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

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

## Second Quarter, 2025 HCPCS Coding Cycle

This document presents a summary of each HCPCS Level II code application and CMS' coding determination for each application processed in CMS' Second Quarter 2025 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 determination. All new coding actions will be effective October 1, 2025, unless otherwise indicated.

The HCPCS Level II coding determinations below will also be included in the October 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 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.

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Final determinations for the Second Quarter 2025 Drug and Biological HCPCS Level II coding applications.

## EMBLAVEO™ - HCP250331K7KP2

### Topic/Issue

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

Applicant's suggested language: JXXXX, "EMBLAVEO™ (aztreonam-avibactam), for injection, for intravenous infusion, per 1.5 g aztreonam and 0.5 g avibactam"

### Summary of Applicant's Submission

AbbVie, Inc. submitted a request to establish a new HCPCS Level II code to identify EMBLAVEO™ (aztreonam and avibactam). EMBLAVEO™ was approved by the Food and Drug Administration (FDA) under a New Drug Application (NDA) on February 7, 2025. EMBLAVEO™ is a combination of aztreonam, a monobactam antibacterial, and avibactam, a beta-lactamase inhibitor, that when used in combination with metronidazole is indicated for individuals 18 years and older who have limited or no alternative options for the treatment of complicated intra-abdominal infections including those caused by the following susceptible gram-negative microorganisms: *Escherichia coli, Klebsiella pneumoniae, Klebsiella oxytoca, Enterobacter cloacae complex, Citrobacter freundii complex,* and *Serratia marcescens*. EMBLAVEO™ is administered in combination with metronidazole and the code request is only for EMBLAVEO™. EMBLAVEO™ is supplied as a white to slightly yellow sterile lyophilized powder for reconstitution in a single-dose, sterile, clear glass vial containing: 2 g aztreonam and avibactam (1.5 g aztreonam and 0.5 g avibactam [equivalent to 0.542 g of avibactam sodium]). EMBLAVEO™ is prescribed by a health care provider and may be administered in the hospital inpatient or hospital outpatient settings. An initial loading dose of 2.67 g is infused intravenously for 3 hours followed by the recommended maintenance dose of 2 g infused intravenously over 3 hours for adults with creatinine clearance of greater than 50 mL/min, Adjustments to the dosing regimen for EMBLAVEO™ are recommended for individuals with estimated creatinine clearance less than or equal to 50 mL/min. EMBLAVEO™ was studied for 5 to 14 days. EMBLAVEO™ is supplied as a carton of 10 single-dose, clear glass vials filled with approximately 2 g of sterile powder containing 1.5 g aztreonam and 0.5 g avibactam.

### CMS Final HCPCS Coding Determination

Establish a new HCPCS Level II code J0458, "Injection, aztreonam/avibactam, 7.5 mg/2.5 mg (10 mg)"

## Epinephrine in Sodium Chloride Injection - HCP250319EF03X

### Topic/Issue

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

Applicant's suggested language: JXXXX, "Injection, epinephrine in sodium chloride (Baxter)"

### Summary of Applicant's Submission

Baxter Healthcare Corporation submitted a request to establish a new HCPCS Level II code to identify Epinephrine in Sodium Chloride Injection. Epinephrine in Sodium Chloride Injection was approved by the Food and Drug Administration (FDA) under the 505(b)(2) New Drug Application (NDA) pathway on February 28, 2025. Epinephrine in Sodium Chloride Injection is indicated to increase blood pressure in adults with hypotension associated with septic shock. Epinephrine in Sodium Chloride Injection is a non-selective alpha- and beta-adrenergic agonist that acts on alpha (α)- and beta (β)-adrenergic receptors. The mechanism of the rise in blood pressure is via direct myocardial stimulation that increases the strength of ventricular contraction, an increased heart rate, and peripheral vasoconstriction. The recommended starting dose is 0.05 mcg/kg/minute to 2 mcg/kg/minute by intravenous infusion for hypotension associated with septic shock. The dosage is titrated to achieve the desired mean arterial pressure and then weaned gradually. The route of administration is via infusion into a large vein. Epinephrine in Sodium Chloride Injection is supplied as a clear, sterile, colorless premixed solution containing 16 mg epinephrine in 250 mL VIAFLO bags. It is supplied as a carton of 20 bags with 16 mg/250 mL (64 mcg/mL) strength.

### CMS Final HCPCS Coding Determination

Establish a new HCPCS Level II code J0164, “Injection, epinephrine in sodium chloride (baxter), 0.1 mg”

## Macugen® - IHC2503232KXMT

### Topic/Issue

Request to discontinue existing HCPCS Level II code J2503, "Injection, pegaptanib sodium, 0.3 mg."

### Summary of Applicant's Submission

An internal request was received to discontinue existing HCPCS Level II code J2503, "Injection, pegatabnib sodium, 0.3 mg," that Macugen® (pegatabnib sodium). On September 17, 2004, the Food and Drug Administration (FDA) approved Macugen® (pegatabnib sodium) under a New Drug Application (NDA) pathway for the treatment of neovascular (wet) age-related macular degeneration. However, the FDA's Orange Book currently lists Macugen® as discontinued from marketing in the United States.[1]

### CMS Final HCPCS Coding Determination

Discontinue existing HCPCS Level II code J2503, "Injection, pegaptanib sodium, 0.3 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.

[1] Product Details for NDA 021756. FDA Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. https://www.accessdata.fda.gov/scripts/cder/ob/search_product.cfm

## ZYNRELEF® - HCP250331DKW1K

### Topic/Issue

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

Applicant's suggested language: JXXXX, “Instillation, bupivacaine and meloxicam (ZYNRELEF®), 1 mg/0.03 mg”

### Summary of Applicant's Submission

Heron Therapeutics, Inc. submitted a request to establish a new HCPCS Level II code for ZYNRELEF® (bupivacaine and meloxicam). ZYNRELEF® was approved by the Food and Drug Administration (FDA) under a 505(b)(2) New Drug Application (NDA) on May 12, 2021. ZYNRELEF® is indicated for use in adults for soft tissue or periarticular instillation to produce postsurgical analgesia for up to 72 hours after bunionectomy, open inguinal herniorrhaphy, and total knee arthroplasty. The label was later expanded on December 8, 2021, to include foot and ankle, small-to-medium open abdominal, and lower extremity total joint arthroplasty surgical procedures, and on January 23, 2024, to include soft tissue and orthopedic surgical procedures including foot and ankle, and other procedures in which direct exposure to articular cartilage is avoided. ZYNRELEF® utilizes a synergistic combination of bupivacaine and low-dose meloxicam, delivered in a Biochronomer® polymer for controlled diffusion over 72 hours. Bupivacaine is a local anesthetic that blocks the generation and conduction of nerve impulses presumably by increasing the threshold for electrical excitation in the nerve, slowing the propagation of the nerve impulse, and reducing the rate of rise of the action potential. As a non-steroidal anti-inflammatory drug, the mechanism of action of meloxicam is not completely understood but involves the inhibition of cyclooxygenase). Because meloxicam is a potent inhibitor of prostaglandin synthesis in vitro, its mode of action may be due to a decrease of prostaglandins in peripheral tissues. ZYNRELEF® extended-release solution is a clear, pale-yellow to yellow, viscous liquid supplied as a kit consisting of a single-dose nonsterile glass vial along with sterile, individually packaged components for administration. Each single-dose glass vial contains a solution of 29.25 mg/mL bupivacaine and 0.88 mg/mL meloxicam. The recommended dose of ZYNRELEF® is based on the size of the surgical site up to a maximum dose of 400 mg/12 mg (14 mL). ZYNRELEF® is used in a variety of surgical procedures, including total hip, knee, and shoulder arthroplasties, hysteroscopies, and carpal tunnel releases, across the hospital outpatient, ambulatory surgical center, and physician office settings.

### CMS Final HCPCS Coding Determination

Establish a new HCPCS Level II code J0668, “Instillation, bupivacaine and meloxicam, 1 mg/0.03 mg”

## ONAPGO™ - HCP2504016KFML

### Topic/Issue

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

Applicant's suggested language: XXXXX, “Injection, apomorphine hydrochloride, 1 mg”

### Summary of Applicant's Submission

Supernus Pharmaceuticals, Inc. submitted a request to establish a new HCPCS Level II code to identify ONAPGO™ (apomorphine hydrochloride). ONAPGO™ was approved by the Food and Drug Administration (FDA) under a New Drug Application (NDA) on February 3, 2025. ONAPGO™ is a dopaminergic agonist indicated for the treatment of motor fluctuations in adults with advanced Parkinson’s disease. The precise mechanism of action of ONAPGO™ as a treatment for Parkinson’s disease is unknown, although it is believed to be due to stimulation of post-synaptic dopamine D2-type receptors within the caudate-putamen in the brain. ONAPGO™ is administered as a subcutaneous infusion with the ONAPGO™ pump, worn by the individual in the home. ONAPGO™ is available in single-dose cartridges of 98 mg/20 mL (4.9 mg/mL). The daily dosage is determined by the users’ individualized titration and is composed of a continuous dosage and as needed extra dose(s). The maximum recommended total daily dosage of ONAPGO™, including the continuous dosage and any extra dose(s), is 98 mg per day, generally administered over the waking day (e.g., 16 hours).

### CMS Final HCPCS Coding Determination

ONAPGO™ is self-administered through a specific delivery system (ONAPGO™ pump). According to the product label, the ONAPGO™ Pump Kit and other ancillary items are supplied separately from the drug itself. Generally, Medicare Part B covers drugs that are furnished “incident to” a physician’s service provided the drugs are not usually self-administered or they are administered via a covered item of durable medical equipment (DME).

DME is defined in Medicare regulations at title 42 Code of Federal Regulations (CFR) 414.202 as equipment furnished by a supplier or a home health agency that meets all of the following conditions:

1. Can withstand repeated use.
2. Effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years.
3. Is primarily and customarily used to serve a medical purpose.
4. Generally is not useful to an individual in the absence of an illness or injury.
5. Is appropriate for use in the home.

All five of these conditions must be met for equipment to be classified as DME.

The Instructions for Use indicates that the maximum service life of the ONAPGO™ pump is one year. As such, the ONAPGO™ pump is not considered DME.

ONAPGO™ meets CMS criteria for classification as a Self-Administered Drug (SAD). CMS is denying the request to establish a new HCPCS Level II code to identify ONAPGO™ as the medication is self-administered through non-durable medical equipment.

## OMLYCLO® - HCP250401T1P9K

### Topic/Issue

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

Applicant's suggested language: QXXXX, “Omalizumab-igec, OMLYCLO®, biosimilar, injection, 5 mg”

### Summary of Applicant's Submission

Celltrion USA, Inc. submitted a request to establish a new HCPCS Level II code to identify OMLYCLO® (omalizumab-igec). OMLYCLO® was approved by the Food and Drug Administration (FDA) under a 351(k) Biologics License Application (BLA) pathway on March 7, 2025. OMLYCLO® is approved as an interchangeable biosimilar to XOLAIR® (omalizumab). OMLYCLO® is an anti-immunoglobulin E (IgE) antibody. It is indicated in individuals 6 years of age and older with moderate to severe persistent asthma with a positive skin test or in vitro reactivity to a perennial aeroallergen and symptoms that are inadequately controlled with inhaled corticosteroids, in adults 18 years of age and older for chronic rhinosinusitis with nasal polyps (CRSwNP) and inadequate response to nasal corticosteroids, in individuals aged 1 year and older as add-on maintenance treatment for IgE-mediated food allergy for the reduction of allergic reactions (Type I), including anaphylaxis, that may occur with accidental exposure to one or more foods, and in individuals 12 years of age and older for chronic spontaneous urticaria (CSU) who remain symptomatic despite H1 antihistamine treatment. For asthma, CRSwNP and IgE-mediated food allergy, omalizumab products inhibit the binding of IgE to the high-affinity IgE receptor (FcεRI) on the surface of mast cells, basophils, and dendritic cells, resulting in FcεRI down-regulation on these cells. For indivuduals with allergic asthma, omalizumab products inhibit IgE-mediated inflammation, as evidenced by reduced blood and tissue eosinophils and reduced inflammatory mediators, including interleukin-4, interleukin-5, and interleukin-13. In CSU, omalizumab products bind to IgE and lowers free IgE levels. Subsequently, FcεRI on cells down-regulate. The mechanism by which these effects of omalizumab products result in an improvement of CSU symptoms is unknown. OMLYCLO® is indicated for subcutaneous administration. Dosing will vary by indication and serum levels of serum total IgE level (IU/mL), measured before the start of treatment, and body weight (kg). For asthma, the dosing range is 75 to 375 mg every 2 to 4 weeks. For CRSwNP and IgE-mediated food allergy, the dosing range is 75 to 600 mg every 2 to 4 weeks. For CSU, the dosing ranges from 150 - 300 mg every 4 weeks. CSU dosing is not dependent on serum total IgE level (IU/mL) or body weight. OMLYCLO® injection is supplied as a sterile, preservative-free, clear to opalescent and colorless to pale brownish-yellow solution in 75 mg/0.5 mL and 150 mg/mL single-dose prefilled syringes.

### CMS Final HCPCS Coding Determination

Establish a new HCPCS Level II code Q5154, “Injection, omalizumab-igec (omlyclo), biosimilar, 5 mg”

## PROBUPHINE® - HCP250331JHR5R

### Topic/Issue

Request to establish a new HCPCS Level II code or reinstate HCPCS Level II code J0570, “Buprenorphine implant, 74.2 mg” to identify PROBUPHINE®.

Applicant's suggested language: JXXXX, “Buprenorphine implant, 74.2 mg”

### Summary of Applicant's Submission

ReacX Pharmaceuticals, Inc. submitted a request to establish a new HCPCS Level II code or reinstate HCPCS Level II code J0570, “Buprenorphine implant, 74.2 mg” to identify PROBUPHINE® (buprenorphine hydrochloride). PROBUPHINE® implant was approved by the Food and Drug Administration (FDA) under a New Drug Application (NDA) on May 26, 2016. HCPCS Level II code J0570 was established effective January 1, 2017. PROBUPHINE® was listed as discontinued by the FDA on October 1, 2020, following its withdrawal from the market by the manufacturer at the time for commercial (not safety) reasons. Therefore, HCPCS Level II code J0570 was no longer being used to submit Medicare claims, which resulted in the discontinuation of the code by CMS effective January 1, 2025. ReacX Pharmaceuticals has acquired PROBUPHINE® from Titan Pharmaceuticals and is relaunching PROBUPHINE® in the United States market.

PROBUPHINE® contains buprenorphine, a partial opioid agonist, and is indicated for the maintenance treatment of opioid dependence in individuals who have achieved and sustained prolonged clinical stability on low-to-moderate doses of a transmucosal buprenorphine-containing product (i.e., doses of no more than 8 mg per day of Subutex or Suboxone sublingual tablet or generic equivalent). PROBUPHINE® should be used as part of a complete treatment program to include counseling and psychosocial support. Each PROBUPHINE® implant is an ethylene vinyl acetate implant containing 74.2 mg of buprenorphine (equivalent to 80 mg of buprenorphine hydrochloride). Four PROBUPHINE® implants are inserted subdermally in the upper arm for six months of treatment and are removed by the end of the sixth month. One PROBUPHINE® implant kit consists of four individually packaged sterile implants and one individually packaged sterile disposable applicator.

### CMS Final HCPCS Coding Determination

Reinstate HCPCS Level II code J0570, “Buprenorphine implant, 74.2 mg” to describe PROBUPHINE®.

## SUNLENCA® - HCP2504011DU46

### Topic/Issue

Request to revise existing HCPCS Level II code J1961, “Injection, lenacapavir, 1 mg” to further identify SUNLENCA® only for use as treatment of human immunodeficiency virus (HIV) and not for use as HIV pre-exposure prophylaxis.

Applicant's suggested language: J1961, “Injection, lenacapavir, 1 mg, only for use as treatment of HIV (not for use as HIV pre-exposure prophylaxis)”

### Summary of Applicant's Submission

Gilead Sciences submitted a request to revise existing HCPCS Level II code J1961, “Injection, lenacapavir, 1 mg” to distinguish SUNLENCA® (lenacapavir) injection, indicated for treatment of individuals with human immunodeficiency virus (HIV), and a potential new lenacapavir product, submitted for approval by the Food and drug Administration (FDA) for HIV pre-exposure prophylaxis (PrEP). SUNLENCA® was approved by the FDA under a New Drug Application (NDA) on December 22, 2022. “Lenacapavir for PrEP” was submitted for FDA approval under a separate NDA with an indication for PrEP, and was granted a Breakthrough Therapy designation by the FDA in October 2024 and has a Prescription Drug User Fee Act deadline date of June 19, 2025. HIV PrEP is covered under Medicare Part B per the National Coverage Determination finalized effective September 30, 2024. A revision to HCPCS Level II code J1961 is needed to distinguish SUNLENCA®, which is indicated for the treatment of HIV-1 infection in heavily treatment-experienced adults with multidrug resistant HIV-1 infection failing their current antiretroviral regimen due to resistance, intolerance, or safety considerations.

### CMS Final HCPCS Coding Determination

1. Revise existing HCPCS Level II code J1961, “Injection, lenacapavir, 1 mg” to instead read “Injection, lenacapavir (only for use as hiv treatment), 1 mg” to describe SUNLENCA®.

   Effective June 18, 2025

2. Establish new HCPCS Level II code J0738, “Injection, lenacapavir, 1 mg, fda approved prescription, only for use as hiv pre-exposure prophylaxis (not for use as treatment for hiv)” to describe injectable lenacapavir for PrEP.

   Effective October 1, 2025

3. Establish new HCPCS Level II code J0752, “Oral, lenacapavir, 300 mg, fda approved prescription, only for use as hiv pre-exposure prophylaxis (not for use as treatment for hiv)” to describe oral lenacapavir for PrEP.

   Effective October 1, 2025

Existing HCPCS Level II code J0799, “Fda approved prescription drug, only for use as hiv pre-exposure prophylaxis (not for use as treatment of hiv), not otherwise classified” is available for use for lenacapavir for HIV PrEP until the new HCPCS Level II codes J0738 and J0752 are established effective October 1, 2025.

## Gvoke VialDx™ - HCP2503310MR9T

### Topic/Issue

Request to establish a new HCPCS Level II code to identify Gvoke VialDx™ injection.

Applicant's suggested language: JXXXX, “Gvoke VialDx (glucagon) injection, for intravenous use, per mg”

### Summary of Applicant's Submission

American Regent, Inc. submitted a request to establish a new HCPCS Level II code to identify Gvoke VialDx™ (glucagon) injection. Gvoke® injection was approved by the Food and Drug Administration (FDA) under a 505(b)(2) New Drug Application (NDA) on September 10, 2019, and the new indication specifically for Gvoke VialDx™ was approved by the FDA under its supplemental NDA on March 14, 2025. Gvoke VialDx™ is indicated for intravenous use in adults as a diagnostic aid during radiological examinations to temporarily inhibit movement of the gastrointestinal tract. There are other Gvoke® products, but Gvoke VialDx™ has the only indication related to medical imaging. Glucagon increases blood glucose concentration by activating hepatic glucagon receptors, thereby stimulating glycogen breakdown and release of glucose from the liver. Hepatic stores of glycogen are necessary for glucagon to produce an antihypoglycemic effect. Extrahepatic effects of glucagon include relaxation of the smooth muscle of the stomach, duodenum, small bowel, and colon. The recommended dose is 0.2 mg to 0.5 mg for relaxation of the stomach, duodenal bulb, duodenum, and small bowel and 0.5 mg to 0.75 mg for relaxation of the colon. The dose should be given intravenously via a 1-minute slow push using consistent pressure. Gvoke VialDx™ is a clear, colorless to pale yellow, sterile solution for intravenous injection available in 1 mg per 0.2 mL vial. Each 0.2 mL of Gvoke VialDx™ contains 1 mg of glucagon prior to dilution with 0.9% sodium chloride. The final concentration of the diluted solution is 0.45 mg/mL of glucagon. Gvoke VialDx™ contains a single dose of glucagon and any unused portion should be discarded.

### CMS Final HCPCS Coding Determination

Establish new HCPCS Level II code J1612, “Injection, glucagon (gvoke), 0.01 mg” to describe applicable Gvoke® products including Gvoke VialDx™.

## GOZELLIX™ - HCP250401115AP

### Topic/Issue

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

Applicant's suggested language: AXXXX, “GOZELLIX (kit for the preparation of gallium Ga-68 gozetotide injection), diagnostic, per 1 millicurie”

### Summary of Applicant's Submission

Telix Innovations SA submitted a request is to establish a new HCPCS Level II code to identify GOZELLIX™. GOZELLIX™ (kit for the preparation of gallium Ga 68 gozetotide injection) was approved by the Food and Drug Administration (FDA) under a 505(b)(2) New Drug Application (NDA) on March 20, 2025. GOZELLIX™ is a radioactive diagnostic agent used in positron emission tomography imaging for prostate-specific membrane antigen positive lesions in individuals with prostate cancer who either have suspected metastasis and are candidates for initial definitive therapy, or have suspected recurrence based on elevated prostate specific antigen (PSA) levels. GOZELLIX™ is used to detect metastasis outside the prostate and can aid in avoiding unnecessary localized treatments, such as external beam radiation therapy, brachytherapy, or radical prostatectomy, when metastatic disease is present. In cases of biochemical recurrence, where rising PSA levels indicate recurrence without identifying the disease location, GOZELLIX™ enables localization of metastatic disease, guiding more precise treatment decisions. GOZELLIX™ contains approximately six times the Ga 68 activity compared to other formulations, and four sources of Ga 68, allowing production at any radiopharmacy with access to either cyclotron-generated Ga 68 (on-site or externally supplied) or high-activity Germanium 68/Ga 68 generators. GOZELLIX™ is administered as an intravenous bolus injection, with a recommended dose of 3 to 7 millicuries. GOZELLIX™ is supplied as a kit in two different carton configurations, each containing the non-radioactive ingredients (gozetotide, acetate buffer, and ascorbic acid) needed to prepare Ga 68 gozetotide injection. The prepared Ga 68 gozetotide injection is a solution containing up to 500 mCi of Ga 68 gozetotide in 10 mL, in a multiple-dose vial.

### CMS Final HCPCS Coding Determination

Establish a new HCPCS Level II code A9616, “Gallium ga-68 gozetotide (gozellix), diagnostic, 1 millicurie”

## AXTLE™ - HCP250401PNMNT

### Topic/Issue

Request to revise existing HCPCS Level II code J9292, "Injection, pemetrexed (avyxa), not therapeutically equivalent to j9305, 10 mg" to identify AXTLE™ in replace of the manufacturer name, Avyxa.

Applicant's suggested language: J9292, "Injection, pemetrexed (axtle), 10 mg"

### Summary of Applicant's Submission

Avyxa Holdings, LLC submitted a request to revise existing HCPCS Level II code J9292 that describes Pemetrexed for Injection to replace the manufacturer name, Avyxa, with the brand name AXTLE™ (Pemetrexed for Injection). Avyxa's Pemetrexed for Injection was approved by the Food and Drug Administration (FDA) under a 505(b)(2) New Drug Application (NDA) on June 28, 2024. The new proprietary name AXTLE™ was approved by the FDA under a supplemental 505(b)(2) NDA on December 2, 2024. HCPCS Level II code J9292, "Injection, pemetrexed (avyxa), not therapeutically equivalent to j9305, 10 mg" was established effective January 1, 2024. Therefore, Avyxa is requesting a revision to HCPCS Level II code J9292 to include the brand name, AXTLE™.

AXTLE™ is a folate analog metabolic inhibitor indicated for initial treatment of individuals with locally advanced or metastatic, non-squamous non-small cell lung cancer (NSCLC) in combination with cisplatin, as a single agent for the maintenance treatment of individuals with locally advanced or metastatic, non-squamous NSCLC whose disease has not progressed after four cycles of platinum-based first-line chemotherapy, or as a single agent for the treatment of individuals with recurrent, metastatic non-squamous NSCLC after prior chemotherapy. The recommended dosing of AXTLE™ is 500 mg/m$^2$ as an intravenous infusion over 10 minutes on day 1 of each 21-day cycle administered in individuals with a creatinine clearance of 45 mL/minute or greater. AXTLE™ is a sterile, preservative free, white-to-light yellow or green-yellow lyophilized powder supplied in 100 mg and a 500 mg single-dose vials for reconstitution.

### CMS Final HCPCS Coding Determination

Effective July 1, 2025, CMS will revise HCPCS Level II code J9292, "Injection, pemetrexed (avyxa), not therapeutically equivalent to j9305, 10 mg" to instead read "Injection, pemetrexed dipotassium, 10 mg" to describe AXTLE™, as announced in our first quarter of 2025 coding cycle.[2]

CMS is denying the request to include the product's brand name in the existing HCPCS Level II code J9292, as there is no claims processing need. In considering that AXTLE™ is

[2] Appendix A of application HCP220517FAENJ in the First Quarter 2025 Drug and Biological HCPCS Level II coding decisions published at the following CMS link: https://www.cms.gov/files/document/2025-hcpcs-application-summary-quarter-1-2025-drugs-and-biologicals.pdf.

identified as pemetrexed dipotassium in the FDA's Orange Book[3], CMS believes including "pemetrexed dipotassium" in the HCPCS Level II code sufficiently distinguishes this product from the other FDA approved pemetrexed disodium or pemetrexed ditromethamine products.

[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.

## OSPOMYV™ and XBRYK™ - HCP250401UE0WH

### Topic/Issue

Request to establish a new HCPCS Level II code to identify OSPOMYV™ and XBRYK™.

Applicant's suggested language: QXXXX, “Injection, denosumab-dssb (OSPOMYV™/XBRYK™), biosimilar, 1 mg”

### Summary of Applicant's Submission

Samsung Bioepis submitted a request to establish a new HCPCS Level II code to identify OSPOMYV™ (denosumab-dssb 60 mg) and XBRYK™ (denosumab-dssb 120 mg). OSPOMYV™ and XBRYK™ were approved by the Food and Drug Administration (FDA) under a 351(k) Biologics License Application (BLA) on February 13, 2025, as biosimilars to their respective biological reference products, PROLIA® and XGEVA®. OSPOMYV™ and XBRYK™ are both sterile, preservative-free, clear, colorless to slightly yellow solutions for subcutaneous use. OSPOMYV™ is supplied in a single-dose prefilled syringe containing 1 mL solution of 60 mg denosumab-dssb, 0.28 mg histidine, 3.81 mg histidine hydrochloride monohydrate, 0.1 mg polysorbate 20, 44 mg sorbitol, and water for injection. XBRYK™ is supplied in a single-dose vial containing 1.7 mL solution of 120 mg denosumab-dssb, 0.44 mg histidine, 6.53 mg histidine hydrochloride monohydrate, 0.17 mg polysorbate 20, 74.8 mg sorbitol, and water for injection. The pH for both products is 5.2. OSPOMYV™ and XBRYK™ bind to receptor activator of nuclear factor kappa-B ligand, a transmembrane or soluble protein essential for the formation, function, and survival of osteoclasts (the cells responsible for bone resorption), thereby modulating calcium release from bone. OSPOMYV™ and XBRYK™ are indicated for individuals with specific conditions of the skeletal system such as those who experience certain types of skeletal bone loss, those with bone tumors, those with hypercalcemia, or those who need to increase bone mass or prevent skeletal-related events.

### CMS Final HCPCS Coding Determination

Establish a new HCPCS Level II code Q5159, “Injection, denosumab-dssb (ospomyv/xbryk), biosimilar, 1 mg”

## Bomyntra® and Conexxence® - HCP250331T7CQ6

### Topic/Issue

Request to establish a new HCPCS Level II code to identify Bomyntra® and Conexxence®.

Applicant's suggested language: QXXXX, “Injection, denosumab-bnht, 1 mg”

### Summary of Applicant's Submission

Fresenius Kabi submitted a request to establish a new HCPCS Level II code to identify Bomyntra® (denosumab-bnht) and Conexxence® (denosumab-bnht). Bomyntra® and Conexxence® were approved by the Food and Drug Administration (FDA) under a 351(k) Biologics License Application (BLA) on March 25, 2025, as biosimilars to their respective biological reference products, Prolia® (denosumab) and Xgeva® (denosumab). Bomyntra® and Conexxence® are receptor activator of nuclear factor kappa-B ligand (RANKL) inhibitors with two different indications. Conexxence® is indicated to: treat postmenopausal women with osteoporosis at a high risk for fracture; increase bone mass in men with osteoporosis at a high risk for fracture; treat individuals with glucocorticoid- induced osteoporosis at a high risk for fracture; increase bone mass in men at a high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer; and increase bone mass in women at a high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer. Bomyntra® is indicated to: prevent skeletal-related events in individuals with multiple myeloma, and in individuals with bone metastases from solid tumors; treat adults and skeletally-mature adolescents with giant cell tumors of bone that are unresectable, or where surgical resection is likely to result in severe morbidity; treat hypercalcemia of malignancy refractory to bisphosphonate therapy. Denosumab products bind to RANKL, a transmembrane or soluble protein essential for the formation, function, and survival of osteoclasts, the cells responsible for bone resorption, thereby modulating calcium release from bone. Increased osteoclast activity, stimulated by RANKL, is a mediator of bone pathology in solid tumors with osseous metastases. Similarly, giant cell tumors of bone consist of stromal cells expressing RANKL and osteoclast-like giant cells expressing RANK receptor, and signaling through the RANK receptor contributes to osteolysis and tumor growth. Denosumab products prevent RANKL from activating its receptor, RANK, on the surface of osteoclasts, their precursors, and osteoclast-like giant cells. Denosumab-bnht has an approximate molecular weight of 147 kilodaltons. Bomyntra® injection is a sterile, preservative-free, clear, colorless to pale yellow solution for subcutaneous use. Each ready-to-use, single-dose prefilled syringe and single-dose vial of Bomyntra® contains 120 mg denosumab-bnht (70 mg/mL solution). The recommended dose of Conexxence® is 60 mg administered as a single subcutaneous injection once every 6 months, given in the upper arm, the upper thigh, or the abdomen.

### CMS Final HCPCS Coding Determination

Establish a new HCPCS Level II code Q5158, “Injection, denosumab-bnht (bomyntra/conexxence), biosimilar, 1 mg”

## STOBOCLO® and OSENVELT® - HCP250401JTP11

### Topic/Issue

Request to establish a new HCPCS Level II code to identify STOBOCLO® and OSENVELT®.

Applicant's suggested language: QXXXX, “Injection, denosumab-bmwo, biosimilar, stoboclo/osenvelt, 1 mg”

### Summary of Applicant's Submission

Celltrion USA, Inc. submitted a request to establish a new HCPCS Level II code to identify STOBOCLO® (denosumab-bmwo) and OSENVELT® (denosumab-bmwo). STOBOCLO® and OSENVELT® were approved by the Food and Drug Administration (FDA) under a 351(k) Biologics License Application (BLA) on February 28, 2025, as biosimilars to their respective biological reference products, Prolia® (denosumab) and Xgeva® (denosumab). STOBOCLO® and OSENVELT® are receptor activator of nuclear factor kappa-B ligand (RANKL) inhibitors with different indications. STOBOCLO® is indicated for the treatment of postmenopausal women with osteoporosis at a high risk for fracture; to increase bone mass in men with osteoporosis at a high risk for fracture; to treat the glucocorticoid-induced osteoporosis in individuals at a high risk for fracture; to increase bone mass in men at a high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer; and to increase bone mass in women at a high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer. OSENVELT® is indicated for the prevention of skeletal-related events in individuals with multiple myeloma; in individuals with bone metastases from solid tumors; treatment of adults and skeletally-mature adolescents with giant cell tumor of bone that is unresectable, or where surgical resection is likely to result in severe morbidity; and for the treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy. Denosumab products bind to RANKL, a transmembrane or soluble protein essential for the formation, function, and survival of osteoclasts, the cells responsible for bone resorption, thereby modulating calcium release from bone. Increased osteoclast activity, stimulated by RANKL, is a mediator of bone pathology in solid tumors with osseous metastases. Similarly, giant cell tumors of bone consist of stromal cells expressing RANKL and osteoclast-like giant cells expressing RANK receptor, and signaling through the RANK receptor contributes to osteolysis and tumor growth. Denosumab products prevent RANKL from activating its receptor, RANK, on the surface of osteoclasts, their precursors, and osteoclast-like giant cells. STOBOCLO® injection is a clear, colorless to pale yellow solution supplied in a 60 mg/mL single-dose prefilled syringe with a safety guard. The prefilled syringe is not made with natural rubber latex. STOBOCLO® is administered every 6 months as a 60 mg subcutaneous injection in the upper arm, upper thigh, or abdomen. OSENVELT® injection is a clear, colorless to pale yellow solution supplied in a 120 mg/1.7 mL single-dose vial. OSENVELT® is administered every 4 weeks as a 120 mg subcutaneous injection with additional doses in the first month of treatment.

### CMS Final HCPCS Coding Determination

Establish a new HCPCS Level II code Q5157, “Injection, denosumab-bmwo (stoboclo/osenvelt), biosimilar, 1 mg”

## YESAFILI™ - HCP250331GF7E0

### Topic/Issue

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

Applicant's suggested language: QXXXX, “Injection, aflibercept-jbvf, (yesafili), 1 mg”

### Summary of Applicant's Submission

Biocon Biologics Inc. submitted a request to establish a new HCPCS Level II code to identify YESAFILI™ (aflibercept-jbvf). YESAFILI™ was approved by the Food and Drug Administration (FDA) under a 351(k) Biologics License Application (BLA) on May 24, 2024. YESAFILI™ is a single-source drug and a biosimilar to EYLEA® (aflibercept). YESAFILI™ is a vascular endothelial growth factor (VEGF) inhibitor indicated for the treatment of neovascular (wet) age-related macular degeneration, macular edema following retinal vein occlusion, diabetic macular edema, and diabetic retinopathy. The active ingredient in YESAFILI™ is aflibercept-jbvf, 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. The recommended dosage of YESAFILI™ varies based on the indication, and is administered via ophthalmic intravitreal injection.

### CMS Final HCPCS Coding Determination

Establish a new HCPCS Level II code Q5155, “Injection, aflibercept-jbvf (yesafili), biosimilar, 1 mg”

## Paragard® Copper Intrauterine Device - HCP250320HV2GQ

### Topic/Issue

Request to revise existing HCPCS Level II code J7300, “Intrauterine copper contraceptive” to further identify Paragard® T380A 10-year duration.

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

### Summary of Applicant's Submission

Cooper Surgical submitted a request to revise existing HCPCS Level II code J7300 to further identify Paragard® T380A 10-year duration. This product was first approved by the Food and Drug Administration (FDA) under a New Drug Application (NDA) on November 15, 1984. Maintaining HCPCS Level II code J7300 is crucial for healthcare providers to ensure market stability and prevent disruptions in reimbursement, stocking, and compliance. Historically, Paragard® has been aligned with this J code, and continuing this alignment is important for consistent access, supply, and regulatory compliance. This stability benefits users, pharmacies, insurance companies, healthcare facilities, and regulatory bodies. Paragard® is a copper-containing intrauterine system used to prevent pregnancy in females of reproductive age, for up to 10 years. The mechanism of action of Paragard® enhances contraceptive efficacy by interfering with sperm transport and fertilization, and possibly preventing implantation, and is given via intrauterine administration by a healthcare provider. Paragard® is packaged as a single-use device.

### CMS Final HCPCS Coding Determination

In the second quarter (Q2) of 2023, CMS denied a request to revise existing HCPCS Level II code J7300 to specifically identify Paragard® T380A. This decision was based on the fact that Paragard® was the only NDA-approved intrauterine copper contraceptive device available for distribution and use at that time. Subsequently, CMS has been made aware of another FDA-approved non-hormonal intrauterine device, MIUDELLA®. As such, CMS has determined to:

Revise existing HCPCS Level II code J7300, “Intrauterine copper contraceptive” to instead read, “Intrauterine copper contraceptive (paragard)” to describe Paragard®.

## AVTOZMA® - HCP250401XUKDV

### Topic/Issue

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

Applicant's suggested language: QXXXX, “Injection, tocilizumab-anoh, biosimilar (avtozma), 1 mg”

### Summary of Applicant's Submission

Celltrion USA, Inc. submitted a request to establish a new HCPCS Level II code to identify AVTOZMA® (tocilizumab-anoh) injection. AVTOZMA® was approved by the Food and Drug Administration (FDA) under a 351(k) Biologics License Application (BLA) on January 24, 2025, and is a biosimilar to ACTEMRA® (tocilizumab). AVTOZMA® is an interleukin-6 (IL-6) receptor antagonist. AVTOZMA® is indicated for the treatment of rheumatoid arthritis (RA), giant cell arteritis (GCA), polyarticular juvenile idiopathic arthritis (PJIA), systemic juvenile idiopathic arthritis (SJIA), and coronavirus disease 2019 (COVID-19). Tocilizumab products bind to both soluble and membrane-bound IL-6 receptors (sIL-6R and mIL-6R) and have been shown to inhibit IL-6-mediated signaling through these receptors. IL-6 is a pleiotropic pro-inflammatory cytokine produced by a variety of cell types including T- and B-cells, lymphocytes, monocytes and fibroblasts. IL-6 has been shown to be involved in diverse physiological processes such as T-cell activation, induction of immunoglobulin secretion, initiation of hepatic acute phase protein synthesis, and stimulation of hematopoietic precursor cell proliferation and differentiation. IL-6 is also produced by synovial and endothelial cells leading to local production of IL-6 in joints affected by inflammatory processes such as RA. AVTOZMA® dosing varies based on diagnosis. For intravenous (IV) dosing in RA, the dose is 4 mg/kg every 4 weeks, followed by an increase to 8 mg/kg every 4 weeks based on clinical response. In GCA, the IV dose is 6 mg/kg every 4 weeks in combination with a tapering course of glucocorticoids. AVTOZMA® can be used alone following discontinuation of glucocorticoids. In PJIA, the IV dose is either 8 mg/kg or 10 mg/kg every 4 weeks based on weight. In SJIA, the IV dose is either 8 mg/kg or 12 mg/kg every 4 weeks based on weight. The dose for adults with COVID-19 is 8 mg/kg administered via a 60-minute IV infusion. AVTOZMA® is a preservative-free, sterile clear to slightly opalescent, colorless to pale yellow solution. For IV infusion, it is supplied in 80 mg/4 mL (20 mg/mL), 200 mg/10 mL (20 mg/mL), 400 mg/20 mL (20 mg/mL) single-dose vials.

### CMS Final HCPCS Coding Determination

1. Establish a new HCPCS Level II code Q5156, “Injection, tocilizumab-anoh (avtozma), biosimilar, 1 mg”

   Effective October 1, 2025

2. Establish a new HCPCS Level II code Q0237, “Injection, tocilizumab-anoh, for hospitalized adult patients with covid-19 who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ecmo) only, 1 mg”

   Effective January 24, 2025

3. Establish a new HCPCS Level II code M0237, "Intravenous infusion, tocilizumab-anoh, for hospitalized adult patients with covid-19 who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ecmo) only, includes infusion and post administration monitoring, first dose"

   Effective January 24, 2025

4. Establish a new HCPCS Level II code M0238, "Intravenous infusion, tocilizumab-anoh, for hospitalized adult patients with covid-19 who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ecmo) only, includes infusion and post administration monitoring, second dose"

   Effective January 24, 2025

AVTOZMA® (tocilizumab-anoh), a biosimilar to ACTEMRA® (tocilizumab), is approved for the treatment of rheumatoid arthritis, giant cell arteritis, polyarticular juvenile idiopathic arthritis, systemic juvenile idiopathic arthritis, and coronavirus disease 2019 (COVID-19). Effective October 1, 2025, CMS will establish HCPCS Level II code Q5156, "Injection, tocilizumab-anoh (avtozma), biosimilar, 1 mg", to describe AVTOZMA®, which is payable under Medicare Part B at a rate of average sales price (ASP) plus 6%. In 2020, CMS established payment policies for monoclonal antibody (mAb) products with an indication for post-exposure prophylaxis or treatment of COVID-19 to be paid under the Medicare Part B preventive vaccine benefit at 95% of the average wholesale price through the end of the calendar year in which the Emergency Use Authorization (EUA) declaration under section 564 of the Federal Food, Drug, and Cosmetic Act ends. To date, the EUA declaration under section 564 of the FD&C Act remains in effect. Effective January 1 of the year following the year in which the EUA declaration for drugs and biological products ends, CMS will pay for COVID-19 mAb products used for the treatment or for post-exposure prophylaxis of COVID-19 as biological products paid under section 1847A of the Social Security Act (the Act), typically at ASP plus 6%; healthcare providers and practitioners will be paid under the applicable payment system, and using the appropriate coding and payment rates, for administering COVID-19 mAb therapies similar to the way they are paid for administering other complex biological products.

Typically, CMS does not establish new HCPCS Level II codes for drug and biological products to distinguish an indication; however, the HCPCS Level II code Q5156 for AVTOZMA® would not be suitable for the treatment of COVID-19 based on CMS' current payment policies, similar to what has been done for prior mAb products with this indication (such as HCPCS Level II code Q0249 for ACTEMRA®) for appropriate Medicare Part B payment. As such, CMS is establishing HCPCS Level II code Q0237 to describe AVTOZMA® for post-exposure prophylaxis or treatment of COVID-19. HCPCS Level II codes Q0237, M0237, and M0238 will become effective the same date as the FDA approval in order to align with the appropriate Medicare payment policies and considering, to date, there is not a "not otherwise classified" (NOC) COVID-19 mAb HCPCS Level II code and associated administrative codes. These codes would be effective through the end of the calendar year in which the EUA declaration under section 564 of the FD&C Act ends. At that time, COVID-19 mAb products used for the treatment or for post-exposure prophylaxis of

COVID-19 as biological products will be paid under section 1847A of the Act and the appropriate HCPCS Level II code Q5156 should be billed for these indications.

In addition, we will be establishing a NOC COVID-19 mAb HCPCS Level II code and associated administrative codes to be used to bill any newly FDA approved COVID-19 mAb products that are not yet assigned to a unique HCPCS Level II code while the EUA declaration under section 564 of the FD&C Act remains in effect.

5. Establish HCPCS Level II code Q0235, "Injection, monoclonal antibody products with an indication for post-exposure prophylaxis or treatment of COVID-19, for hospitalized adults and/or pediatric patients who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ecmo) only, not otherwise classified, 1 mg"

   Effective October 1, 2025

6. Establish HCPCS Level II code M0235, "Intravenous infusion, monoclonal antibody products with an indication for post-exposure prophylaxis or treatment of COVID-19, for hospitalized adults and/or pediatric patients who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ecmo) only, includes infusion and post administration monitoring, not otherwise classified, first dose"

   Effective October 1, 2025

7. Establish HCPCS Level II code M0236, "Intravenous infusion, monoclonal antibody products with an indication for post-exposure prophylaxis or treatment of COVID-19, for hospitalized adults and/or pediatric patients who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ecmo) only, includes infusion and post administration monitoring, not otherwise classified, second dose"

   Effective October 1, 2025

These codes (HCPCS Level II codes Q0235, M0235, and M0236) would be effective through the end of the calendar year in which the EUA declaration under section 564 of the FD&C Act ends. At that time, COVID-19 mAb products used for the treatment or for post-exposure prophylaxis of COVID-19 as biological products will be paid under section 1847A of the Act and the appropriate HCPCS Level II J or Q code should be billed for these indications.

## RYONCIL® - HCP250331GQG2D

### Topic/Issue

Request to establish a new HCPCS Level II code to RYONCIL®.

Applicant's suggested language: JXXXX, “Injection, remestemcel-L-rknd, per therapeutic dose”

### Summary of Applicant's Submission

Mesoblast. Inc. submitted a request to establish a new HCPCS Level II code to identify RYONCIL® (remestemcel-L-rknd) suspension. RYONCIL® was approved by the Food and Drug Administration (FDA) under a 351(a) Biologics License Application (BLA) on December 18, 2024. RYONCIL® is an allogeneic bone marrow-derived mesenchymal stromal cell (MSC) therapy indicated for the treatment of individuals 2 months of age and older with steroid-refractory acute graft versus host disease (aGvHD). Steroid-refractory aGvHD is a severe and life-threatening complication of allogeneic hematopoietic stem cell transplantation. Steroid refractory aGvHD is associated with significantly worse pediatric health outcomes and with economic burden thought to be greater than that seen with steroid-responsive aGvHD. The recommended dosage of RYONCIL® is $2 \times 10^6$ MSC/kg body weight per intravenous infusion, administered twice per week for 4 consecutive weeks, for a total of 8 infusions. These infusions are administered at least 3 days apart. The individual’s response is then assessed on day 28 ± 2 days after the first RYONCIL® dose, with the need for further infusions as appropriate based on the clinical response. RYONCIL® is supplied as a sterile, cryopreserved cell suspension of ex-vivo culture-expanded allogeneic bone marrow-derived MSC in vials. RYONCIL® is provided in customized kits to meet single dosing requirements for each individual’s weight band. Each kit contains sufficient vials of RYONCIL® MSC necessary for one infusion based on the individual’s weight and sufficient alcohol wipes for preparation of the RYONCIL® infusion.

### CMS Final HCPCS Coding Determination

Establish a new HCPCS Level II code J3402, “Injection, remestemcel-l-rknd, per therapeutic dose”

## ALHEMO® - HCP2503212NJFC

### Topic/Issue

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

Applicant's suggested language: XXXXX, “Inj., concizumab-mtci, 1 mg”

### Summary of Applicant's Submission

Novo Nordisk, Inc. submitted a request to establish a new HCPCS Level II code to identify ALHEMO® (concizumab-mtci). ALHEMO® was approved by the Food and Drug Administration (FDA) under a 351(a) Biologics License Application (BLA) on December 20, 2024. ALHEMO® is a tissue factor pathway inhibitor (TFPI)-antagonist indicated for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric individuals 12 years of age and older with hemophilia A (congenital factor VIII (FVIII) deficiency) with FVIII inhibitors, and hemophilia B (congenital factor IX (FIX) deficiency) with FIX inhibitors. As an anti-TFPI antibody, ALHEMO® enhances blood coagulation factor X (FXa) production during the initiation phase of coagulation which leads to improved thrombin generation and clot formation to achieve hemostasis in individuals with hemophilia A or B with or without inhibitors. ALHEMO® is once-daily single-use prefilled pen administered by subcutaneous injection to the abdomen or thigh with daily rotation of injection site. The recommended dosing regimen includes a loading dose of 1 mg/kg on day 1, followed by a once-daily dose of 0.20 mg/kg on day 2 until the individualization of a maintenance dose at least four weeks after initiation of treatment. An individualized maintenance dose is based on monitoring ALHEMO® plasma concentrations. ALHEMO® solution for injection is a clear to slightly opalescent, colorless to slightly yellow liquid, that may contain translucent to white particles of proteins. ALHEMO® is available in 60 mg/1.5 mL (40 mg/mL); 150 mg/1.5 mL (100 mg/mL); and 300 mg/3 mL (100 mg/mL).

### CMS Final HCPCS Coding Determination

Establish a new HCPCS Level II code J7173, “Injection, concizumab-mtci, 0.5 mg”

## FRINDOVYX™ - HCP2504018CKYB

### Topic/Issue

Request to revise existing HCPCS Level II code J9072, “Injection, cyclophosphamide (avyxa), 5 mg” to change the manufacturer from Avyxa to the brand name FRINDOVYX™.

Applicant's suggested language: J9072, “Injection, cyclophosphamide (frindovyx), 5mg”

### Summary of Applicant's Submission

Avyxa Holdings, LLC submitted a request to revise HCPCS Level II code J9072 that describes cyclophosphamide injection to change the manufacturer from Avyxa to the brand name FRINDOVYX™. FRINDOVYX™ (cyclophosphamide) was approved by the Food and Drug Administration (FDA) under a 505(b)(2) Supplemental New Drug Application (sNDA) on January 24, 2025. Cyclophosphamide was assigned HCPCS Level II code J9072, “Injection, cyclophosphamide (avyxa), 5 mg” effective January 1, 2025, however, Avyxa Holdings, LLC received approval for the brand name FRINDOVYX™ and is therefore requesting a change.

### CMS Final HCPCS Coding Determination

Revise existing HCPCS Level II code J9072, “Injection, cyclophosphamide (avyxa), 5 mg” to instead read “Injection, cyclophosphamide (frindovyx), 5 mg”

## ENCELTO™ - HCP2503274H9JE

### Topic/Issue

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

Applicant's suggested language: QXXXX, “Revakinagene taroretcel-lwey, up to 440,000 allogeneic retinal pigment epithelial cells expressing recombinant human ciliary neurotrophic factor”

### Summary of Applicant's Submission

Neurotech Pharmaceuticals submitted a request to establish a new HCPCS Level II code to identify ENCELTO™ (revakinagene taroretcel-lwey). ENCELTO™ was approved by the Food and Drug Administration (FDA) under a 351(a) Biologics License Application (BLA) on March 5, 2025. ENCELTO™ is an allogeneic encapsulated cell-based gene therapy. ENCELTO™ is indicated for the treatment of adults with idiopathic macular telangiectasia. ENCELTO™ is a single-dose implant that contains 200,000 to 440,000 allogeneic retinal pigment epithelial cells expressing recombinant human ciliary neurotrophic factor (rhCNTF) for intravitreal surgical placement. The recommended dose is one ENCELTO™ implantation per affected eye, containing 200,000 to 440,000 allogeneic retinal pigment epithelial cells expressing rhCNTF. ENCELTO™ is administered by a single surgical intravitreal procedure performed in an operating room by an ophthalmologist.

### CMS Final HCPCS Coding Determination

Establish a new HCPCS Level II code J3403, “Revakinagene taroretcel-lwey, per implant”

## Qfitlia™ - HCP250401C2EK2

### Topic/Issue

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

Applicant's suggested language: JXXXX, “Injection fitusiran injection, 10 mcg”

### Summary of Applicant's Submission

Sanofi submitted a request to establish a new HCPCS Level II code to identify Qfitlia™ (fitusiran). Qfitlia™ was approved by the Food and Drug Administration (FDA) under a 505(b)(2) New Drug Application (NDA) on March 28, 2025. Qfitlia™ is an antithrombin-directed small interfering ribonucleic acid indicated for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in individuals 12 years and older with hemophilia A or B with or without factor VIII or IX inhibitors. The starting dose of Qfitlia™ is 50 mg every 2 months. The dose should be adjusted if needed, to maintain antithrombin activity between 15-35%. Qfitlia™ is supplied as a sterile, preservative-free solution for subcutaneous administration in 50 mg/0.5 mL in a single-dose prefilled pen and 20 mg/0.2 mL in a single-dose vial.

### CMS Final HCPCS Coding Determination

Establish a new HCPCS Level II code J7174, "Injection, fitusiran, 0.04 mg"

For Medicare, QFITLIA™ meets CMS’ definition of a blood clotting factor (BCF) and is eligible for a furnishing fee. CMS believes that a 40 mcg dose descriptor for QFITLIA™ will appropriately recognize the cost of furnishing BCF therapies regardless of dosing frequency.

## DATROWAY® - HCP250201JUF8U

### Topic/Issue

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

Applicant's suggested language: JXXXX, “Injection, datopotamab deruxtecan-dlnk, 1 mg”

### Summary of Applicant's Submission

Daiichi Sankyo, Inc. submitted a request to establish a new HCPCS Level II code to identify DATROWAY® (datopotamab deruxtecan-dlnk). DATROWAY® was approved by the Food and Drug Administration (FDA) under a 351(a) Biologics License Application (BLA) pathway on January 17, 2025. DATROWAY® is indicated for the treatment of adults with unresectable or metastatic hormone receptor positive, human epidermal growth factor receptor 2-negative breast cancer who have received prior endocrine-based therapy and chemotherapy for unresectable or metastatic disease. DATROWAY® is a trophoblast cell surface antigen 2-directed antibody-drug conjugate. DATROWAY® is packaged as a white to yellowish white lyophilized powder in a 100 mg single-dose vial.

### CMS Final HCPCS Coding Determination

1. Establish a new HCPCS Level II code J9011, “Injection, datopotamab deruxtecan-dlnk, 1 mg”

2. Discontinue HCPCS Level II code C9174, “Injection, datopotamab deruxtecan-dlnk, 1 mg”

## ZEVTERA® - HCP25032822WVU

### Topic/Issue

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

The applicant did not submit any suggested language.

### Summary of Applicant's Submission

Innoviva Specialty Therapeutics submitted a request to establish a new HCPCS Level II code to identify ZEVTERA® (ceftobiprole medocaril sodium). ZEVTERA® was approved by the Food and Drug Administration (FDA) under a New Drug Application (NDA) on April 3, 2024. ZEVTERA® is an intravenous cephalosporin antibacterial indicated for the treatment of adults with Staphylococcus aureus bloodstream infections (bacteremia), including those with right-sided infective endocarditis; adults with acute bacterial skin and skin structure infections; and individuals 3 months to less than 18 years old with community-acquired bacterial pneumonia. ZEVTERA® is available in a single-dose vial with 667 mg of ceftobiprole medocaril sodium for reconstitution for each administration.

### CMS Final HCPCS Coding Determination

Establish a new HCPCS Level II code J0681, “Injection, ceftobiprole medocaril sodium, 3 mg”

## GRAFAPEX - HCP250401B9CTA

### Topic/Issue

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

Applicant's suggested language: XXXXX, “Injection, treosulfan, 1 gram”

### Summary of Applicant's Submission

Medexus submitted a request to establish a new HCPCS Level II code to identify GRAFAPEX (treosulfan). GRAFAPEX was approved by the Food and Drug Administration (FDA) under a New Drug Application (NDA) on January 21, 2025. GRAFAPEX is a deoxyribonucleic acid alkylating agent indicated for the use in combination with fludarabine as a preparative regimen for allogenic hematopoietic stem cell transplant (alloHSCT) in individuals one year of age and older with acute myeloid leukemia; and used in combination with fludarabine as a preparative regimen for alloHSCT in individuals one year of age and older with myelodysplastic syndrome. GRAFAPEX is supplied as a lyophilized powder to be reconstituted before use. GRAFAPEX is available in two sizes of single-use vials for reconstitution and injection: a 1 gram vial containing 1 gram of treosulfan and a 5 gram vial containing 5 grams of treosulfan.

### CMS Final HCPCS Coding Determination

1. Establish a new HCPCS Level II code J0614, “Injection, treosulfan, 50 mg”

2. Discontinue HCPCS Level II code C9175, “Injection, treosulfan, 50 mg”

While HCPCS Level II codes for drugs specify the amount of drug (e.g., mg or microgram) in their descriptors, CMS does not specifically create codes based on the powder weight of drugs. Instead, CMS has a long-standing convention to assign dose descriptors based on the smallest amount that can be billed in multiple units to accommodate various doses and facilitate streamlined billing. This means the code descriptor focuses on the drug dosage itself, not the form (powder or solution) it comes in, hence the distinction between the applicant’s suggested dosage and HCPCS Level II code J0614.

## Ascendion™ - HCP250328BD9DA

### Topic/Issue

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

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

### Summary of Applicant's Submission

Ascension Biologics submitted a request to establish a new HCPCS Level II code to identify Ascendion™. Ascendion™ 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.” Ascendion™ is a minimally manipulated, dehydrated human amniotic membrane allograft. The graft is designed for homologous use as a wound covering, providing a protective barrier for damaged or inadequate integumental tissue, such as diabetic foot ulcers, venous leg ulcers, and pressure ulcers. The graft is available in a range of sizes and can accommodate various wound dimensions. Each graft is double-packaged and sealed within a pouch to maintain sterility and integrity during storage and transit. All grafts are labeled in compliance with federal regulatory requirements and terminally sterilized to preserve the tissue's biological integrity. Ascendion™ has a shelf life of up to 5 years when stored under ambient conditions, maintaining a temperature range of 15-30 degrees Celsius.

### CMS Final HCPCS Coding Determination

After review of the Food and Drug Administration’s (FDA’s) Tissue Reference Group (TRG) letter submitted by the applicant, Ascendion™, “when intended for use ‘barrier’ and ‘cover,’ appear[s] 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 Q4390, “Ascendion, per square centimeter”

This coding determination applies to the Ascendion™ product described in the application and accompanying FDA TRG letter dated December 3, 2024, when intended for use as a “barrier” and “cover.”

## Axolotl Graft™ Ultra - HCP250324F4PP0

### Topic/Issue

Request to establish a new HCPCS Level II code to identify Axolotl Graft™ Ultra.

Applicant's suggested language: XXXXX, “Axolotl Graft ™ Ultra, per square centimeter”

### Summary of Applicant's Submission

Axolotl Biologix submitted a request to establish a new HCPCS Level II code to identify Axolotl Graft™ Ultra (UHAG). Axolotl Graft™ Ultra 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 “wound covering” and to act as a “barrier.” Axolotl Graft™ Ultra is indicated as a resorbable, chorion-free, single-layer, cross-linked human amnion allograft derived from donated human birth tissue. The allografts are intended for homologous use as a wound covering. As such, Axolotl Graft™ Ultra allografts act as a structural barrier to protect the wound. The dosage is determined and is administered topically to the individual’s wound areas by a licensed physician as a single application. The Axolotl DualGraft™ Ultra allograft may be sutured, glued, or placed into position without attachment. The allografts are initially packaged into primary sterile packaging of poly Mangar Kapak pouches and sealed using a validated heat-sealing process. After this process, the allograft pouches are packaged into poly/Tyvek™ medical trays as a second sterile barrier. Sealed trays are processed for terminal sterilization by gamma irradiation, with dose mapping verification performed to assure a sterility assurance level of 10-6 before distribution.

### CMS Final HCPCS Coding Determination

After review of the Food and Drug Administration’s (FDA’s) Tissue Reference Group (TRG) letter submitted by the applicant, Axolotl Graft™ Ultra, “when intended for use as a ‘wound covering’ and to act as a ‘barrier,’…appear[s] 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 Q4383, “Axolotl graft ultra, per square centimeter”

This coding determination applies to the Axolotl Graft™ Ultra product described in the application and accompanying FDA TRG letter dated December 10, 2024, when intended as a “wound covering” and to act as a “barrier.”

## Axolotl DualGraft™ Ultra - HCP250324TTEF5

### Topic/Issue

Request to establish a new HCPCS Level II code to identify Axolotl DualGraft™ Ultra.

Applicant's suggested language: XXXXX, “Axolotl DualGraft™ Ultra, per square centimeter”

### Summary of Applicant's Submission

Axolotl Biologix submitted a request to establish a new HCPCS Level II code to identify Axolotl DualGraft™ Ultra. Axolotl DualGraft™ Ultra 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 “wound covering” and to act as a “barrier.” Axolotl DualGraft™ Ultra is indicated as a resorbable, chorion-free, cross-linked human amnion allograft derived from donated human birth tissue. The allografts are intended for homologous use as a wound covering. As such, Axolotl DualGraft™ Ultra allografts act as a structural barrier to protect the wound. The dosage is determined by a licensed physician and is administered topically to the individual’s wound area as a single application. The Axolotl DualGraft™ Ultra allograft may be sutured, glued, or placed into position without attachment. The allografts are initially packaged into primary sterile packaging of poly Mangar Kapak pouches and sealed using a validated heat-sealing process. After this process, the allograft pouches are packaged into poly/Tyvek™ medical trays as a second sterile barrier. Sealed trays are processed for terminal sterilization by gamma irradiation, with dose mapping verification performed to assure a sterility assurance level of 10-6 before distribution.

### CMS Final HCPCS Coding Determination

After review of the Food and Drug Administration’s (FDA’s) Tissue Reference Group (TRG) letter submitted by the applicant, Axolotl DualGraft™ Ultra, “when intended for use as a ‘wound covering’ and to act as a ‘barrier,’…appear[s] 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 Q4384, “Axolotl dualgraft ultra, per square centimeter”

This coding determination applies to the Axolotl DualGraft™ Ultra product described in the application and accompanying FDA TRG letter dated December 10, 2024, when intended as a “wound covering” and to act as a “barrier.”

## AmnioPlast Double - HCP250329FT1C5

### Topic/Issue

Request to establish a new HCPCS Level II code to identify AmnioPlast Double.

Applicant's suggested language: AmnioPlast Double, per square centimeter

### Summary of Applicant's Submission

Cellution Biologics Inc. submitted a request to establish a new HCPCS Level II code to identify AmnioPlast Double. AmnioPlast Double 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 "cover and barrier." AmnioPlast Double is a minimally manipulated, dehydrated dual-layer amnion membrane allograft intended for homologous use. The allograft is derived from the human placental membrane, retaining the structural and functional characteristics of the tissue. AmnioPlast Double acts as a barrier and provides protective coverage from the surrounding environment for acute and chronic wounds such as partial and full-thickness wounds, pressure sores/ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds (e.g., donor site/grafts, post-laser surgery, post-Mohs surgery, podiatric wounds, wound dehiscence), trauma wounds (e.g., abrasions, lacerations, partial thickness burns, skin tears), and draining wounds. AmnioPlast Double can also be used as a cover or barrier applied to the ocular surface following repair or reconstruction procedures of ocular disease and/or abnormalities. AmnioPlast Double is processed using aseptic techniques and terminally sterilized by gamma irradiation and packaged in a hermetically sealed aluminum-PVC foil pouch. The dosage is based on the size of the wound or site of application, measured per square centimeter, and it can be reapplied as needed. AmnioPlast Double must be stored in a clean, dry environment at ambient room temperature before application. It is available in multiple sizes to accommodate various sized wounds.

### CMS Final HCPCS Coding Determination

After review of the Food and Drug Administration's (FDA's) Tissue Reference Group (TRG) letter submitted by the applicant, AmnioPlast Double, "when intended for use as a cover and barrier, appear[s] 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 Q4391, "Amnioplast double, per square centimeter"

This coding determination applies to the AmnioPlast Double product described in the application and accompanying FDA TRG letter dated February 24, 2025, when intended for use as a "cover and barrier."

## Acesso TrifACA - HCP250325RJRKX

### Topic/Issue

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

The applicant did not submit any suggested language.

### Summary of Applicant's Submission

Dynamic Medical Services LLC dba Acesso Biologics submitted a request to establish a new HCPCS Level II code to identify Acesso TrifACA. Acesso TrifACA 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 provides protective coverage … to acute and chronic wounds." Acesso TrifACA allograft is a full-thickness amnion/chorion/amnion membrane, indicated as a sterile, single-use, dehydrated resorbable allograft derived from donated human placental birth tissue.

### CMS Final HCPCS Coding Determination

After review of the Food and Drug Administration's (FDA's) Tissue Reference Group (TRG) letter submitted by the applicant, Acesso TrifACA, "when intended for use 'as a barrier and provides protective coverage … to acute and chronic wounds,' appear[s] 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 Q4386, "Acesso trifaca, per square centimeter"

This coding determination applies to the Apollo FT product described in the application and accompanying FDA TRG letter dated September 29, 2023, when intended for use as a "barrier and provides protective coverage … to acute and chronic wounds."

## Apollo FT- HCP250325FP07Q

### Topic/Issue

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

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

### Summary of Applicant's Submission

Dynamic Medical Services LLC dba Acesso Biologics submitted a request to establish a new HCPCS Level II code to identify Apollo FT. Apollo FT 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.” Apollo FT is a full-thickness amnion/chorion membrane. It is designed for single use as a sterile, dehydrated, resorbable allograft derived from donated human placental birth tissue.

### CMS Final HCPCS Coding Determination

After review of the Food and Drug Administration’s (FDA’s) Tissue Reference Group (TRG) letter submitted by the applicant, Apollo FT, “when intended for use as a barrier, … appear[s] 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 Q4385, “Apollo ft, per square centimeter”

This coding determination applies to the Apollo FT product described in the application and accompanying FDA TRG letter dated November 19, 2024, when intended for use as a “barrier.”

## Summit AAA - HCP2504011ALW2

### Topic/Issue

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

The applicant did not submit any suggested language.

### Summary of Applicant's Submission

Legacy Medical Consultants, LLC submitted a request to establish a new HCPCS Level II code to identify Summit AAA. Summit AAA 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 or barrier." Summit AAA is a triple-layer graft consisting of amnion/amnion/amnion membrane. Summit AAA is a sterile, single use, dehydrated, resorbable allograft derived from donated human placental birth tissue. Summit AAA provides an extracellular matrix scaffold intended for use as a protective wound covering and barrier in acute and chronic wounds.

### CMS Final HCPCS Coding Determination

After review of the Food and Drug Administration's (FDA's) Tissue Reference Group (TRG) letter submitted by the applicant, Summit AAA, "when intended for use as a covering or barrier, appear[s] 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 Q4397, "Summit aaa, per square centimeter"

This coding determination applies to the Summit AAA product described in the application and accompanying FDA TRG letter dated March 24, 2025, when intended for use as a "covering or barrier."

## NeoThelium FT - HCP250327DC0V9

### Topic/Issue

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

The applicant did not submit any suggested language.

### Summary of Applicant's Submission

Neostim, LLC dba NSM Biologics submitted a request to establish a new HCPCS Level II code to identify NeoThelium FT. NeoThelium FT 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 provides protective coverage … to acute and chronic wounds." NeoThelium FT allograft is a full-thickness amnion/chorion membrane, indicated as a sterile, single-use, dehydrated resorbable allograft derived from donated human placental birth tissue.

### CMS Final HCPCS Coding Determination

After review of the Food and Drug Administration's (FDA's) Tissue Reference Group (TRG) letter submitted by the applicant, NeoThelium FT, "when intended for use 'as a barrier and provides protective coverage … to acute and chronic wounds,' appear[s] 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 Q4387, "Neothelium ft, per square centimeter"

This coding determination applies to the NeoThelium FT product described in the application and accompanying FDA TRG letter dated March 28, 2024, when intended for use as a "barrier and provides protective coverage … to acute and chronic wounds."

## NeoThelium 4L - HCP250327H9WGJ

### Topic/Issue

Request to establish a new HCPCS Level II code to identify NeoThelium 4L.

The applicant did not submit any suggested language.

### Summary of Applicant's Submission

Neostim, LLC dba NSM Biologics submitted a request to establish a new HCPCS Level II code to identify NeoThelium 4L. NeoThelium 4L 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 provides protective coverage … to acute and chronic wounds." NeoThelium 4L membrane is a full-thickness amnion/chorion/chorion/amnion allograft, intended for use as a protective wound covering and barrier in acute and chronic wounds. NeoThelium 4L allograft is a sterile, single use, dehydrated resorbable allograft derived from donated human placental birth tissue.

### CMS Final HCPCS Coding Determination

After review of the Food and Drug Administration's (FDA's) Tissue Reference Group (TRG) letter submitted by the applicant, NeoThelium 4L, "when intended for use 'as a barrier and provides protective coverage … to acute and chronic wounds,' appear[s] 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 Q4388, "Neothelium 4l, per square centimeter"

This coding determination applies to the NeoThelium 4L product described in the application and accompanying FDA TRG letter dated March 28, 2024, when intended for use as a "barrier and provides protective coverage … to acute and chronic wounds."

## NeoThelium 4L+ - HCP250327VEQUR

**Topic/Issue**

Request to establish a new HCPCS Level II code to identify NeoThelium 4L+.

The applicant did not submit any suggested language.

**Summary of Applicant's Submission**

Neostim, LLC dba NSM Biologics submitted a request to establish a new HCPCS Level II code to identify NeoThelium 4L+. NeoThelium 4L+ 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 provides protective coverage … to acute and chronic wounds." NeoThelium 4L+ membrane is a full-thickness quad-layer chorion/ amnion/amnion/chorion allograft indicated as a barrier and provides protective coverage from the surrounding environment to acute and chronic wounds. NeoThelium 4L+ allograft is a sterile, single use, dehydrated resorbable allograft derived from donated human placental birth tissue, applied topically over the wound.

**CMS Final HCPCS Coding Determination**

After review of the Food and Drug Administration's (FDA's) Tissue Reference Group (TRG) letter submitted by the applicant, NeoThelium 4L+, "when intended for use 'as a barrier and provides protective coverage … to acute and chronic wounds,' appear[s] 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 Q4389, "Neothelium 4l plus, per square centimeter"

This coding determination applies to the NeoThelium 4L+ product described in the application and accompanying FDA TRG letter dated March 28, 2024, when intended for use as a "barrier and provides protective coverage … to acute and chronic wounds."

## Acelagraft® - HCP250331FT381

### Topic/Issue

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

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

### Summary of Applicant's Submission

RMBB Health submitted a request to establish a new HCPCS Level II code to identify Acelagraft®. Acelagraft® 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, wrap or barrier … to partial- and full-thickness, acute and chronic wounds.” Acelagraft® is a bi-layered, decellularized, dehydrated human amniotic membrane allograft. It is terminally sterilized with e-beam irradiation and supplied as a sterile, single-use sheet for use as a biological covering. Acelagraft® provides a protective barrier from the external environment and serves as a cover or barrier for acute and chronic wounds. Acelagraft® is indicated for use as a covering for surgical sites, partial- and full-thickness wounds, acute and chronic wounds, including traumatic wounds, burns, diabetic, venous, arterial, and pressure ulcers, and wounds with exposed tendon, muscle, or bone. Acelagraft® acts to cover and protect damaged tissue by providing a barrier and preserving the wound environment. It is applied per square centimeter based on wound size; sheets may be trimmed to size. It is supplied in a sterile double-peel, single-use pouch in various sizes with a shelf-life of 10 years when stored at room temperature.

### CMS Final HCPCS Coding Determination

After review of the Food and Drug Administration’s (FDA’s) Tissue Reference Group (TRG) letter submitted by the applicant, Acelagraft®, “when intended for use as a ‘covering, wrap or barrier … to partial- and full-thickness, acute and chronic wounds,’ appear[s] 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 Q4395, “Acelagraft, per square centimeter”

This coding determination applies to the Acelagraft® product described in the application and accompanying FDA TRG letter dated December 19, 2024, when intended for use as a “covering, wrap or barrier … to partial- and full-thickness, acute and chronic wounds.”

## Natalin® - HCP250331Y8YF4

### Topic/Issue

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

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

### Summary of Applicant's Submission

RMBB Health submitted a request to establish a new HCPCS Level II code to identify Natalin®. Natalin® 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, wrap or barrier … to partial- and full-thickness, acute and chronic wounds.” Natalin® is a tri-layer, decellularized, dehydrated human amniotic membrane allograft that is terminally sterilized with e-beam irradiation. Natalin® serves as a biological membrane covering to protect wounds and surgical sites from the surrounding environment and support healing. It is trimmed and applied directly to the wound or surgical site. Natalin® is intended for use as a wound covering or surgical barrier for acute and chronic wounds, including diabetic, venous, arterial, and pressure ulcers, burns, surgical sites (including Mohs), and complex wounds with exposed structures (tendon, bone, muscle). Natalin® acts as a protective barrier, supporting wound coverage and healing. Natalin® is applied based on wound size; customizable and measured per square centimeter, and is available in single-use, sterile, dehydrated sheets in sealed, double-peel pouches ranging in various sizes.

### CMS Final HCPCS Coding Determination

After review of the Food and Drug Administration’s (FDA’s) Tissue Reference Group (TRG) letter submitted by the applicant, Natalin®, “when intended for use as a ‘covering, wrap or barrier … to partial- and full-thickness, acute and chronic wounds,’ appear[s] 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 Q4396, “Natalin, per square centimeter”

This coding determination applies to the Natalin® product described in the application and accompanying FDA TRG letter dated December 19, 2024, when intended for use as a “covering, wrap or barrier … to partial- and full-thickness, acute and chronic wounds.”

## GRAFIX DUO- HCP2503310U6X0

### Topic/Issue

Request to establish a new HCPCS Level II code to identify GRAFIX DUO.

Applicant's suggested language: Q4XXX, “GRAFIX DUO, per square centimeter”

### Summary of Applicant's Submission

Smith and Nephew submitted a request to establish a new HCPCS Level II code to identify GRAFIX DUO. GRAFIX DUO 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 “wound cover, wrap, and barrier.” GRAFIX DUO is a sterile, dual-layered, dehydrated, amniotic membrane-based skin substitute product. GRAFIX DUO is indicated for use in the management of acute and chronic wounds. The product acts as a wound cover, wrap, and barrier. The dosage (i.e., the quantity and size of product used) will vary based on wound size. The product is applied to the wound bed as a cover, wrap, and barrier. GRAFIX DUO is supplied in a variety of five sizes and is packaged within a heat-sealed pouch contained within a tertiary box. The sealed pouch containing the product is sterilized to provide a sterile barrier.

### CMS Final HCPCS Coding Determination

After review of the Food and Drug Administration’s (FDA’s) Tissue Reference Group (TRG) letter submitted by the applicant, GRAFIX DUO, “when intended for use as a ‘wound cover, wrap, and barrier,’ appear[s] 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 Q4392, “Grafix duo, per square centimeter”

This coding determination applies to the GRAFIX DUO product described in the application and accompanying FDA TRG letter dated November 27, 2024, when intended for use as a “wound cover, wrap, and barrier.”

## SurGraft AC - HCP250331MB7U6

### Topic/Issue

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

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

### Summary of Applicant's Submission

Surgenex, LLC submitted a request to establish a new HCPCS Level II code to identify SurGraft AC. SurGraft AC 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 protective cover to acute and chronic wounds.” SurGraft AC is a sterile, dehydrated dual-layer amnion chorion membrane allograft derived from donated human amniotic and chorionic membrane placenta. SurGraft AC functions as a barrier and provides protective coverage to acute and chronic wounds.

### CMS Final HCPCS Coding Determination

After review of the Food and Drug Administration’s (FDA’s) Tissue Reference Group (TRG) letter submitted by the applicant, SurGraft AC, “when intended for use as a barrier and protective cover to acute and chronic wounds, appear[s] 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 Q4393, “Surgraft ac, per square centimeter”

This coding determination applies to the SurGraft AC product described in the application and accompanying FDA TRG letter dated March 5, 2021, when intended for use as a “barrier and protective cover to acute and chronic wounds.”

## SurGraft ACA - HCP250331BAJCJ

### Topic/Issue

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

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

### Summary of Applicant's Submission

Surgenex, LLC submitted a request to establish a new HCPCS Level II code to identify SurGraft ACA. SurGraft ACA 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 or cover for acute and chronic wounds.” SurGraft ACA is a sterile, dehydrated, triple-layer amnion/chorion/amnion membrane allograft. SurGraft ACA functions as a barrier and provides protective coverage to acute and chronic wounds. SurGraft ACA is for single use only and is applied directly to the wound bed after standard wound bed preparation. SurGraft ACA is packaged in a solid bleached sulfate paperboard shelf box that contains a primary foil pouch and a secondary Tyvek™ pouch, which is sterilized by e-beam, meeting sterility assurance level of 10-6. SurGraft ACA triple-layer amniotic/chorionic/amniotic membrane allograft is available in multiple sizes.

### CMS Final HCPCS Coding Determination

After review of the Food and Drug Administration’s (FDA’s) Tissue Reference Group (TRG) letter submitted by the applicant, SurGraft ACA, “when intended for use as a barrier or cover for acute and chronic wounds, appear[s] 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 Q4394, “Surgraft aca, per square centimeter”

This coding determination applies to the SurGraft ACA product described in the application and accompanying FDA TRG letter dated October 25, 2021, when intended for use as a “barrier or cover for 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[4], 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[5] to identify the correct billing and payment code for each applicable product.

**CMS Final HCPCS Coding Determination**

Establish fourteen new HCPCS Level II codes and discontinue three 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.

[4] 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.

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

CMS intends to continue our review in subsequent HCPCS 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 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 |
|---|---|---|
| A9612 | Add | Injection, fluorescein, 1 mg |
| C9248 | Delete | Injection, clevidipine butyrate, 1 mg |
| J0163 | Add | Injection, epinephrine in sodium chloride (endo), 0.1 mg |
| J0462 | Add | Injection, atropine sulfate, not therapeutically equivalent to j0461, 0.01 mg |
| J0525* | Add | Injection, cefotetan disodium, 10 mg |
| J0582 | Add | Injection, bivalirudin (endo), not therapeutically equivalent to j0583, 1 mg |
| J0675 | Add | Injection, carboprost tromethamine, 0.1 mg |
| J0759 | Add | Injection, clevidipine butyrate, 1 mg |
| J1370 | Add | Injection, esomeprazole sodium, 1 mg |
| J1807 | Add | Injection, ethacrynate sodium, 1 mg |
| J1809 | Add | Injection, fosdenopterin, 0.1 mg |
| J1834 | Add | Injection, isoniazid, 1 mg |
| J2150 | Delete | Injection, mannitol, 25% in 50 ml |
| J2151* | Add | Injection, mannitol, 250 mg |
| J2291 | Add | Injection, nafcillin sodium (baxter), 20 mg |
| J3290 | Add | Injection, tranexamic acid, 5 mg |
| S0074 | Delete | Injection, cefotetan disodium, 500 mg |

*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.