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

First 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' First 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 July 1, 2025, unless otherwise indicated.

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

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

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

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

Bupivacaine Hydrochloride with Epinephrine - HCP241028MX0DP

Topic/Issue

Request to establish a new HCPCS Level II code to identify bupivacaine hydrochloride (HCl) with epinephrine.

Applicant's suggested language: JXXXX, “Injection, bupivacaine with epinephrine, 0.5 mg”

Summary of Applicant's Submission

Myers and Stauffer submitted a request to establish a new HCPCS Level II code to identify bupivacaine HCl with epinephrine. Bupivacaine HCl with epinephrine was approved by the Food and Drug Administration (FDA) under a New Drug Application (NDA) on October 3, 1972. Bupivacaine HCl with epinephrine is indicated in adults for the production of local or regional anesthesia or analgesia for surgery, dental and oral surgery procedures, diagnostic and therapeutic procedures, and for obstetrical procedures. The dosage of bupivacaine HCl with epinephrine administered varies with the anesthetic procedure, the area to be anesthetized, the vascularity of the tissues, the number of neuronal segments to be blocked, the depth of anesthesia and degree of muscle relaxation required, the duration of anesthesia desired, individual tolerance, and the physical condition of the individual. Routes of administration include infiltration, perineural, caudal, and epidural. Bupivacaine HCl with epinephrine injection is a clear, colorless solution available as 0.25%, 0.5%, and 0.75% single- and multiple-dose vials.

CMS Final HCPCS Coding Determination

It is our understanding that bupivacaine HCl with epinephrine, a local or regional anesthesia or analgesia for surgery, would generally be used in a procedure reported with a HCPCS Level I, Current Procedural Terminology (CPT®) code. We have not identified a specific need for this item to be separately paid, since we believe that a particular payer may elect to pay for the service in which this product is used. For instance, Medicare would typically reflect the costs of the supply in the payment for the procedure, if it is used, and as such it would not be separately payable.

BLUDIGO - HCP241220N2VVA

Topic/Issue

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

Applicant's suggested language: JXXXX, “indigotindisulfonate sodium injection, 8 mg/mL”

Summary of Applicant's Submission

Provepharm, Inc. submitted a request to establish a new HCPCS Level II code to identify BLUDIGO (indigotindisulfonate sodium injection). BLUDIGO was approved by the Food and Drug Administration (FDA) under a 505(b)(2) New Drug Application (NDA) on July 8, 2022. BLUDIGO is indicated for use in adults as a visualization aid in the cystoscopic assessment of the integrity of the ureters following urological and gynecological open, robotic, or endoscopic surgical procedures. BLUDIGO is excreted by the kidney through tubular secretion and enhances visualization of the ureteral orifices by its deep blue color. The recommended dose is 5 mL given intravenously over 1 minute. BLUDIGO 40 mg/5 mL (8 mg/mL) is a dark blue or bluish-purple solution supplied in a carton of 5 single-dose amber glass ampules.

CMS Final HCPCS Coding Determination

1. Establish a new HCPCS Level II code J9220, “Injection, indigotindisulfonate sodium, 1 mg”

   Effective July 1, 2025

2. Discontinue HCPCS Level II code C9300, “Injection, indigotindisulfonate sodium, 1 mg”

   Effective June 30, 2025

Tepylute - HCP250101PGYN0

Topic/Issue

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

Applicant's suggested language: JXXXX, “Injection, thiotepa (Tepylute), 1 mg”

Summary of Applicant's Submission

Shorla Oncology submitted a request to establish a new HCPCS Level II code to identify Tepylute (thiotepa). Tepylute was approved by the Food and Drug Administration (FDA) under a 505(b)(2) New Drug Application (NDA) on June 25, 2024. Tepylute is an alkylating agent indicated for the treatment of adenocarcinoma of the breast or ovary. Tepylute is an alkylating drug of the polyfunctional type, related chemically and pharmacologically to the nitrogen mustard. The radiomimetic action of Tepylute is believed to occur through the release of ethyleneimine radicals which, like irradiation, disrupt the bonds of DNA. One of the principal bond disruptions is initiated by alkylation of guanine at the N-7 position, which severs the linkage between the purine base and the sugar and liberates alkylated guanines.

CMS Final HCPCS Coding Determination[1]

Establish a new HCPCS Level II code J9341, “Injection, thiotepa (tepylute), 1 mg”

[1] Please refer to Appendix A for additional HCPCS Level II coding actions regarding thiotepa.

BIZENGRI® - HCP241231CBG1T

Topic/Issue

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

Applicant's suggested language: JXXXX, “Injection, zenocutuzumab-zbco, 375 mg”

Summary of Applicant's Submission

Partner Therapeutics, Inc. submitted a request to establish a new HCPCS Level II code to identify BIZENGRI® (zenocutuzumab-zbco). BIZENGRI® was approved by the Food and Drug Administration (FDA) under a 351(a) Biologics License Application (BLA) on December 4, 2024. BIZENGRI® is a bispecific human epidermal growth factor receptor (HER) (HER2 and HER3) directed antibody indicated for adults with advanced, unresectable or metastatic non-small cell lung cancer harboring a neuregulin 1 (NRG1) gene fusion with disease progression on or after prior systemic therapy and adults with advanced, unresectable or metastatic pancreatic adenocarcinoma harboring a NRG1 gene fusion with disease progression on or after prior systemic therapy. BIZENGRI® binds to the extracellular domains of HER2 and HER3 which are expressed on the surface of cells, including tumor cells, inhibiting HER2:HER3 dimerization and preventing NRG1 binding to HER3. The recommended dosage of BIZENGRI® is 750 mg as an intravenous infusion every 2 weeks until disease progression or unacceptable toxicity. BIZENGRI® is administered as an intravenous infusion, after dilution, over 4 hours. BIZENGRI® is a sterile, clear to slightly opalescent, colorless to slightly yellow, preservative-free injection for intravenous infusion in single-dose vials. Each BIZENGRI® vial contains 375 mg/18.75 mL of zenocutuzumab-zbco at a concentration of 20 mg/mL.

CMS Final HCPCS Coding Determination

Establish a new HCPCS Level II code J9382, “Injection, zenocutuzumab-zbco, 1 mg”

OPUVIZ™ - HCP2412319PBHR

Topic/Issue

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

Applicant's suggested language: XXXXX, “Injection, aflibercept-yszy, biosimilar, 1mg”

Summary of Applicant's Submission

Samsung Bioeps submitted a request to establish a new HCPCS Level II code for OPUVIZ™ (aflibercept-yszy). OPUVIZ™ was approved by the Food and Drug Administration (FDA) under a 351(k) Biologics License Application (BLA) pathway on May 20, 2024. OPUVIZ™ is a biosimilar to EYLEA® (aflibercept). OPUVIZ™ is indicated for the treatment of individuals with neovascular (wet) age-related macular degeneration, macular edema following retinal vein occlusion, diabetic macular edema, and diabetic retinopathy. OPUVIZ™ is administered by intravitreal injection, and dosing varies by indication. OPUVIZ™ is a clear, colorless to pale yellow solution that is supplied as a 2 mg (0.05 mL of 40 mg/mL) solution in a single-dose vial.

CMS Final HCPCS Coding Determination

Establish a new HCPCS Level II code Q5153, “Injection, aflibercept-yszy (opuviz), biosimilar, 1 mg”

Lenmeldy™ - HCP241217X32RA

Topic/Issue

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

Applicant's suggested language: JXXXX, “Injection, atidarsagene autotemcel, per treatment”

Summary of Applicant's Submission

Orchard Therapeutics submitted a request to establish a new HCPCS Level II code to identify Lenmeldy™ (atidarsagene autotemcel). Lenmeldy™ was approved by the Food and Drug Administration (FDA) under a 351(a) Biologics License Application (BLA) pathway on March 18, 2024. Lenmeldy™ is indicated for the treatment of individuals with pre-symptomatic late infantile, pre-symptomatic early juvenile, or early symptomatic early juvenile metachromatic leukodystrophy (MLD). Lenmeldy™ is intended for one-time administration via an autologous stem cell transplant procedure and consists of autologous CD34+ cells, containing hematopoietic stem cells, transduced with a lentiviral vector encoding the human arylsulfatase A gene. Lenmeldy™ is composed of one to eight infusion bags which contain 2 to 11.8 x 10^6 cells/mL (1.8 to 11.8 x 10^6 CD34+ cells/mL) suspended in cryopreservation solution. Dosing of Lenmeldy™ is determined based on the number of CD34+ cells in the infusion bag(s) per kilogram of body weight and the MLD disease subtype.

CMS Final HCPCS Coding Determination

Establish a new HCPCS Level II code J3391, “Injection, atidarsagene autotemcel, per treatment”

BEIZRAY - HCP241231R2UJU

Topic/Issue

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

Applicant's suggested language: JXXXX, “Injection, docetaxel (beizray), 1 mg”

Summary of Applicant's Submission

Zhuhai Beihai Biotech Co., Ltd., submitted a request to establish a new HCPCS Level II code to identify BEIZRAY (docetaxel). BEIZRAY was approved by the Food and Drug Administration (FDA) under a 505(b)(2) New Drug Application (NDA) on October 23, 2024. BEIZRAY is indicated for the treatment of individuals with breast cancer, non-small cell lung cancer, castration-resistant prostate cancer, gastric adenocarcinoma, and squamous cell carcinoma of the head and neck. Per the FDA label, BEIZRAY has “different administration instructions from other docetaxel products.” BEIZRAY is supplied as a kit consisting of two single dose vials each containing docetaxel 80 mg/4 mL, and one single dose vial of intravenous solution stabilizer that is 50 mL of 25% human albumin solution for infusion.

CMS Final HCPCS Coding Determination

Establish a new HCPCS Level II code J9174, “Injection, docetaxel (beizray), 1 mg”

Vancomycin Hydrocholoride for Injection - HCP241226RN106

Topic/Issue

Request to revise existing HCPCS Level II code J3371, "Injection, vancomycin hcl (mylan), not therapeutically equivalent to J3370, 500 mg" so the unit descriptor instead reads "250 mg" to further describe Vancomycin Hydrocholoride for Injection.

Applicant's suggested language: J3371, "Injection, vancomycin hcl (mylan) not therapeutically equivalent to J3370, 250 mg"

Summary of Applicant's Submission

Mylan Pharmaceuticals Inc. submitted a request to revise existing HCPCS Level II code J3371 to further define the unit descriptor for Vancomycin Hydrochloride for Injection. Vancomycin Hydrochloride for Injection was first approved by the Food and Drug Administration (FDA) under a 505(b)(2) New Drug Application (NDA) on July 10, 2018, for the following strengths: 250 mg/vial; 750 mg/vial, 1.25 g/vial; and 1.5 g/vial. On June 26, 2024, the FDA approved a 505(b)(2) supplemental NDA for two additional strengths, 1.75 g/vial and 2 g/vial. Vancomycin Hydrochloride for Injection is indicated for the treatment of individuals with serious or severe infections caused by susceptible strains of methicillin-resistant (β-lactam-resistant) staphylococci; for individuals allergic to penicillin, who cannot receive or who have failed to respond to other drugs, including the penicillins or cephalosporins; individuals with infections caused by vancomycin-susceptible organisms that are resistant to other antimicrobial drugs; and as initial therapy of individuals when methicillin-resistant staphylococci are suspected, but after susceptibility data are available, therapy should be adjusted accordingly. Vancomycin Hydrochloride for Injection is supplied as single-dose vials containing vancomycin hydrochloride (HCl), United States Pharmacopeia equivalent to 250 mg, 750 mg, 1.25 g, 1.5 g, 1.75 g or 2 g of vancomycin base. Note, the 250 mg/vial strength is not marketed. The current HCPCS Level II code descriptor of J3371, "Injection, vancomycin hcl (mylan) not therapeutically equivalent to J3370, 500 mg" allows billing in units of 500 mg and thus does not accommodate doses of the available strengths. Single-dose vials of 250 mg, 750 mg, 1.25 g, and 1.75 g cannot be accurately billed in units of 500 mg.

CMS Final HCPCS Coding Determination[2]

1. Establish a new HCPCS Level II code J3374, "Injection, vancomycin hydrochloride (mylan) not therapeutically equivalent to j3373, 10 mg"

   Effective July 1, 2025

2. Discontinue HCPCS Level II code J3371, "Injection, vancomycin hcl (mylan) not therapeutically equivalent to j3370, 500 mg"

   Effective June 30, 2025

[2] Please refer to Appendix A for additional HCPCS Level II coding actions regarding vancomycin.

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.

VYALEV® - HCP241218YNWMD

Topic/Issue

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

Applicant's suggested language: JXXXX, “VYALEV (foscarbidopa/foslevodopa), for subcutaneous infusion, per 12 mg foscarbidopa and 240 mg foslevodopa”

Summary of Applicant's Submission

AbbVie submitted a request to establish a new HCPCS Level II code to identify VYALEV® (foscarbidopa/foslevodopa) for subcutaneous infusion. VYALEV® was approved by the Food and Drug Administration (FDA) under a New Drug Application (NDA) on October 16, 2024. VYALEV® is indicated for the treatment of motor fluctuations in adults with advanced Parkinson’s disease (PD). VYALEV® is a pro-drug combination of foscarbidopa (carbidopa monophosphate) and foslevodopa (levodopa monophosphate) [ratio 1:20] in a solution intended to be administered as a 24 hour/day continuous subcutaneous infusion in individuals with advanced PD, using the VYAFUSER™ pump. VYALEV® is prescribed by a health care provider and may be self-administered in the individual’s home. Initial doses may be furnished in the hospital outpatient or health care provider office settings to titrate the dosage for the individual. The recommended starting infusion rate of VYALEV® is determined by converting the daytime levodopa intake to levodopa equivalents (LE), and then increasing it to account for a 24-hour administration. The dose may be adjusted to reach a clinical response that maximizes the functional “on” time and minimizes the number and duration of “off” episodes and “on” episodes with troublesome dyskinesia. The maximum recommended daily dose of VYALEV® is 3,525 mg of the foslevodopa component (approximately 2,500 mg LE) administered over 24 hours. VYALEV® is supplied as a carton of 7 single-dose glass vials filled with approximately 10 mL of solution.

CMS Final HCPCS Coding Determination

Establish a new HCPCS Level II code J7356, “Injection, foscarbidopa 0.25 mg/foslevodopa 5 mg”

Lutrate Depot - HCP250102CKW2K

Topic/Issue

Request to revise existing HCPCS Level II code J1954, “Injection, leuprolide acetate for depot suspension (cipla), 7.5 mg” to include the brand name (Lutrate Depot) instead of the marketing company name (Cipla).

Applicant's suggested language: J1954, “For injection, Leuprolide Acetate for depot suspension, (Lutrate Depot), 7.5 mg”

Summary of Applicant's Submission

Cipla Pharmaceuticals (Cipla) submitted a request to revise existing HCPCS Level II code J1954 to include the brand name (Lutrate Depot) instead of the marketing company name (Cipla). Lutrate Depot (leuprolide acetate) was approved by the Food and Drug Administration (FDA) under a 505(b)(2) New Drug Application (NDA) on August 28, 2018. While Cipla will retain the NDA, Avyxa Pharmaceuticals became the marketing entity effective January 1, 2025. Lutrate Depot is indicated for palliative treatment of advanced prostate cancer. Due to different release characteristics, the dosage strengths are not additive and must be selected based upon the desired dosing schedule. Lutrate Depot is a depot suspension that is dosed at 22.5 mg that is administered for 3 months as a single intramuscular injection every 12 weeks. Lutrate Depot is packaged in a single-dose vial as a kit with a prefilled syringe containing diluent and a MixJect® transfer device. Lutrate Depot is a gonadotropin-releasing hormone agonist, acts as an inhibitor of gonadotropin secretion. In humans, administration of leuprolide acetate results in an initial increase in circulating levels of luteinizing hormone (LH) and follicle stimulating hormone (FSH), leading to a transient increase in levels of the gonadal steroids (testosterone and dihydrotestosterone in male individuals, and estrone and estradiol in pre-menopausal individuals). However, continuous administration of leuprolide acetate results in decreased levels of LH and FSH. In males, testosterone is reduced to below castrate threshold. In pre-menopausal females, estrogens are reduced to post-menopausal concentrations. These decreases occur within two to four weeks after initiation of treatment. Long-term studies have shown that continuation of therapy with leuprolide acetate maintains testosterone below the castrate level for more than five years.

CMS Final HCPCS Coding Determination

Revise existing HCPCS Level II code J1954, “Injection, leuprolide acetate for depot suspension (cipla), 7.5 mg” to instead read “Injection, leuprolide acetate for depot suspension (lutrate depot), 7.5 mg”

AUCATZYL® - HCP241126WA5QX

Topic/Issue

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

Applicant's suggested language: JXXXX, "Obecabtagene autoleucel, up to 410 million CD19 CAR-positive viable T cells, per therapeutic dose"

Summary of Applicant's Submission

Autolus Therapeutics plc submitted a request to establish a new HCPCS Level II code to identify AUCATZYL® (obecabtagene autoleucel) suspension for intravenous infusion. AUCATZYL® was approved by the Food and Drug Administration (FDA) under a 351(a) Biologics License Application (BLA) on November 8, 2024. AUCATZYL® is a fast off-rate CD19-directed genetically modified autologous chimeric antigen receptor (CAR)-T cell immunotherapy, with tumor burden-guided dosing, indicated for the treatment of adults with relapsed or refractory (R/R) B cell precursor acute lymphoblastic leukemia (B-ALL). AUCATZYL® is specifically designed to overcome the limitations in clinical activity and safety compared to currently available CD19 CAR-T cell therapies for the treatment of adult R/R B-ALL. The CAR in AUCATZYL®'s distinct immune-modulating mechanism of action is constructed using a differentiated 4-1BB co-stimulatory domain with a unique, proprietary low affinity, fast off-rate CAT hybridoma-derived CD19 single-chain variable fragment (CAT19 binding domain). Further, AUCATZYL® is specifically designed to follow a manageable, personalized tumor burden-guided dosing schedule based on the level of disease present in each individual's bone marrow (BM) to minimize immune-related toxicity associated with increased tumor burden, namely severe cytokine release syndrome and high rates of severe immune effector cell-associated neurotoxicity syndrome. AUCATZYL® is supplied as a cryopreserved autologous cell suspension packaged in 3 to 5 infusion bags overall containing a cell dispersion of the total recommended tumor burden-guided dose of 410 x 10^6 CD19 CAR-positive viable T cells for the single AUCATZYL® treatment. The first dose (administered on day 1) is determined by the individual's BM disease burden within 7 days prior to lymphodepletion; the second dose (administered on day 10 [± 2]) is tailored for a total dose of 410 x 10^6 CAR-T cells to complete the single treatment of AUCATZYL®.

CMS Final HCPCS Coding Determination[3]

1. Establish a new HCPCS Level II code Q2058, "Obecabtagene autoleucel, 10 up to 400 million cd19 car-positive viable t cells, including leukapheresis and dose preparation procedures, per infusion"

   Effective July 1, 2025

2. Discontinue HCPCS Level II code C9301, "Obecabtagene autoleucel, up to 400 million cd19 car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose"

[3] Updated on April 30, 2025 to revise HCPCS Level II code Q2058 from "per therapeutic dose" to instead read "per infusion" and to adjust the dosage to read "10 up to 400 million." Additional language was added on how to appropriately bill for AUCATZYL®.

Effective June 30, 2025

AUCATZYL® has a total recommended dose of 410 x 10^6 CD19 chimeric antigen receptor (CAR)-positive viable T cells for split dose administration. The treatment regimen consists of a split dose infusion: the first infusion on day one and, in most cases, a second infusion on day ten (+/-2 days). Depending on the percentage of bone marrow blasts, the first infusion could be either 10 x 10^6 administered from syringe or 100 x10^6 administered from one infusion bag. Then, the second infusion could be either 400 x10^6 administered from two infusion bags or 310 x10^6 administered from one syringe and one infusion bag. To facilitate billing for each infusion individually and to take into account all possible infusions of the split dose (based on the FDA approved labeling), the description is "10 up to 400 million cd19 car-positive viable t cells" which should be used to bill for each of the two infusions of the treatment regimen.

For each infusion of the split dose regimen, the unit quantity on the claim line is 1 (a total of 2 billing units for the complete regimen of 2 infusions). Should a second infusion not be furnished, the hospital should not submit a claim to Medicare. Since the product is not a "single-dose container" based on the FDA-approved label, the JW/JZ modifier policy does not apply, and the modifiers are not necessary for billing. Specifically, no modifier is necessary for an administered infusion, and it is not appropriate to bill Medicare for a second infusion that was not administered using the JW modifier on the claim submission.

VYLOY® - HCP241218QPPXD

Topic/Issue

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

Applicant's suggested language: JXXXX, “Injection, zolbetuximab-clzb, 1mg”

Summary of Applicant's Submission

Astellas submitted a request to establish a new HCPCS Level II code to identify VYLOY® (zolbetuximab-clzb). VYLOY® was approved by the Food and Drug Administration (FDA) under a 351(a) Biologics License Application (BLA) on October 18, 2024. VYLOY® is a claudin (CLDN) 18.2-directed cytolytic antibody and is indicated in combination with fluoropyrimidine- and platinum-containing chemotherapy for the first-line treatment of adults with locally advanced unresectable or metastatic human epidermal growth factor receptor 2-negative gastric or gastroesophageal junction adenocarcinoma whose tumors are CLDN 18.2 positive as determined by an FDA-approved test. VYLOY® is administered by intravenous infusion only (not administered as an intravenous push or bolus). The recommended first dose of VYLOY® is 800 mg/m^2, followed by 600 mg/m^2 every 3 weeks, or 400 mg/m^2 every 2 weeks. This 100 mg lyophilized powder is packaged in a single-dose vial.

CMS Final HCPCS Coding Determination[4]

1. Establish a new HCPCS Level II code J1326, “Injection, zolbetuximab-clzb, 2 mg"

   Effective July 1, 2025

2. Discontinue HCPCS Level II code C9303, “Injection, zolbetuximab-clzb, 1 mg"

   Effective June 30, 2025

[4] Updated on April 7, 2025, to revise the HCPCS Level II code C9303, “Injection, zolbetuximab-clzb, 2 mg" to instead read “Injection, zolbetuximab-clzb, 1 mg".

UNLOXCYT - HCP241216Y3FVW

Topic/Issue

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

Applicant's suggested language: JXXXX, “Injection, cosibelimab-ipdl, 1mg”

Summary of Applicant's Submission

Checkpoint Therapeutics, Inc. submitted a request to establish a new HCPCS Level II code to identify UNLOXCYT (cosibelimab-ipdl). UNLOXCYT was approved by the Food and Drug Administration (FDA) under a 351(a) Biologics License Application (BLA) on December 13, 2024. UNLOXCYT is a programmed death-ligand 1 (PD-L1) blocking antibody, indicated for the treatment of adults with metastatic cutaneous squamous cell carcinoma (CSCC) or locally advanced CSCC who are not candidates for curative surgery or curative radiation. UNLOXCYT is a high-affinity, human immunoglobulin G monoclonal antibody that binds to PD-L1 and blocks the PD-L1 interaction with the PD-1 and B7-1 receptors. The recommended dosage of UNLOXCYT is 1,200 mg as an intravenous infusion over 60 minutes every 3 weeks. UNLOXCYT is supplied as a 300 mg/5 mL (60 mg/mL) solution in a single-dose vial for infusion.

CMS Final HCPCS Coding Determination

Establish a new HCPCS Level II code J9275, “Injection, cosibelimab-ipdl, 2 mg”

ZIIHERA - HCP241127EFBHL

Topic/Issue

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

Applicant's suggested language: JXXXX, “Injection, zanidatamab-hrii, 1 mg”

Summary of Applicant's Submission

Jazz Pharmaceuticals submitted a request to establish a new HCPCS Level II code to identify ZIIHERA (zanidatamab-hrii). ZIIHERA was approved by the Food and Drug Administration (FDA) under a 351(a) Biologics License Application (BLA) on November 20, 2024. ZIIHERA is a bispecific human epidermal growth factor receptor 2 (HER2)-directed antibody that binds to two extracellular sites on HER2. ZIIHERA is indicated for the treatment of adults with previously treated, or metastatic HER2-positive immunohistochemical 3+ biliary tract cancer, as detected by an FDA-approved test. Binding of ZIIHERA with HER2 results in internalization, leading to a reduction of the receptor on the tumor cell surface. The recommended dose of ZIIHERA is 20 mg/kg, administered as an intravenous infusion once every 2 weeks until disease progression or unacceptable toxicity. ZIIHERA is supplied in a single-dose vial containing 300 mg lyophilized powder for reconstitution.

CMS Final HCPCS Coding Determination

1. Establish a new HCPCS Level II code J9276, “Injection, zanidatamab-hrii, 2 mg”

   Effective July 1, 2025

2. Discontinue HCPCS Level II code C9302, “Injection, zanidatamab-hrii, 2 mg

   Effective June 30, 2025

HYMPAVZI® - HCP241216Y9GAF

Topic/Issue

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

Applicant's suggested language: JXXXX, “Injection, marstacimab-hncq, 1 mg”

Summary of Applicant's Submission

Pfizer Inc. submitted a request to establish a new HCPCS Level II code to identify HYMPAVZI® (marstacimab-hncq). HYMPAVZI® was approved by the Food and Drug Administration (FDA) under a 351(a) Biologics License Application (BLA) on October 11, 2024. HYMPAVZI® is a tissue factor pathway inhibitor antagonist that directly integrates into the coagulation cascade to restore balance, allowing for stable blood clot formation and hemostasis. HYMPAVZI® is indicated for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in individuals 12 years of age and older with hemophilia A (congenital factor VIII deficiency) without factor VIII inhibitors, or hemophilia B (congenital factor IX deficiency) without factor IX inhibitors. HYMPAVZI® is administered by subcutaneous injection, once weekly, at any time of the day. The recommended dose of HYMPAVZI® is 300 mg (loading dose) on day 1, and 150 mg (maintenance dose) on day 8 and weekly thereafter on the same day each week. If more than one injection is required to deliver a complete dose, each injection should be administered at a different injection site. A dose adjustment to 300 mg weekly can be considered in individuals weighing greater than or equal to 50 kg when control of bleeding events is judged to be inadequate by the healthcare provider. The safety and efficacy of HYMPAVZI® at doses above 300 mg weekly have not been sufficiently established. HYMPAVZI® is supplied as a single-dose 150 mg/mL (1 mL) prefilled pen.

CMS Final HCPCS Coding Determination

1. Establish a new HCPCS Level II code J7172, “Injection, marstacimab-hncq, 0.5 mg”

   Effective July 1, 2025

2. Discontinue HCPCS Level II code C9304, “Injection, marstacimab-hncq, 0.5 mg”

   Effective June 30, 2025

OPDIVO Qvantig™ - HCP24123141KB8

Topic/Issue

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

Applicant's suggested language: JXXXX, “Injection, nivolumab and hyaluronidase-nvhy, per 10 mg”

Summary of Applicant's Submission

Bristol Myers Squibb submitted a request to establish a new HCPCS Level II code to identify OPDIVO Qvantig™ (nivolumab and hyaluronidase-nvhy). OPDIVO Qvantig™ was approved by the Food and Drug Administration (FDA) under a 351(a) Biologics License Application (BLA) on December 27, 2024. OPDIVO Qvantig™ is indicated for the treatment of individuals with various tumor types, including renal cell carcinoma, melanoma, non-small cell lung cancer, squamous cell carcinoma of the head and neck, urothelial carcinoma, colorectal cancer, hepatocellular carcinoma, esophageal cancer, gastric cancer, gastroesophageal junction cancer, and esophageal adenocarcinoma. OPDIVO Qvantig™ is administered by a healthcare provider as a subcutaneous injection. OPDIVO Qvantig™ is supplied as an individually packaged single-dose vial providing 600 mg nivolumab and 10,000 units hyaluronidase per 5 mL (120 mg/ 2,000 units per mL).

CMS Final HCPCS Coding Determination

Establish a new HCPCS Level II code J9289, “Injection, nivolumab, 2 mg and hyaluronidase-nvhy”

IMULDOSA™ - HCP241209A9FPV

Topic/Issue

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

Applicant's suggested language: QXXXX, “Injection, ustekinumab-srlf (imuldosa), 1mg”

Summary of Applicant's Submission

Accord Biopharma submitted a request to establish a new HCPCS Level II code to identify IMULDOSA™ (ustekinumab-srlf). IMULDOSA™ was approved by the Food and Drug Administration (FDA) under a 351(k) Biologics License Application (BLA) on October 10, 2024. IMULDOSA™ is biosimilar to STELARA® (ustekinumab). IMULDOSA™ is indicated for the treatment of individuals 6 years of age and older with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy and active psoriatic arthritis. IMULDOSA™ is also indicated for the treatment of adults with moderately to severely active Crohn's disease and ulcerative colitis. The recommended dose is based on body weight. The route of administration for IMULDOSA™ is either intravenous or subcutaneous, or both, depending on the indications for which it is being used as per the label. IMULDOSA™ injection is supplied as individually packaged, single-dose prefilled syringes or single-dose vials.

CMS Final HCPCS Coding Determination

Establish a new HCPCS Level II code Q5098, “Injection, ustekinumab-srlf (imuldosa), biosimilar, 1 mg”

CMS generally creates codes for products themselves, without specifying a route of administration in the code descriptor, as there might be multiple routes of administration for the same product. Drugs that fall under this category should be billed with either the JA modifier for the intravenous infusion of the drug or billed with the JB modifier for subcutaneous injection of the drug.

SELARSDI™ (Subcutaneous) - HCP241218AJ636

Topic/Issue

Request to revise existing HCPCS Level II code Q9998, “Injection, ustekinumab-aekn (selarsdi), 1 mg” to distinguish SELARSDI™ subcutaneous (SC) injection from SELARSDI™ intravenous (IV) infusion.

Applicant's suggested language: Q9998, “Injection, ustekinumab-aekn (selarsdi), biosimilar, subcutaneous, 1 mg”

Summary of Applicant's Submission

Teva Pharmaceuticals, Inc. submitted a request to revise existing HCPCS Level II code Q9998 to distinguish SELARSDI™ (SC) injection from SELARSDI™ (IV) infusion. SELARSDI™ (ustekinumab-aekn) was approved by the Food and Drug Administration (FDA) under a 351(k) Biologics License Application (BLA) on April 16, 2024. SELARSDI™ (SC) is indicated for the treatment of individuals with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy, adults with active psoriatic arthritis, adults with moderately to severe active Crohn’s disease, and adults with moderately to severe active ulcerative colitis. SELARSDI™ (SC) is also indicated for treating individuals 6 years and older with moderate to severe plaque psoriasis, who are candidates for phototherapy or systemic therapy and active psoriatic arthritis. The recommended dosage of SELARSDI™ (SC) varies based on indication as well as the weight of the individual. SELARSDI™ (SC) is packaged in a 45 mg/0.5 mL single-dose prefilled syringe and a 90 mg/mL single-dose prefilled syringe.

CMS Final HCPCS Coding Determination

Revise existing HCPCS Level II code Q9998, “Injection, ustekinumab-aekn (selarsdi), 1 mg” to instead read “Injection, ustekinumab-aekn (selarsdi), biosimilar, 1 mg”

CMS agrees that it is appropriate to revise the existing HCPCS Level II code Q9998 to add the word “biosimilar” to the language. CMS generally creates codes for products themselves, without specifying a route of administration in the code descriptor, as there might be multiple routes of administration for the same product. Drugs that fall under this category should be billed with either the JA modifier for the intravenous infusion of the drug or billed with the JB modifier for subcutaneous injection of the drug.

SELARSDI™ (Intravenous) - HCP241218W7VAY

Topic/Issue

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

Applicant's suggested language: QXXXX, “Injection, ustekinumab-aekn (selarsdi), biosimilar, intravenous, 1 mg”

Summary of Applicant's Submission

Teva Pharmaceuticals, Inc. submitted a request to establish a new HCPCS Level II code to identify SELARSDI™ (ustekinumab-aekn) for IV infusion. SELARSDI™ was approved by the Food and Drug Administration (FDA) under a 351(k) Biologics License Application (BLA) on October 18, 2024. A new code is necessary to distinguish SELARSDI™ (ustekinumab-aekn) IV infusion from SELARSDI™ (ustekinumab-aekn) subcutaneous injection, which is the subject of another HCPCS Level II code application in this quarterly cycle. SELARSDI™ (IV) is a human interleukin -12 and -23 antagonist for IV infusion. SELARSDI™ (IV) is indicated for treating adults with moderately to severe active Crohn’s disease and adults with moderate to severe active ulcerative colitis. The recommended dosage of SELARSDI™ (IV) varies based on indication as well as the weight of the individual.

CMS Final HCPCS Coding Determination

Revise existing HCPCS Level II code Q9998, “Injection, ustekinumab-aekn (selarsdi), 1 mg” to instead read “Injection, ustekinumab-aekn (selarsdi), biosimilar, 1 mg”

CMS agrees that it is appropriate to revise the existing HCPCS Level II code Q9998 to add the word “biosimilar” to the language. CMS generally creates codes for products themselves, without specifying a route of administration in the code descriptor, as there might be multiple routes of administration for the same product. Drugs that fall under this category should be billed with either the JA modifier for the intravenous infusion of the drug or billed with the JB modifier for subcutaneous injection of the drug.

YESINTEK™ (Subcutaneous) - HCP250101YW19B

Topic/Issue

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

Applicant's suggested language: QXXXX, “Injection, ustekinumab-kfce (yesintek), subcutaneous, 1 mg”

Summary of Applicant's Submission

Biocon Biologics submitted a request to establish a new HCPCS Level II code to identify YESINTEK™ (ustekinumab-kfce) for SC injection. YESINTEK™ was approved by the Food and Drug Administration (FDA) under a 351(k) Biologics License Application (BLA) on November 29, 2024. YESINTEK™ is single source drug product indicated for the treatment of individuals with moderate to severe plaque psoriasis (PsO) who are candidates for phototherapy or systemic therapy; active psoriatic arthritis (PsA); moderately to severely active Crohn’s disease; or moderately to severely active ulcerative colitis. It is also indicated for treating individuals 6 years and older with moderate PsO, who are candidates for phototherapy or systemic therapy, or active PsA. The recommended dosage of YESINTEK™ varies based on the indication as well as the individual’s weight. YESINTEK™ is administered via intravenous infusion or SC injection.

CMS Final HCPCS Coding Determination

Establish a new HCPCS Level II code Q5100, “Injection, ustekinumab-kfce (yesintek), biosimilar, 1 mg”

CMS generally creates codes for products themselves, without specifying a route of administration in the code descriptor, as there might be multiple routes of administration for the same product. Drugs that fall under this category should be billed with either the JA modifier for the intravenous infusion of the drug or billed with the JB modifier for subcutaneous injection of the drug.

YESINTEK™ (Intravenous) - HCP250101HG1GC

Topic/Issue

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

Applicant's suggested language: QXXXX, “Injection, Ustekinumab-kfce (yesintek), intravenous, 1 mg”

Summary of Applicant's Submission

Biocon Biologics submitted a request to establish a new HCPCS Level II code to identify YESINTEK™ (ustekinumab-kfce) for IV infusion. YESINTEK™ was approved by the Food and Drug Administration (FDA) under a 351(k) Biologics License Application (BLA) on November 29, 2024. YESINTEK™ is a single source drug product indicated for the treatment of individuals with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy; active psoriatic arthritis; moderately to severely active Crohn’s disease; or moderately to severely active ulcerative colitis. It is also indicated for treating individuals 6 years and older with moderate to severe plaque psoriasis, who are candidates for phototherapy or systemic therapy, or active psoriatic arthritis. The recommended dosage of YESINTEK™ varies based on the indication as well as the individual’s weight. YESINTEK™ is administered via IV infusion or subcutaneous injection.

CMS Final HCPCS Coding Determination

Establish a new HCPCS Level II code Q5100, “Injection, ustekinumab-kfce (yesintek), biosimilar, 1 mg”

CMS generally creates codes for products themselves, without specifying a route of administration in the code descriptor, as there might be multiple routes of administration for the same product. Drugs that fall under this category should be billed with either the JA modifier for the intravenous infusion of the drug or billed with the JB modifier for subcutaneous injection of the drug.

STEQEYMA® (Subcutaneous) - HCP2501023GYAQ

Topic/Issue

Request to establish a new HCPCS Level II code to identify STEQEYMA® for subcutaneous (SC) injection.

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

Summary of Applicant's Submission

CELLTRION Inc. submitted a request to establish a new HCPCS Level II code to identify STEQEYMA® (ustekinumab-stba) for SC injection. STEQEYMA® was approved by the Food and Drug Administration (FDA) under a 351(k) Biologics License Application (BLA) on December 17, 2024. STEQEYMA® is a biosimilar to STELARA® (ustekinumab). STEQEYMA® (SC) is a human interleukin-12 and -23 antagonist indicated for the treatment of adults with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy, active psoriatic arthritis, moderately to severely active Crohn’s disease, and moderately to severely active ulcerative colitis. STEQEYMA® is also approved for individuals 6 years and older with moderate to severe plaque psoriasis, who are candidates for phototherapy or systemic therapy, and individuals with active psoriatic arthritis. While STEQEYMA® has been approved with both intravenous (IV) and SC dosage forms, CELLTRION is requesting a unique HCPCS Level II code for STEQEYMA® (SC) to distinguish it from the IV induction dosage form. The recommended dosage will vary by the weight of the individual. STEQEYMA® (SC) is not interchangeable with STEQEYMA® (IV) and cannot be substituted as an induction dose for Crohn’s disease or ulcerative colitis. STELARA®, the reference product for STEQEYMA®, as well as other STELARA® biosimilars, have separate HCPCS codes for IV and SC formulations, therefore, in addition to the clinical need as described above, to reduce provider and beneficiary confusion, two HCPCS Level II codes would be recommended.

CMS Final HCPCS Coding Determination

Establish a new HCPCS Level II code Q5099, “Injection, ustekinumab-stba (steqeyma), biosimilar, 1 mg”

CMS generally creates codes for products themselves, without specifying a route of administration in the code descriptor, as there might be multiple routes of administration for the same product. Drugs that fall under this category should be billed with either the JA modifier for the intravenous infusion of the drug or billed with the JB modifier for subcutaneous injection of the drug.

STEQEYMA® (Intravenous) - HCP250102PJLDX

Topic/Issue

Request to establish a new HCPCS Level II code to identify STEQEYMA® for intravenous (IV) infusion.

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

Summary of Applicant's Submission

CELLTRION Inc. submitted a request to establish a new HCPCS Level II code to identify STEQEYMA® (ustekinumab-stba) for IV infusion. STEQEYMA® was approved by the Food and Drug Administration (FDA) under a 351(k) Biologics License Application (BLA) on December 17, 2024. STEQEYMA® is a biosimilar to STELARA® (ustekinumab). STEQEYMA® is a human interleukin-12 and -23 antagonist indicated for the treatment of adults with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy, active psoriatic arthritis, moderately to severely active Crohn’s disease, and moderately to severely active ulcerative colitis. STEQEYMA® is also approved for individuals 6 years and older with moderate to severe plaque psoriasis, who are candidates for phototherapy or systemic therapy, and individuals with active psoriatic arthritis. While STEQEYMA® has been approved with both IV and subcutaneous (SC) dosage forms, CELLTRION is requesting a unique HCPCS Level II code for STEQEYMA® (IV) as it is only recommended for use as the initial induction dose for adults with Crohn’s disease or ulcerative colitis. The recommended dosage will vary by the weight of the individual. STEQEYMA® (IV) is available in a 130 mg/26 mL (5 mg/mL) solution in a single-dose vial. Given that STEQEYMA® (IV) is a larger loading dose compared to SC maintenance dosing, only used in limited indications, and only approved as an infused induction dose, it should have a unique HCPCS Level II code to distinguish it from STEQEYMA® (SC), which has very different strengths and utility. STELARA®, the reference product for STEQEYMA®, as well as other STELARA® biosimilars, have separate HCPCS Level II codes for IV and SC formulations, therefore, in addition to the clinical need as described above, to reduce provider and beneficiary confusion, two HCPCS Level II codes would be recommended.

CMS Final HCPCS Coding Determination

Establish a new HCPCS Level II code Q5099, “Injection, ustekinumab-stba (steqeyma), biosimilar, 1 mg”

CMS generally creates codes for products themselves, without specifying a route of administration in the code descriptor, as there might be multiple routes of administration for the same product. Drugs that fall under this category should be billed with either the JA modifier for the intravenous infusion of the drug or billed with the JB modifier for subcutaneous injection of the drug.

Cocaine Hydrochloride Nasal Solution- HCP241231FJA2V

Topic/Issue

Request to establish a new HCPCS Level II code to identify Cocaine hydrochloride nasal solution.

Applicant's suggested language: XXXXX, “Solution, cocaine hydrochloride, 1 mg”

Summary of Applicant's Submission

LXO Group submitted a request to establish a new HCPCS Level II code to identify Cocaine hydrochloride nasal solution. Cocaine hydrochloride nasal solution was approved by the Food and Drug Administration (FDA) under a 505(b)(2) New Drug Application (NDA) on December 14, 2017. Cocaine hydrochloride nasal solution is a single source drug administered to adults for the induction of local anesthesia of the mucous membranes when performing diagnostic procedures and surgeries on or through the nasal cavities. The method of action for cocaine hydrochloride is to prevent conduction in nerve fibers by reversibly blocking sodium channels and preventing the transient rise in sodium conductance. The recommended dose of cocaine hydrochloride nasal solution is two soaked cottoned pledgets placed in each nasal cavity, equivalent to 40 mg cocaine hydrochloride per pledget, for a total dose of 160 mg for four pledgets. The route of administration is intranasal. Cocaine hydrochloride nasal solution is a clear, green-colored liquid available in a dosage strength of 160 mg/4 mL (40 mg/mL or 4%) in a single-use bottle, equivalent to 142.4 mg/4 mL (35.6 mg/mL) cocaine free-base.

CMS Final HCPCS Coding Determination

It is our understanding that Cocaine hydrochloride nasal solution would generally be used in a procedure reported with a HCPCS Level I, Current Procedural Terminology (CPT®) code. We have not identified a specific need for this supply to be separately paid, since we believe that a particular payer may elect to pay for the service in which this product is used. For instance, Medicare would typically reflect the costs of the product in the payment for the procedure, if it is used, and as such it would not be separately payable.

AmchoThick™ - HCP24122426V9E

Topic/Issue

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

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

Summary of Applicant's Submission

Cellution Biologics, LLC submitted a request to establish a new HCPCS Level II code to identify AmchoThick™. AmchoThick™ 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.” AmchoThick™ is a minimally manipulated, dehydrated, human amnion chorion amnion membrane allograft. AmchoThick™ is intended for homologous use. It acts as a barrier and provides protective coverage for acute and chronic wounds from the surrounding environment. The allograft is processed using aseptic techniques and terminally sterilized by gamma irradiation to meet a sterility assurance level of 10-6. AmchoThick™ is for topical application. It can be applied to a wound or injury site using sterile forceps following wound preparation. AmchoThick™ is supplied in a sealed, single-use sterile double-pouched package consisting of a primary aluminum polyester and a secondary aluminum pouch. Allografts must be stored in a clean and dry environment at ambient room temperature before application. AmchoThick™ is available in various sizes and configuration sheets.

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, AmchoThick™, “when intended for use as a barrier and cover appears to meet the criteria for regulation solely under section 361 of the PHS Act and the regulations in 21 CFR part 1271.” As a result of our review of the TRG’s feedback, CMS has decided to:

Establish a new HCPCS Level II code Q4368, “Amchothick, per square centimeter”

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

AmnioPlast 3™ - HCP2412241J5G8

Topic/Issue

Request to establish a new HCPCS Level II code to identify AminoPlast 3™.

Applicant's suggested language: XXXXX, “AmnioPlast 3™, per square centimeter”

Summary of Applicant's Submission

Cellution Biologics, LLC submitted a request to establish a new HCPCS Level II code to identify AmnioPlast 3™. AmnioPlast 3™ 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 3™ is a minimally manipulated, decellularized, dehydrated, tri-layer amnion membrane allograft intended for homologous use. It is designed for use as a biological ocular cover. It acts as a barrier and provides protective coverage from the surrounding environment following repair or reconstruction procedures for ocular diseases and/or abnormalities. The allograft is processed using aseptic techniques and terminally sterilized by gamma irradiation to meet a sterility assurance level of 10-6. AmnioPlast 3™ is packaged in a hermetically sealed primary aluminum-PVC foil pouch and a secondary aluminum foil pouch. The dosage of AmnioPlast 3™ is measured in square centimeters, depending on the size of the wound, and it can be reapplied as needed. AmnioPlast 3™ must be stored in a clean, dry environment at ambient room temperature before application. It is supplied in various sizes and configuration sheets.

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 3™, “when intended for use as a cover and barrier appears to meet the criteria for regulation solely under section 361 of the PHS Act and the regulations in 21 CFR part 1271.” As a result of our review of the TRG’s feedback, CMS has decided to:

Establish a new HCPCS Level II code Q4369, “Amnioplast 3, per square centimeter”

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

AmchoPlast EXCEL™ - HCP241224MG6TY

Topic/Issue

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

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

Summary of Applicant's Submission

Cellution Biologics, LLC submitted a request to establish a new HCPCS Level II code to identify AmchoPlast EXCEL™. AmchoPlast EXCEL™ is regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) solely under section 361 of the Public Health Service (PHS) Act and 21 CFR part 1271 when intended for use as a “barrier and cover.” AmchoPlast EXCEL™ is a minimally manipulated, dehydrated, human amnion chorion membrane allograft for homologous use. It acts as a barrier and provides protective coverage for acute and chronic wounds from the surrounding environment. AmchoPlast EXCEL™ is sterile and supplied in a single-use package for topical application. AmchoPlast EXCEL™ is processed using aseptic techniques and chemically sterilized. It is supplied in a sealed, sterile double-pouched package consisting of a primary aluminum polyester pouch and a secondary aluminum pouch. Allografts must be stored in a clean and dry environment at ambient room temperature before application. AmchoPlast EXCEL™ is available 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, AmchoPlast EXCEL™, “when intended for use as a barrier and cover appears to meet the criteria for regulation solely under section 361 of the PHS Act and the regulations in 21 CFR part 1271.” As a result of our review of the TRG’s feedback, CMS has decided to:

Establish a new HCPCS Level II code Q4372, “Amchoplast excel, per square centimeter”

This coding determination applies to the AmchoPlast EXCEL™ product described in the application and accompanying FDA TRG letter dated September 16, 2024, when intended for use as a “barrier and cover.”

AéroGuard™ - HCP241230KY1YH

Topic/Issue

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

Applicant's suggested language: QXXXX, “AéroGuard™, per square centimeter”

Summary of Applicant's Submission

C5 Biomedical, LLC submitted a request to establish a new HCPCS Level II code to identify AéroGuard™. AéroGuard™ 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.” AéroGuard™ is a sterile, dehydrated single-layer human amniotic membrane allograft product derived from donated, healthy human birth tissue. The allograft product is aseptically processed using minimal manipulation and terminally sterilized to a sterility assurance level of 10-6. AéroGuard™ is intended for homologous use as a protective wound covering or barrier for acute and chronic wounds. It is available in various sizes and configuration sheets.

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, AéroGuard™, “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 Q4370, “Aeroguard, per square centimeter”

This coding determination applies to the AéroGuard™ product described in the application and accompanying FDA TRG letter dated October 3, 2024, when intended as a “covering” or “barrier.”

NéoGuard™ - HCP241230KUBRU

Topic/Issue

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

Applicant's suggested language: QXXXX, "NéoGuard™, per square centimeter"

Summary of Applicant's Submission

C5 Biomedical, LLC submitted a request to establish a new HCPCS Level II code to identify NéoGuard™. NéoGuard™ 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." NéoGuard™ is a sterile, dehydrated double-layer human amniotic membrane allograft product derived from donated, healthy human birth tissue. The allograft product is aseptically processed using minimal manipulation and terminally sterilized to a sterility assurance level of 10-6. NéoGuard™ is intended for homologous use as a protective wound covering or barrier. It is available in various sizes and configuration sheets.

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, NéoGuard™, "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 Q4371, "Neoguard, per square centimeter"

This coding determination applies to the NéoGuard™ product described in the application and accompanying FDA TRG letter dated October 3, 2024, when intended as a "covering" or "barrier."

Membrane Wrap-Lite™ - HCP241226T3DG2

Topic/Issue

Request to establish a new HCPCS Level II code to identify Membrane Wrap-Lite™.

The applicant did not submit any suggested language.

Summary of Applicant's Submission

BioLab Holdings, Inc. submitted a request to establish a new HCPCS Level II code to identify Membrane Wrap-Lite™. Membrane Wrap-Lite™ 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." Membrane Wrap-Lite™ dosage is per square centimeter. This product is indicated for chronic and acute wounds. After preparation of the wound site, the human amnion single layer allograft is applied to the wound surface by a licensed health care provider and secured in place by their choice of fixation. Reapplication is determined by the clinician. The route of administration is topical, applying the product on the wound base. This product serves as a protective covering from the surrounding environment. It is available in various sizes to be used by the clinician. The product comes in a double pouch for aseptic presentation of the packaged product onto the sterile field. The inner pouch is both sterile and has a moisture barrier. The outer pouch is a peel pouch for aseptic presentation to the sterile field and is transparent on one side to allow for visualization of the contents.

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, Membrane Wrap-Lite™, "when intended for use as a 'barrier' and 'cover,' appear[s] to meet all the criteria for regulation solely under section 361 of the PHS Act and the regulations in 21 CFR part 1271." As a result of our review of the TRG's feedback, CMS has decided to:

Establish a new HCPCS Level II code Q4373, "Membrane wrap-lite, per square centimeter"

This coding determination applies to the Membrane Wrap-Lite™ product described in the application and accompanying FDA TRG letter dated December 19, 2024, when intended for use as a "barrier" and "cover."

Duograft AA™ - HCP2412194JX89

Topic/Issue

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

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

Summary of Applicant's Submission

RegenTX Partners submitted a request to establish a new HCPCS Level II code to identify Duograft AA™. Duograft AA™ 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.” Duograft AA™ is a dehydrated dual-layer amniotic membrane allograft that is intended to act as a barrier or protective cover at the local site of injury or surgical site. Duograft AA™ is supplied in various-sized sheets.

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, Duograft AA™, “when intended as a barrier or cover, appears to meet the criteria for regulation solely under section 361 of the PHS Act and the regulations in 21 CFR part 1271.” As a result of our review of the TRG’s feedback, CMS has decided to:

Establish a new HCPCS Level II code Q4376, “Duograft aa, per square centimeter”

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

duoGRAFT AC™ - HCP2412196XWA4

Topic/Issue

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

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

Summary of Applicant's Submission

RegenTX Partners LLC submitted a request for a new HCPCS Level II code to identify duoGRAFT AC™. duoGRAFT 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 or cover.” duoGRAFT AC™ is a dehydrated full-thickness placental membrane allograft that is processed using a proprietary processing technology to ensure all naturally occurring components of birth tissue remain intact through processing. duoGRAFT AC™ is a multi-layer graft that contains the amnion, chorion as well as the important intermediate layer/spongy layer of the placenta. duoGRAFT AC™ is intended to act as a barrier or protective cover at the local site of injury or surgical site. The human amniotic membrane is a thin collagenous membrane derived from the submucosa of the placenta, the area in which the human fetus grows and develops within the mother’s uterus, and is a basement membrane comprised of collagen layers and an extracellular stromal matrix. duoGRAFT AC™ is supplied in sheets of 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, duoGRAFT AC™, “when intended for use as a barrier or cover, appears to meet the criteria for regulation solely under section 361 of the PHS Act and the regulations in 21 CFR part 1271.” As a result of our review of the TRG’s feedback, CMS has decided to:

Establish a new HCPCS Level II code Q4375, “Duograft ac, per square centimeter”

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

triGRAFT FT™ - HCP241219L49KH

Topic/Issue

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

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

Summary of Applicant's Submission

RegenTX Partners submitted a request to establish a new HCPCS Level II code to identify triGRAFT FT™. triGRAFT 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 or cover.” triGRAFT FT™ is a dehydrated triple-layer placental membrane for which its three layers consist of amnion, spongy layer, and chorion. triGRAFT FT™ is intended to act as a barrier or protective cover at the local site of injury or surgical site. triGRAFT FT™ retains the placental membrane’s natural structure and relevant characteristics. The placental membrane adheres closely to its underlying surface as a cover protecting wounds and may help prevent the formation of dead space on the wound. triGRAFT FT™ is supplied in sheets of 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, triGRAFT FT™, “when intended as a barrier or cover, appears to meet the criteria for regulation solely under section 361 of the PHS Act and the regulations in 21 CFR part 1271.” As a result of our review of the TRG’s feedback, CMS has decided to:

Establish a new HCPCS Level II code Q4377, “Trigraft ft, per square centimeter”

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

Renew™ FT Matrix - HCP2412209YPUJ

Topic/Issue

Request to establish a new HCPCS Level II code to identify Renew™ FT Matrix.

Applicant's suggested language: QXXXX, “Renew™ FT Matrix, per cm2”

Summary of Applicant's Submission

Sequence LifeScience, Inc. submitted a request to establish a new HCPCS Level II code to identify Renew™ FT Matrix. Renew™ FT Matrix 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 wound cover.” Renew™ FT Matrix is a full-thickness minimally manipulated human placental membrane product derived from donated placental tissues that retain the structural and functional characteristics of the tissues. The final product is dehydrated, packaged in different-size sheets, and terminally sterilized by irradiation. Renew™ FT Matrix is composed of extracellular matrix proteins and serves as a natural, biological barrier or wound cover. The typical population receiving treatment includes individuals with chronic full-thickness ulcers and other skin defects where a biological barrier or cover is required. Renew™ FT Matrix is ordered by a licensed physician for individual use. The dosage is per centimeter square, depending on the size of the injury or site of application. Renew™ FT Matrix is supplied in various sizes and configuration sheets and is stored at ambient room temperature (15-30° C or 59-86° F).

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, Renew™ FT Matrix, “when intended for use as a ‘barrier or wound cover,’ appears to meet the criteria for regulation solely under section 361 of the PHS Act and the regulations in 21 CFR part 1271.” As a result of our review of the TRG’s feedback, CMS has decided to:

Establish a new HCPCS Level II code Q4378, “Renew ft matrix, per square centimeter”

This coding determination applies to the Renew™ FT Matrix product described in the application and accompanying FDA TRG letter dated December 19, 2024, when intended for use as a “barrier or wound cover.”

AmnioDefend™ FT Matrix - HCP241220DEN08

Topic/Issue

Request to establish a new HCPCS Level II code to identify AmnioDefend™ FT Matrix.

Applicant's suggested language: QXXXX, “AmnioDefend™ Matrix, per cm2”

Summary of Applicant's Submission

Sequence LifeScience, Inc. submitted a request to establish a new HCPCS Level II code to identify AmnioDefend™ FT Matrix. AmnioDefend™ FT Matrix 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 wound cover.” AmnioDefend™ FT Matrix consists of all three layers of the placental membranes including amnion, intermediate layer, and chorion. It is a minimally manipulated human placental membrane product derived from donated placental tissues that retain the structural and functional characteristics of the tissues. The final product is dehydrated, packaged in different-size sheets, and terminally sterilized by irradiation. AmnioDefend™ FT Matrix is composed of extracellular matrix proteins and serves as a natural, biological barrier or wound cover. The typical population receiving treatment includes individuals who require a barrier or wound cover for acute and chronic wounds. AmnioDefend™ FT Matrix is ordered by a licensed physician for individual use. The dosage is per centimeter square, depending on the size of the injury or site of application. AmnioDefend™ FT Matrix is supplied in various size and configuration sheets and is stored at ambient temperature (15-30° C or 59-86° F).

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, AmnioDefend™ FT Matrix, “when intended for use as a ‘barrier or wound cover,’ appears to meet the criteria for regulation solely under section 361 of the PHS Act and the regulations in 21 CFR part 1271.” As a result of our review of the TRG’s feedback, CMS has decided to:

Establish a new HCPCS Level II code Q4379, “Amniodefend ft matrix, per square centimeter”

This coding determination applies to the AmnioDefend™ FT Matrix product described in the application and accompanying FDA TRG letter dated December 19, 2024, when intended for use as a “barrier or wound cover.”

AdvoGraft One - HCP250102E1LLX

Topic/Issue

Request to establish a new HCPCS Level II code to identify AdvoGraft One.

Applicant's suggested language: XXXXX, “AdvoGraft One, per sq cm”

Summary of Applicant's Submission

RMBB Health submitted a request to establish a new HCPCS Level II code to identify AdvoGraft One. AdvoGraft One 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.” AdvoGraft One, a single-layer amniotic membrane. It is derived from processed human placental tissue and consists of a dehydrated sheet of amniotic and/or chorionic membrane. Donated tissue is cleaned, soaked, washed, spread and dried, cut, and sterilized with irradiation. AdvoGraft One is intended for use as a barrier and cover for acute and chronic wounds. AdvoGraft One is ordered and used by a licensed physician for individual use. The membrane is available in various sizes. The product is stored at ambient room temperature (15-30° C).

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, AdvoGraft One, “when intended for use as a 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 Q4380, “Advograft one, per square centimeter”

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

AdvoGraft Membrane Dual - HCP250102EGVK1

Topic/Issue

Request to establish a new HCPCS Level II code to identify AdvoGraft Membrane Dual.

Applicant's suggested language: XXXXX, “AdvoGraft Membrane Dual, per sq cm”

Summary of Applicant's Submission

RMBB Health submitted a request to establish a new HCPCS Level II code to identify AdvoGraft Membrane Dual. AdvoGraft Dual is regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) solely under section 361 of the Public Health Service (PHS) Act and 21 CFR part 1271 when intended for use as a “barrier and cover.” AdvoGraft Membrane Dual is a dual-layer amniotic membrane derived from processed human placental tissue. Donated tissue is cleaned, soaked, washed, spread, dried, cut, and sterilized with irradiation. AdvoGraft Membrane Dual is intended for use as a biological barrier to provide protective coverage from the surrounding environment for acute and chronic wounds. The allograft is a dehydrated sheet of amniotic and/or chorionic membrane and is intended for use by or on the order of a licensed physician for single-patient use on a single occasion. The membrane is available in various sizes and is stored at ambient room temperature (15–30° C).

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, AdvoGraft Dual, “when intended for us as a 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 Q4382, “Advograft dual, per square centimeter”

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

Matrix HD Allograft Dermis, Non-Fenestrated - HCP250102Y6FWB

Topic/Issue

Request to establish a new HCPCS Level II code to identify Matrix HD Allograft Dermis, Non-Fenestrated.

Applicant's suggested language: QXXXX, "Matrix HD Allograft Dermis, Non-Fenestrated, per square centimeter"

Summary of Applicant's Submission

Royal Wound-X submitted a request to establish a new HCPCS Level II code to identify Matrix HD Allograft Dermis, Non-Fenestrated. Matrix HD Allograft Dermis 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 for various wounds including diabetic foot ulcers and burns." Matrix HD Allograft Dermis, Non-Fenestrated is intended as a wound cover to help repair, replace, reconstruct, or supplement damaged soft tissue in acute and chronic wounds including diabetic foot ulcers and burns. The wound cover barrier will protect the wounds from the surrounding environment. Following standard wound preparation, Matrix HD Allograft Dermis, Non-Fenestrated can be applied directly to the wound. Matrix HD Allograft Dermis, Non-Fenestrated is a single-use product, packaged in a primary film-Tyvek® pouch and a secondary film-Tyvek® pouch, and sterilized with gamma irradiation of 10-6. Matrix HD Allograft Dermis, Non-Fenestrated is available in multiple sizes.

CMS Final HCPCS Coding Determination[5]

After review of the Food and Drug Administration's (FDA's) Tissue Reference Group (TRG) letter submitted by the applicant, Matrix HD Allograft Dermis, "when intended for use as a 'wound cover for various wounds including diabetic foot ulcers and burns', appears to meet the criteria for regulation solely under section 361 of the PHS Act and the regulations in 21 CFR part 1271." As a result of our review of the TRG's feedback, CMS has decided to assign:

Existing HCPCS Level II code Q4345, "Matrix hd allograft dermis, per square centimeter" to describe Matrix HD Allograft Dermis, Non-Fenestrated.

This coding determination applies to the Matrix HD Allograft Dermis product described in the application and accompanying FDA TRG letter dated March 2, 2021, when intended for use as a "wound cover for various wounds including diabetic foot ulcers and burns."

[5] Updated on May 12, 2025 to assign existing HCPCS Level II code Q4345, as Matrix HD Allograft Dermis was previously assigned Q4345 effective October 1, 2024, and a new HCPCS Level II code would be redundant.

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[6], and are therefore considered single source products. Also, this effort will help reduce use of the not otherwise classified (NOC) codes.

In order to conform with the general approach used for the assignment of products paid under section 1847A of the Social Security Act (the Act) to HCPCS 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[7] to identify the correct billing and payment code for each applicable product.

CMS Final HCPCS Coding Determination

Establish thirteen new HCPCS Level II codes, revise one existing HCPCS Level II code, and discontinue seven HCPCS Level II codes to either separately identify products approved by the FDA after October 2003, and not rated as therapeutically equivalent to a reference listed product in an existing code, or to more accurately identify multiple source products accordingly.

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

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[6] The FDA's Orange Book, officially entitled, *Approved Drug Products With Therapeutic Equivalence Evaluations,* identifies drug products approved on the basis of safety and effectiveness by the FDA, and is published at the following FDA link: https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm.

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

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
J0165	Add	Injection, epinephrine, not otherwise specified, 0.1 mg
J0166	Add	Injection, epinephrine (bpi), not therapeutically equivalent to j0165, 0.1 mg
J0167	Add	Injection, epinephrine (hospira), not therapeutically equivalent to j0165, 0.1 mg
J0168	Add	Injection, epinephrine (international medication systems), not therapeutically equivalent to j0165, 0.1 mg
J0169	Add	Injection, epinephrine (adrenalin), not therapeutically equivalent to j0165, 0.1 mg
J0171*	Delete	Injection, adrenalin, epinephrine, 0.1 mg
J0173*	Delete	Injection, epinephrine (belcher), not therapeutically equivalent to j0171, 0.1 mg
J0616	Add	Injection, metoprolol tartrate, 1 mg
J0618	Add	Injection, calcium chloride, 2 mg
J1163	Add	Injection, diltiazem hydrochloride, 0.5 mg
J2310*	Delete	Injection, naloxone hydrochloride, per 1 mg
J2311*	Delete	Injection, naloxone hydrochloride (zimhi), 1 mg
J2312**	Add	Injection, naloxone hydrochloride, not otherwise specified, 0.01 mg
J2313**	Add	Injection, naloxone hydrochloride (zimhi), 0.01 mg
J3370*	Delete	Injection, vancomycin hcl, 500 mg
J3372*	Delete	Injection, vancomycin hcl (xellia), not therapeutically equivalent to j3370, 500 mg
J3373**	Add	Injection, vancomycin hydrochloride, 10 mg
J3375**	Add	Injection, vancomycin hydrochloride (xellia), not therapeutically equivalent to j3373, 10 mg
J9292	Revise	From "Injection, pemetrexed (avyxa), not therapeutically equivalent to j9305, 10 mg" to instead read "Injection, pemetrexed dipotassium, 10 mg"
J9340*	Delete	Injection, thiotepa, 15 mg
J9342**	Add	Injection, thiotepa, not otherwise specified, 1 mg

*The effective date for the discontinuation of this code is June 30, 2025.

**The dose descriptor is being reduced because CMS has a long-standing convention to assign dose descriptors in the smallest amount that could be billed in multiple units to accommodate a variety of doses and support streamlined billing. This long-standing policy makes coding more robust and facilitates accurate payment and reporting of the exact dose administered, as only 999 units can appear on a claim line for Medicare fee-for-service using the CMS-1500 form.