applicant's Submission**

An internal request was received to discontinue existing HCPCS Level II code J1890, "Injection, cephalothin sodium, up to 1 gram" that identifies Keflin (cephalothin sodium). Prior to January 1, 1982, the Food and Drug Administration (FDA) approved Keflin (cephalothin sodium) under a New Drug Application (NDA) to prevent infection in individuals during surgery and to treat many kinds of infections of the blood, bone or joints, respiratory tract, skin, and urinary tract. However, the FDA's Orange Book[3] currently lists Keflin (cephalothin sodium) as discontinued from marketing in the United States. As such, existing HCPCS Level II code J1810 is no longer being utilized.

**CMS Final HCPCS Coding Decision**

Discontinue existing HCPCS Level II code J1890, "Injection, cephalothin sodium, up to 1 gram"

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

[3] Product Details for NDA 050482. FDA Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations, https://www.accessdata.fda.gov/scripts/cder/ob/results_product.cfm?Appl_Type=N&Appl_No=050482

## Decadron-LA - IHC241119QPG93

### Topic/Issue

Request to discontinue existing HCPCS Level II code J1094, "Injection, dexamethasone acetate, 1 mg."

### Summary of Applicant's Submission

An internal request was received to discontinue existing HCPCS Level II code J1094, "Injection, dexamethasone acetate, 1 mg" that identifies Decadron-LA (dexamethasone acetate). Prior to January 1, 1982, the Food and Drug Administration (FDA) approved Decadron-LA (dexamethasone acetate) under a New Drug Application (NDA) for the treatment of individuals with inflammatory respiratory, allergic, autoimmune, and other conditions, as well as in combination with other agents to treat individuals with myeloma and lymphomas. However, the FDA's Orange Book[4] currently lists Decadron-LA (dexamethasone acetate) as discontinued from marketing in the United States. As such, existing HCPCS Level II code J1094 is no longer being utilized.

### CMS Final HCPCS Coding Decision

Discontinue existing HCPCS Level II code J1094, "Injection, dexamethasone acetate, 1 mg"

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

[4] Product Details for NDA 016675. FDA Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations, https://www.accessdata.fda.gov/scripts/cder/ob/results_product.cfm?Appl_Type=N&Appl_No=016675

# PalinGen® Dual-Layer Membrane - HCP240930CVBBM

## Topic/Issue

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

Applicant's suggested language: XXXXX, “PalinGen® Dual-Layer Membrane, per square centimeter”

## Summary of Applicant's Submission

Amnio Technology submitted a request to establish a new HCPCS Level II code to identify PalinGen® Dual-Layer Membrane. PalinGen® Dual-Layer Membrane is regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) solely under section 361 of the Public Health Service (PHS) Act and 21 CFR Part 1271 when intended for use as a “barrier.” PalinGen® Dual-Layer Membrane is a dehydrated human allograft derived from the placenta, specifically these are two layers of amniotic membrane which have the epithelial side facing out. They are minimally manipulated preserving many of the natural growth factors normally present in amniotic tissue. PalinGen® is supplied in various size and configuration sheets.

## CMS Final HCPCS Coding Decision

After review of the Food and Drug Administration’s (FDA’s) Tissue Reference Group (TRG) letter submitted by the applicant, PalinGen® Dual-Layer Membrane, “when intended for use as ‘a barrier,’ appear to meet all the criteria for regulation solely under section 361 of the 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 Q4354, “Palingen dual-layer membrane, per square centimeter"

This coding decision applies to the PalinGen® Dual-Layer Membrane product described in the application and accompanying FDA TRG letter dated September 30, 2021, when intended as a “barrier.”

# Abiomend Membrane and Abiomend Hydromembrane - HCP240930BNWBA

## Topic/Issue

Request to establish a new HCPCS Level II code to identify Abiomend Membrane and Abiomend Hydromembrane.

Applicant's suggested language: XXXXX, “Abiomend Membrane and Abiomend Hydromembrane, per square centimeter”

## Summary of Applicant's Submission

Amnio Technology submitted a request to establish a new HCPCS Level II code to identify Abiomend Membrane and Abiomend Hydromembrane. Abiomend Membrane and Abiomend Hydromembrane are regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) solely under section 361 of the Public Health Service (PHS) Act and 21 CFR Part 1271 when intended for use as a “covering,” a “semipermeable barrier,” or to “protect the wound.” Abiomend Membrane and Abiomend Hydromembrane are amniotic membrane products 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, Abiomend Membrane and Abiomend Hydromembrane, “when intended for use as a ‘covering,’ a ‘semipermeable barrier,’ or to ‘protect the wound,’ appear to meet all the criteria for regulation solely under section 361 of the 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 Q4356, “Abiomend membrane and abiomend hydromembrane, per square centimeter”

This coding decision applies to the Abiomend Membrane and Abiomend Hydromembrane products described in the application and accompanying FDA TRG letter dated August 14, 2024, when intended for use as a “covering,” a “semipermeable barrier,” or to “protect the wound.”

**Abiomend Xplus Membrane and Abiomend Xplus Hydromembrane - HCP240930D9UH6**

## Topic/Issue

Request to establish a new HCPCS Level II code to identify Abiomend Xplus Membrane and Abiomend Xplus Hydromembrane.

Applicant's suggested language: XXXXX, "Abiomend Xplus Membrane and Abiomend Xplus Hydromembrane, per square centimeter"

## Summary of Applicant's Submission

Amnio Technology submitted a request to establish a new HCPCS Level II code to identify Abiomend Xplus Membrane and Abiomend Xplus Hydromembrane. Abiomend Xplus Membrane and Abiomend Xplus Hydromembrane are regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) solely under section 361 of the Public Health Service (PHS) Act and 21 CFR Part 1271 when intended for use as a "covering," a "semi-permeable barrier," or to "protect the wound." Abiomend Xplus Membrane and Abiomend Xplus Hydromembrane are amniotic membrane products 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, Abiomend Xplus Membrane and Abiomend Xplus Hydromembrane, "when intended for use as a 'covering,' a 'semi-permeable barrier,' or to 'protect the wound,' appear to meet all the criteria for regulation solely under section 361 of the 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 Q4355, "Abiomend xplus membrane and abiomend xplus hydromembrane, per square centimeter"

This coding decision applies to the Abiomend Xplus Membrane and Abiomend Xplus Hydromembrane products described in the application and accompanying FDA TRG letter dated August 14, 2024, when intended for use as a "covering," a "semi-permeable barrier," or to "protect the wound."

# XWRAP Plus® - HCP240909VJK1G

## Topic/Issue

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

Applicant's suggested language: XXXXX, “XWRAP Plus®, per square centimeter”

## Summary of Applicant's Submission

Applied Biologics, LLC submitted a request to establish a new HCPCS Level II code to identify XWRAP Plus®. XWRAP Plus® is regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) solely under section 361 of the Public Health Service (PHS) Act and 21 CFR Part 1271 when intended for use as a “protective barrier and wound covering.” XWRAP Plus® is a single layer, chorion-free amniotic membrane allograft. XWRAP Plus® is intended for homologous use as a wound barrier or cover applied to partial and full thickness acute and chronic wounds such as diabetic, venous, arterial, pressure and other ulcers, including those with exposed tendon, muscle, bone, or other vital structures, as well as traumatic and complex wounds, burns, surgical and Mohs surgery sites. XWRAP Plus® is supplied in various size and configuration sheets.

## CMS Final HCPCS Coding Decision

After review of the Food and Drug Administration’s (FDA’s) Tissue Reference Group (TRG) letter submitted by the applicant, XWRAP Plus®, “when intended for use as a ‘protective barrier and wound covering,’ appears to meet all the criteria for regulation solely under section 361 of the 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 Q4357, “Xwrap plus, per square centimeter”

This coding decision applies to the XWRAP Plus® product described in the application and accompanying FDA TRG letter dated September 5, 2024, when intended for use as a “protective barrier and wound covering.”

# XWRAP Dual® - HCP240909MWV6U

## Topic/Issue

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

Applicant's suggested language: XXXXX, “XWRAP Dual®, per square centimeter”

## Summary of Applicant's Submission

Applied Biologics, LLC submitted a request to establish a new HCPCS Level II code to identify XWRAP Dual®. XWRAP Dual® is regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) solely under section 361 of the Public Health Service (PHS) Act and 21 CFR Part 1271 when intended for use as a “protective barrier and wound covering.” XWRAP Dual® is a double layer, chorion-free amniotic membrane allograft applied to partial and full thickness acute and chronic wounds such as diabetic, venous, arterial, pressure and other ulcers, including those with exposed tendon, muscle, bone, or other vital structures, as well as traumatic, and complex wounds, burns, surgical and Mohs surgery sites. XWRAP Dual® is supplied in various sizes and configuration sheets.

## CMS Final HCPCS Coding Decision

After review of the Food and Drug Administration’s (FDA’s) Tissue Reference Group (TRG) letter submitted by the applicant, XWRAP Dual®, “when intended for use as a ‘protective barrier and wound covering,’ appears to meet all the criteria for regulation solely under section 361 of the 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 Q4358, “Xwrap dual, per square centimeter”

This coding decision applies to the XWRAP Dual® product described in the application and accompanying FDA TRG letter dated September 5, 2024, when intended for use as a “protective barrier and wound covering.”

# ChoriPly - HCP240819486GV

## Topic/Issue

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

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

## Summary of Applicant's Submission

International Tissue Inc. submitted a request to establish a new HCPCS Level II code to identify ChoriPly. ChoriPly is regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) solely under section 361 of the Public Health Service (PHS) Act and 21 CFR Part 1271 when intended for use as a "barrier and cover for wounds." ChoriPly is an amniotic membrane graft. It comes in a single layer option. ChoriPly is a collagenous membrane derived from the submucosa of the placenta. The product serves multiple functions. It can be used in surgical procedures such as tendon repairs and spinal fusions. It can also be utilized as a wound covering for chronic, non-healing wounds such as diabetic foot ulcers, venous leg ulcer, and pressure ulcers. The graft is either placed into the wound bed or to the affected area. It is then covered using the physician's choice of a dressing to keep the graft in place. There are numerous sizes of ChoriPly.

## 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, ChoriPly, "when intended as a barrier and cover for wounds, appears to meet the criteria for regulation solely under section 361 of the 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 Q4359, "Choriply, per square centimeter"

This coding decision applies to the ChoriPly product described in the application and accompanying FDA TRG letter dated August 2, 2024, when intended as a "barrier and cover for wounds."

# AmchoPlast FD™ - HCP240928ARN52

## Topic/Issue

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

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

## Summary of Applicant's Submission

LifeCell International Pvt Ltd. submitted a request to establish a new HCPCS Level II code to identify AmchoPlast FD™. AmchoPlast FD™ is regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) solely under section 361 of the Public Health Service (PHS) Act and 21 CFR Part 1271 when intended for use as a “barrier and cover.” AmchoPlast FD™ is a sterile, lyophilized allograft derived from donated human amnion-chorion membrane. It consists of a basement membrane and stromal matrix collagen layer. The allograft is processed using aseptic techniques and terminally sterilized by gamma radiation. AmchoPlast FD™ is intended for topical application. AmchoPlast FD™ 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, AmchoPlast FD™, “when intended for use as a barrier and cover, appears to meet the criteria for regulation solely under section 361 of the 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 Q4360, “Amchoplast fd, per square centimeter”

This coding decision applies to the AmchoPlast FD™ product described in the application and accompanying FDA TRG letter dated August 2, 2024, when intended as a “barrier and cover.”

# EPIXPRESS - HCP2409255PDCR

## Topic/Issue

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

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

## Summary of Applicant's Submission

MiMedx Group, Inc. submitted a request to establish a new HCPCS Level II code to identify EPIXPRESS. EPIXPRESS is regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) solely under section 361 of the Public Health Service (PHS) Act and 21 CFR Part 1271 when intended for use “as a barrier, to provide a protective environment in acute and chronic wounds EPIXPRESS is a minimally manipulated, lyophilized, non-viable cellular allograft derived from human amniotic membrane. After lyophilization, EPIXPRESS undergoes subsequent laser cutting to create X-pattern fenestrations in the tissue without the loss of surface area. EPIXPRESS preserves multiple extracellular matrix components and other proteins present in amniotic tissue. EPIXPRESS includes the amnion layer, intermediate layer, and chorion layers obtained from donated human placental tissue. The X-pattern in EPIXPRESS overcomes the inconvenience and clinical shortcomings of manual fenestration. The X-pattern was designed to evenly distribute the fenestrations for appropriate fluid egress, while maintaining the tissue integrity such that the allograft can be secured in place. EPIXPRESS can be used with or without negative pressure wound therapy. The fenestrations in EPIXPRESS make it conducive to the consistent pressure differential across the wound and transfer of exudate, while providing full therapeutic coverage with EPIXPRESS. EPIXPRESS 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, EPIXPRESS, “when intended for use ‘as a barrier, to provide a protective environment in acute and chronic wounds,’ appears to meet the criteria for regulation solely under section 361 of the 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 Q4361, “Epixpress, per square centimeter”

This coding decision applies to the EPIXPRESS product described in the application and accompanying FDA TRG letter dated September 9, 2024, when intended for use “as a barrier, to provide a protective environment in acute and chronic wounds.”

# Amnio Burgeon Membrane and Hydromembrane - HCP240923H894J

## Topic/Issue

Request to establish a new HCPCS Level II code to identify Amnio Burgeon Membrane and Hydromembrane.

Applicant's suggested language: XXXXX, “Amnio burgeon membrane and hydromembrane, per square centimeter”

## Summary of Applicant's Submission

One BioTech LLC submitted a request to establish a new HCPCS Level II code to identify Amnio Burgeon Membrane and Hydromembrane. Amnio Burgeon Membrane and Hydromembrane is regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) solely under section 361 of the Public Health Service (PHS) Act and 21 CFR Part 1271 then intended for use as a “covering,” a “semi-permeable barrier” and “to protect the wound.” Amnio Burgeon Membrane and Hydromembrane are amniotic membrane products 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, Amnio Burgeon Membrane and Hydromembrane, “when intended for ‘covering,’ a ‘semi-permeable barrier’ and to ‘protect the wound,’ appears to meet the criteria for regulation solely under section 361 of the 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 Q4363, “Amnio burgeon membrane and hydromembrane, per square centimeter”

This coding decision applies to the Amnio Burgeon Membrane and Hydromembrane products described in the application and accompanying FDA TRG letter dated August 14, 2024, when intended for use as a “covering,” a “semi-permeable barrier” and “to protect the wound.”

# Amnio Burgeon XPlus Membrane and XPlus Hydromembrane - HCP240923G6D8B

## Topic/Issue

Request to establish a new HCPCS Level II code to identify Amnio Burgeon XPlus Membrane and XPlus Hydromembrane.

Applicant's suggested language: XXXXX, “Amnio Burgeon XPlus Membrane, and XPlus Hydromembrane, per square centimeter”

## Summary of Applicant's Submission

One BioTech LLC submitted a request to establish a new HCPCS Level II code to identify Amnio Burgeon XPlus Membrane and XPlus Hydromembrane. Amnio Burgeon XPlus and XPlus Hydromembrane are regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) solely under section 361 of the Public Health Service (PHS) Act and 21 CFR Part 1271 when intended for use as a “covering,” a “semi-permeable barrier” and “to protect the wound.” Amnio Burgeon XPlus Membrane and XPlus Hydromembrane are amniotic membrane products 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, Amnio Burgeon XPlus Membrane and XPlus Hydromembrane, “when intended for ‘covering’, a ‘semi-permeable barrier’ and to ‘protect the wound,’ appears to meet the criteria for regulation solely under section 361 of the 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 Q4364, “Amnio burgeon xplus membrane and xplus hydromembrane, per square centimeter”

This coding decision applies to the Amnio Burgeon XPlus Membrane and XPlus Hydromembrane products described in the application and accompanying FDA TRG letter dated August 14, 2024, when intended for use as a “covering,” a “semi-permeable barrier” and “to protect the wound.”

# Amnio Burgeon Dual-Layer Membrane - HCP240924DR58J

## Topic/Issue

Request to establish a new HCPCS Level II code to identify Amnio Burgeon Dual-Layer Membrane.

Applicant's suggested language: XXXXX, “Amnio Burgeon Dual-Layer Membrane, per square centimeter”

## Summary of Applicant's Submission

One BioTech LLC submitted a request to establish a new HCPCS Level II code to identify Amnio Burgeon Dual-Layer Membrane. Amnio Burgeon Dual-Layer Membrane is regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) solely under section 361 of the Public Health Service (PHS) Act and 21 CFR Part 1271 when intended for use as a “covering,” a “semi-permeable barrier” and “to protect the wound.” Amnio Burgeon Dual-Layer Membrane is 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, Amnio Burgeon Dual-Layer Membrane, “when intended for ‘covering,’ a ‘semi-permeable barrier’ and to ‘protect the wound,’ appears to meet the criteria for regulation solely under section 361 of the 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 Q4365, “Amnio burgeon dual-layer membrane, per square centimeter”

This coding decision applies to the Amnio Burgeon Dual-Layer Membrane product described in the application and accompanying FDA TRG letter dated August 14, 2024, when intended for use as a “covering,” a “semi-permeable barrier” and “to protect the wound.”

# Dual Layer Amnio Burgeon X-Membrane - HCP240927WWYNM

## Topic/Issue

Request to establish a new HCPCS Level II code to identify Dual Layer Amnio Burgeon X-Membrane.

Applicant's suggested language: XXXXX, “Dual Layer Amnio Burgeon X-Membrane, per square centimeter”

## Summary of Applicant's Submission

One BioTech LLC submitted a request to establish a new HCPCS Level II code to identify Dual Layer Amnio Burgeon X-Membrane. Dual Layer Amnio Burgeon X-Membrane is regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) solely under section 361 of the Public Health Service (PHS) Act and 21 CFR Part 1271 when intended for use as a “covering,” a “semi-permeable barrier” and “to protect the wound.” Dual Layer Amnio Burgeon X-Membrane is 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, Dual Layer Amnio Burgeon X-Membrane, “when intended for ‘covering,’ a ‘semi-permeable barrier’ and ‘to protect the wound,’ appears to meet the criteria for regulation solely under section 361 of the 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 Q4366, “Dual layer amnio burgeon x-membrane, per square centimeter”

This coding decision applies to the Dual Layer Amnio Burgeon X-Membrane product described in the application and accompanying FDA TRG letter dated August 14, 2024, when intended for use as a “covering,” a “semi-permeable barrier” and “to protect the wound.”

# AmnioCore SL - HCP240923BWK4Q

## Topic/Issue

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

Applicant's suggested language: XXXXX, “AmnioCore SL (Amniotic Membrane Allograft – Single Layer)”

## Summary of Applicant's Submission

Stability Biologics submitted a request to establish a new HCPCS Level II code to identify AmnioCore SL. AmnioCore SL is regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) solely under section 361 of the Public Health Service (PHS) Act and 21 CFR Part 1271 when intended for use as a “barrier” and “covering.” AmnioCore SL is comprised of donated human tissue that has been screened, recovered, and serologically/microbiologically tested. AmnioCore SL is a single-layer allogeneic amniotic membrane allograft for use as a barrier and applied as a single use 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, AmnioCore SL “when intended for use as a ‘barrier’ and ‘covering,’ appear to meet all the criteria for regulation solely under section 361 of the 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 Q4367, “Amniocore sl, per square centimeter"

This coding decision applies to the AmnioCore SL product described in the application and accompanying FDA TRG letter dated September 5, 2024, when intended as a “barrier” and “covering.”

## CYGNUS Disk - HCP240924Y6PU3

### Topic/Issue

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

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

### Summary of Applicant's Submission

VIVEX Biologics (Vivex) submitted a request to establish a new HCPCS Level II code to identify CYGNUS Disk. CYGNUS Disk is regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) solely under section 361 of the Public Health Service (PHS) Act and 21 CFR Part 1271 when intended for use as a “barrier” and “covering.” CYGNUS Disk is a multilayer allograft derived from the amnion and chorion layers of the placental membrane and is manufactured using Integrity Processing™ Methodology, which helps to maintain the inherent levels of key extracellular matrices, including proteins, carbohydrates, growth factors, and cytokines. CYGNUS Disk retains the structural and functional characteristics of the membrane to provide a barrier or covering, protecting injured tissue from the external environment. The intended use of CYGNUS Disk is to serve as a tissue barrier or covering, protecting injured tissue from the external environment. CYGNUS Disk is most often used for acute and chronic complex wounds and burns. CYGNUS Disk 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, CYGNUS disk “when intended for use as a ‘barrier’ and ‘covering,’ appear to meet all the criteria for regulation solely under section 361 of the 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 Q4362, “Cygnus disk, per square centimeter"

This coding decision applies to the CYGNUS Disk product described in the application and accompanying FDA TRG letter dated September 5, 2024, when intended as a “barrier” and “covering.”

## 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 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[6] 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 seven HCPCS Level II codes to either 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, or to more accurately identify multiple source products accordingly.

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 BLA pathways after October 2003, and not rated as therapeutically equivalent to a reference

[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.

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 |
|---|---|---|
| J1271 | Add | Injection, doxycycline hyclate, 1 mg |

| | | |
|---|---|---|
| J0281 | Add | Injection, aminocaproic acid, 1 gram |
| J1299** | Add | Injection, eculizumab, 2 mg |
| J1300* | Delete | Injection, eculizumab, 10 mg |
| J1308 | Add | Injection, famotidine, 0.25 mg |
| J1808 | Add | Injection, folic acid, 0.1 mg |
| J1938** | Add | Injection, furosemide, 1 mg |
| J1940* | Delete | Injection, furosemide, up to 20 mg |
| J2804 | Add | Injection, rifampin, 1 mg |
| J2865 | Add | Injection, sulfamethoxazole 5 mg and trimethoprim 1 mg |
| J7521 | Add | Tacrolimus, granules, oral suspension, 0.1 mg |
| Q5139* | Delete | Injection, eculizumab-aeeb (bkemv), biosimilar, 10 mg |
| Q5152** | Add | Injection, eculizumab-aeeb (bkemv), biosimilar, 2 mg |
| S0017* | Delete | Injection, aminocaproic acid, 5 grams |
| S0028* | Delete | Injection, famotidine, 20 mg |
| S0032* | Delete | Injection, nafcillin sodium, 2 grams |
| S0039* | Delete | Injection, sulfamethoxazole and trimethoprim, 10 ml |

*The effective date for the discontinuation of this code is March 31, 2025.

**The dose descriptor is being reduced because 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.