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

Third Quarter, 2025 HCPCS Coding Cycle

This document presents a summary of each HCPCS Level II code application and CMS' coding determination for e
ach application processed in CMS' Third 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 January 1, 2026[1], unless otherwise indicated.

The HCPCS Level II coding determinations below will also be included in the January 2026 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 manufacturer or 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.

[1] Updated on November 14, 2025 to reflect that the HCPCS Level II code modifications will be effective January 1, 2026, unless otherwise indicated, and not January 1, 2025.

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Epinephrine - HCP2506307BKFL

Topic/Issue

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

The applicant did not submit any suggested language.

Summary of Applicant's Submission

Fresenius Kabi submitted a request to establish a new HCPCS Level II code for epinephrine. Epinephrine was approved by the Food and Drug Administration (FDA) under a 505(b)(2) New Drug Application (NDA) on March 13, 2025. Epinephrine is a non-selective alpha- and beta-adrenergic agonist indicated for use in adults and pediatrics for the emergency treatment of allergic reactions (Type 1), including anaphylaxis, and in adults to increase mean arterial blood pressure with hypotension associated with septic shock. Epinephrine injection, United States Pharmacopeia is a clear, colorless, sterile solution containing 1 mg/mL, packaged as a 30 mL solution in a multiple dose amber vial. Epinephrine is administered intramuscularly or subcutaneously into anterolateral thigh every 5 to10 minutes as needed in adults and pediatrics for anaphylaxis, and is infused intravenously in adults with hypotension associated with septic shock. Epinephrine acts on both alpha- and beta- adrenergic receptors. Through its action on alpha-adrenergic receptors, epinephrine lessens the vasodilation and increased vascular permeability that occurs during anaphylaxis, which can lead to loss of intravascular fluid volume and hypotension. Through its action on beta-adrenergic receptors, epinephrine causes bronchial smooth muscle relaxation and helps alleviate bronchospasm, wheezing and dyspnea that may occur during anaphylaxis. Epinephrine also alleviates pruritus, urticaria, and angioedema. It may also relieve gastrointestinal and genitourinary symptoms associated with anaphylaxis because of its relaxer effects on the smooth muscle of the stomach, intestine, uterus and urinary bladder. In hypotension, epinephrine acts on both alpha and beta-adrenergic receptors. The mechanism of the rise in blood pressure is 3-fold: a direct myocardial stimulation that increases the strength of ventricular contraction (positive inotropic action), an increased heart rate (positive chronotropic action), and peripheral vasoconstriction.

CMS Final HCPCS Coding Determination

Establish a new HCPCS Level II code J0162, “Injection, epinephrine (fresenius), not therapeutically equivalent to j0165, 0.1 mg”

ZUSDURI™ - HCP2506209VK0Q

Topic/Issue

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

Applicant's suggested language: JXXXX, “Mitomycin intravesical instillation (ZUSDURI), 1 mg”

Summary of Applicant's Submission

UroGen Pharma, Inc. submitted a request to establish a new HCPCS Level II code to identify ZUSDURI™ (mitomycin). ZUSDURI™ was approved by the Food and Drug Administration (FDA) under a New Drug Application (NDA) on June 12, 2025. ZUSDURI™ is designed to enable longer exposure of bladder tissue to mitomycin, thereby enabling the treatment of tumors by non-surgical means. Its function is as an alkylating drug indicated for use in adults with recurrent low-grade intermediate-risk non-muscle invasive bladder cancer. ZUSDURI™ inhibits the synthesis of deoxyribonucleic acid (DNA). The guanine and cytosine content in the DNA correlates with the degree of mitomycin-induced cross-linking. At high concentrations of the drug, cellular ribonucleic acid and protein synthesis are also suppressed. ZUSDURI™ for intravesical solution is a sterile, lyophilized, grey to greyish-purple, cake or powder that contains mitomycin 40 mg in each vial. Mannitol is used as a bulking agent in this mitomycin formulation. ZUSDURI™ must be reconstituted with UroGen Pharma's proprietary RTGel® technology, a sustained release, hydrogel-based formulation, under chilled conditions. The hydrogel is a sterile, clear, colorless gel with or without bubbles at room temperature or clear, colorless liquid at 2 degrees C to 8 degrees C (36°F to 46°F), which contains 0.11 g hydroxypropyl methylcellulose, 17.12 g poloxamer, 0.63 g polyethylene glycol, and water for injection in each vial. The sterile hydrogel is a clinical component of the product and not a diluent; ZUSDURI™ cannot be used without the hydrogel. The recommended dosage of ZUSDURI™ is 75 mg (56 mL) instilled once weekly for six weeks. The route of administration of ZUSDURI™ is intravesical instillation only; it is not for pyelocalyceal instillation or by any other route. It is instilled into the bladder via urinary catheter. ZUSDURI™ is packaged in a kit containing the following: two 40 mg (each) single-dose vials of mitomycin for intravesical solution; and one vial of 60 mL sterile hydrogel for reconstitution.

CMS Final HCPCS Coding Determination

Establish a new HCPCS Level II code J9282, “Mitomycin, intravesical instillation, 1 mg”

JOURNAVX™ - HCP250630C25HP

Topic/Issue

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

Applicant's suggested language: JXXXX, “Suzetrigine, oral, 50 mg”

Summary of Applicant's Submission

Vertex Pharmaceuticals Inc. submitted a request to establish a new HCPCS Level II code for JOURNAVX™ (suzetrigine). JOURNAVX™ was approved by the Food and Drug Administration (FDA) under a New Drug Application (NDA) on January 30, 2025. JOURNAVX™ is a sodium channel blocker indicated for use in adults for the treatment of moderate to severe acute pain. JOURNAVX™ is a first-in-class, oral, non-opioid, highly selective pain signal inhibitor that is selective for the voltage-gated sodium (NaV) channel, NaV1.8, relative to other NaV channels. NaV1.8 is selectively expressed in peripheral pain-sensing neurons (nociceptors), where its role is to transmit pain signals (action potentials). Because NaV1.8 channels are not expressed in the brain, JOURNAVX™ only works by blocking pain signals in the periphery.Past CMS guidance indicates that non-opioid treatments as defined under Section 4135 of the Consolidated Appropriations Act, 2023 for pain relief will be covered under Part B, as appropriate, when a product is supplied immediately following a surgical procedure to aid recovery. JOURNAVX™ is “directly related” to the procedure as administration of JOURNAVX™ will be part of perioperative pain management that aims to reduce post-operative pain. Per the approved prescribing information, the recommended starting dose of JOURNAVX™ is 100 mg orally, beginning 12 hours after the starting dose, individuals can take 50 mg of JOURNAVX™ orally every 12 hours. JOURNAVX™ is supplied as a tablet. Each tablet is 50 mg, blue, film-coated, oblong tablets debossed with “VX50” on one side and plain on the other.

CMS Final HCPCS Coding Determination

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. JOURNAVX™ meets CMS’ criteria for classification as a self-administered drug. CMS is denying the request to establish a HCPCS Level II code to identify JOURNAVX™ as the medication is self-administered.

If a HCPCS code is needed to effectuate a payment policy under the Outpatient Prospective Payment System (OPPS)/Ambulatory Surgical Center (ASC) Payment System, then the HCPCS code may be created through the relevant regulatory vehicles, such as the OPPS/ASC annual notice and comment rulemaking.

JOBEVNE™ - HCP250624L6C5W

Topic/Issue

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

Applicant's suggested language: QXXXX, "Injection, bevacizumab-nwgd, biosimilar, (jobevne), 100 mg/4 mL"

Summary of Applicant's Submission

Biocon Biologics Inc. submitted a request to establish a new HCPCS Level II code to identify JOBEVNE™ (bevacizumab-nwgd). JOBEVNE™ was approved by the Food and Drug Administration (FDA) under a 351(k) Biologics License Application (BLA) on April 10, 2025. JOBEVNE™ is indicated for the treatment of certain individuals with metastatic colorectal cancer, non-squamous non-small cell lung cancer, recurrent glioblastoma, metastatic renal cell carcinoma, persistent, recurrent, and metastatic cervical cancer, or epithelial ovarian, fallopian tube, or primary peritoneal cancer. JOBEVNE™ is a biosimilar to AVASTIN® (bevacizumab). The active ingredient in JOBEVNE™ is bevacizumab-nwgd, a human monoclonal antibody that prevents the growth of certain types of blood vessels to cancer cells. The recommended dosage of JOBEVNE™ varies based on the indication ranging from 5 mg/kg to 15 mg/kg every 2 or 3 weeks. JOBEVNE™ is a sterile, preservative-free clear to slightly opalescent, colorless to pale brown solution in a single-dose vial for intravenous infusion. JOBEVNE™ contains bevacizumab-nwgd at a concentration of 25 mg/mL in either a 100 mg or 400 mg single-dose vial.

CMS Final HCPCS Coding Determination

Establish a new HCPCS Level II code Q5160, "Injection, bevacizumab-nwgd (jobevne), biosimilar, 10 mg"

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. This framework explains the distinction between the applicant's proposed dosage of 100 mg/4 mL and the HCPCS Level II code Q5160 designation of 10 mg.

AVGEMSI - HCP250701D3TYK

Topic/Issue

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

Applicant's suggested language: JXXXX, "Injection, gemcitabine (avgemsi), 200 mg"

Summary of Applicant's Submission

AVYXA Pharma, LLC submitted a request to establish a new HCPCS Level II code to identify AVGEMSI (gemcitabine) injection. AVGEMSI was approved by the Food and Drug Administration (FDA) under a 505(b)(2) New Drug Application (NDA) on June 27, 2025. AVGEMSI is a nucleoside metabolic inhibitor approved for the following indications: in combination with carboplatin, for the treatment of individuals with advanced ovarian cancer that has relapsed at least 6 months after completion of platinum-based therapy; in combination with paclitaxel, for first-line treatment of individuals with metastatic breast cancer after failure of prior anthracycline-containing adjuvant chemotherapy, unless anthracyclines were clinically contraindicated; in combination with cisplatin, for the first-line treatment of individuals with inoperable, locally advanced or metastatic non-small cell lung cancer and as first-line treatment for individuals with locally advanced or metastatic adenocarcinoma of the pancreas. AVGEMSI is for intravenous use only. Dosing is based on indication and ranges from 1,000 mg/m^2 to 1,250 mg/m^2 on specified days within a 21-day or 28-day cycle. AVGEMSI is a clear and colorless to light straw-colored solution individually packaged at a concentration of 38 mg/mL available in either 200 mg, 1,000 mg and 2,000 mg in sterile multiple-dose vials.

CMS Final HCPCS Coding Determination

Establish a new HCPCS Level II code J9184, "Injection, gemcitabine hydrochloride (avyxa), 200 mg"

CMS aims to mitigate marketing biases within the HCPCS Level II code set. Accordingly, CMS has a longstanding policy to first 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 either the brand name or the company name. In specific instances, CMS will incorporate the company name for drugs approved by the FDA under a 505(b)(2) NDA when the original drug code does not already include a brand name.

MIUDELLA® Copper Intrauterine System - HCP250618WCT0T

Topic/Issue

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

Applicant's suggested language: JXXXX, “Intrauterine copper contraceptive (MIUDELLA®) (3 year duration)”

Summary of Applicant's Submission

Sebela Women's Health Inc. submitted a request to establish a new HCPCS Level II code to identify MIUDELLA®, a copper-containing intrauterine system. MIUDELLA® was approved by the Food and Drug Administration (FDA) under a New Drug Application (NDA) on February 24, 2025. MIUDELLA® is a small, flexible, hormone-free intrauterine system with copper attached to a flexible wire frame that allows it to fit different uterus shapes and sizes. MIUDELLA® is indicated for the prevention of pregnancy in females of reproductive potential, for up to 3 years. Copper continuously released into the uterine cavity contributes to the contraceptive effectiveness of MIUDELLA®. Mechanism(s) by which copper enhances contraceptive efficacy includes interference with sperm transport and fertilization of an egg. MIUDELLA® has a nitinol frame with copper sleeves and monofilament polymer retrieval thread, preloaded in a sterile inserter. MIUDELLA® has 175 mm^2 exposed copper surface area. MIUDELLA® is supplied in a sterile sealed package with a sterile single-use inserter for placement. A single MIUDELLA® is inserted at the fundus of the uterine cavity only by a trained healthcare provider using clean technique and must be removed or replaced after 3 years. MIUDELLA® is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the MIUDELLA® REMS program, to ensure healthcare providers are trained on the proper insertion of MIUDELLA® prior to first use.

CMS Final HCPCS Coding Determination

Establish a new HCPCS Level II code J7299, “Intrauterine copper contraceptive (miudella)”

ZEVASKYN™ - HCP2506279545U

Topic/Issue

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

Applicant's suggested language: JXXXX, “Topical application, prademagene zamikeracel, per treatment”

Summary of Applicant's Submission

Abeona Therapeutics submitted a request to establish a new HCPCS Level II code to identify ZEVASKYN™ (prademagene zamikeracel). ZEVASKYN™ was approved by the Food and Drug Administration (FDA) under a 351(a) Biologics License Application (BLA) on April 28, 2025. ZEVASKYN™ is an autologous cell sheet-based gene therapy product. The function of ZEVASKYN™ is indicated for the treatment of wounds in adult and pediatric individuals with recessive dystrophic epidermolysis bullosa (RDEB). ZEVASKYN™’s mechanism of action is to genetically modify individuals’ own cells through retroviral vector transduction to express the COL7A1 gene to produce the collagen 7 (C7) protein, which would otherwise be absent (or at low levels) in individuals with RDEB, due to mutations of the COL7A1 gene. The recommended dose of ZEVASKYN™ is based on the surface area of the wound(s) to be treated, and up to twelve ZEVASKYN™ sheets may be manufactured from individual’s biopsies and supplied for potential use in a single dose. ZEVASKYN™ is administered topically via surgical application by a qualified healthcare provider. ZEVASKYN™ is suppled as a single dose of up to twelve cellular sheets, each measuring 41.25 cm^2 (5.5 cm x 7.5 cm), and consisting of individuals’ own viable, gene-modified cells that contain functional copies of the COLA7A1 gene, which express the C7 protein. ZEVASKYN™ is packaged in a clam-shell, and scaled transport pouch containing sterile transport media.

CMS Final HCPCS Coding Determination

Establish a new HCPCS Level II code J3389, “Topical administration, prademagene zamikeracel, per treatment”

HYMOVIS® ONE - HCP2506179DGAP

Topic/Issue

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

Applicant's suggested language: JXXXX, “Hyaluronan or derivative, HYMOVIS ONE, for intra-articular injection, per dose”

Summary of Applicant's Submission

Fidia Pharma USA Inc. submitted a request to establish a new HCPCS Level II code to identify HYMOVIS® ONE. HYMOVIS® ONE was approved by the Food and Drug Administration (FDA) under a premarket approval (PMA) on April 9, 2025. There are other hyaluronan (HA) viscosupplement products on the market, however, HYMOVIS® ONE is a sterile syringe, viscoelastic hydrogel containing an ultra-pure HA (32 mg/4 mL total concentration) in buffered saline, making HYMOVIS® ONE distinct from all other HA viscosupplement products in terms of mg/mL dosing, its therapeutic clinical benefit, and its base molecular structure and formulation. HYMOVIS® ONE is indicated for the treatment of individuals with osteoarthritis knee joint pain, in a single intra-articular injection, in order to supplement the synovial fluid. Its function is to provide lubrication, cushioning, and pain relief as well as improvement in joint physical function, and for individuals who have failed to respond adequately to conservative non-pharmacologic therapy, or simple analgesics (e.g., acetaminophen). HYMOVIS® ONE is an ultra-pure HA hydrogel, engineered using a proprietary process to increase viscosity, elasticity, and joint residence time without chemical cross-linking. This results in a stable, ultrapure, highly viscoelastic hydrogel with increased lubricating, cushioning, and shock-absorbing properties to relieve pain and improve joint physical function. HYMOVIS® ONE is supplied in a single-use, 5 mL syringe containing 4 mL of this product. The contents of the syringe are sterile and non-pyrogenic and contain no latex. The syringe is then packaged in a blister pack and placed in a box.

CMS Final HCPCS Coding Determination

Revise existing HCPCS Level II code J7322, “Hyaluronan or derivative, hymovis, for intra-articular injection, 1 mg” to instead read “Hyaluronan or derivative, hymovis or hymovis one, for intra-articular injection, 1 mg” to describe HYMOVIS® ONE.

HYMOVIS® ONE was approved as a supplement to the original HYMOVIS® product, shares the same FDA PMA number, and contains identical ingredients with only variations in ingredient quantities.

Qamzova™ - HCP25070164BCE

Topic/Issue

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

Applicant's suggested language: XXXXX, “Injection, meloxicam (Qamzova), 1 mg”

Summary of Applicant's Submission

Delova Biotech Inc. submitted a request to establish a new HCPCS Level II code to identify Qamzova™ (meloxicam injection). Qamzova™ was approved by the Food and Drug Administration (FDA) under a 505(b)(2) New Drug Application (NDA) on April 22, 2025. Qamzova™ contains meloxicam, which is a nonsteroidal anti-inflammatory drug (NSAID). Qamzova™ is indicated for use in adults for the management of moderate to severe pain, alone or in combination with non-NSAID analgesics. Because of delayed onset of analgesia, Qamzova™ alone is not recommended for use when rapid onset of analgesia is required. Meloxicam has analgesic, anti-inflammatory and anti-pyretic properties. The recommended dose of Qamzova™ is 30 mg once daily, administered as an intravenous injection over 15 seconds. Qamzova™ is supplied as a sterile, clear, greenish-yellow, solution in single-dose vials containing 30 mg/mL. Each mL contains 30 mg of meloxicam and 300 mg of polyethylene glycol 400 in water for injection. The potential of hydrogen (pH) of the solution is adjusted with sodium hydroxide and citric acid monohydrate if necessary. The solution pH ranges from 7.4 to 8.4.

CMS Final HCPCS Coding Determination

Establish a new HCPCS Level II code J1736, “Injection, meloxicam (delova), 1 mg”

XIFYRM - HCP250626ECCRW

Topic/Issue

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

Applicant's suggested language: JXXXX, “Intravenous Injection, XIFYRM (meloxicam) injection, 30 mg/mL”

Summary of Applicant's Submission

Azurity Pharmaceuticals, Inc. submitted a request to establish a new HCPCS Level II code to identify XIFYRM (meloxicam injection). XIFYRM was approved by the Food and Drug Administration (FDA) under a 505(b)(2) New Drug Application (NDA) on June 5, 2025. XIFYRM contains meloxicam, which is a nonsteroidal anti-inflammatory drug (NSAID). XIFYRM is indicated for use in adults for the management of moderate-to-severe pain, alone or in combination with non-NSAID analgesics. Because of delayed onset of analgesia, XIFYRM alone is not recommended for use when rapid onset of analgesia is required. Meloxicam has analgesic, anti-inflammatory and anti-pyretic properties. The recommended dose of XIFYRM is 30 avgemsi mg once daily, administered as an intravenous injection over 15 seconds. XIFYRM is supplied as a sterile, clear, pale-yellow, solution in single-dose vials containing 30 mg/mL. Each mL solution contains 30 mg of meloxicam, 150 mg of hydroxypropyl betadex, 20 mg of meglumine, 60 mg of povidone and water for injection. The potential of hydrogen of the meloxicam injection is 8.0 to 9.5.

CMS Final HCPCS Coding Determination

Establish a new HCPCS Level II code J1737, “Injection, meloxicam (azurity), 1 mg”

ANDEMBRY® - HCP25062779YLW

Topic/Issue

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

Applicant's suggested language: JXXXX, “Injection, garadacimab-gxii, 200 mg”

Summary of Applicant's Submission

CSL Berhing, LLC submitted a request to establish a new HCPCS Level II code to identify ANDEMBRY® (garadacimab-gxii). ANDEMBRY® was approved by the Food and Drug Administration (FDA) under a 351(a) Biologics License Application (BLA) on June 16, 2025. ANDEMBRY® is a recombinant, fully human, monoclonal antibody produced in Chinese hamster ovary cells. ANDEMBRY® is indicated for prevention of hereditary angioedema attacks in adults and adolescents 12 years and older. ANDEMBRY® is self-administered or administered by a caregiver. An initial loading dose of 400 mg is administered subcutaneously on the first day of treatment followed by a monthly maintenance dose of 200 mg. ANDEMBRY® is supplied in a single-dose prefilled autoinjector or prefilled syringe with needle safety device.

CMS Final HCPCS Coding Determination

ANDEMBRY® is a self-administered drug (SAD) that can be administered by the individual or a caregiver. 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). ANDEMBRY® meets CMS’ criteria for classification as a SAD. CMS is denying the request to establish a new HCPCS Level II code to identify ANDEMBRY® as the medication is self-administered.

AMTAGVI® - HCP250630QY8AH

Topic/Issue

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

Applicant's suggested language: JXXXX, “Lifileucel, up to 72 x 10^9 viable cells, including cell extraction from tumor tissue and dose preparation procedures, per therapeutic dose”

Summary of Applicant's Submission

Iovance Biotherapeutics, Inc. submitted a request to establish a new HCPCS Level II code to identify AMTAGVI® (lifileucel). AMTAGVI® was approved by the Food and Drug Administration (FDA) under a 351(a) Biologics License Application (BLA) on February 16, 2024. AMTAGVI® is a tumor-derived autologous T-cell immunotherapy, used for treatment of adults with unresectable or metastatic melanoma previously treated with a PD-1 blocking antibody, and if BRAF V600 mutation positive, a BRAF inhibitor with or without a MEK inhibitor. When cancer develops and prevails, the body’s natural immune cells can no longer perform their intended function to fight cancer. These tumor-derived T-cells are believed to recognize and kill cancer cells. AMTAGVI® is a cell suspension for intravenous infusion. A single dose of AMTAGVI® contains 7.5 x 10^9 to 72 x 10^9 viable cells suspended in 1 to 4 individual specific intravenous infusion bags. Each bag contains 100 mL to 125 mL of viable cells per bag in individual protective cassettes.

CMS Final HCPCS Coding Determination

CMS is denying the applicant’s request to establish a new HCPCS Level II code for AMTAGVI® based on a setting of use. Based on the FDA label, AMTAGVI® is to be administered “in an inpatient hospital setting under the supervision of a physician experienced in the use of anticancer agents. An intensive care facility and specialists skilled in cardiopulmonary or intensive care medicine must be available.” Generally, for Medicare, drugs administered during an inpatient hospital setting are paid as part of the Diagnosis Related Group payment. As such, a unique HCPCS Level II code is not necessary.

IMAAVY™ - HCP250626FD05M

Topic/Issue

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

Applicant's suggested language: JXXXX, “Injection, Nipocalimab-aahu, 1 mg, for intravenous use”

Summary of Applicant's Submission

Johnson & Johnson Healthcare Systems, Inc. submitted a request to establish a new HCPCS Level II code to identify IMAAVY™ (nipocalimab-aahu). IMAAVY™ was approved by the Food and Drug Administration (FDA) under a 351(a) Biologics License Application (BLA) on April 29, 2025. IMAAVY™ is a neonatal Fc receptor blocker indicated for the treatment of generalized myasthenia gravis in individuals 12 years of age and older who are anti-acetylcholine receptor or anti-muscle-specific tyrosine kinase antibody positive. The recommended initial dose of IMAAVY™ is 30 mg/kg administered once as an intravenous infusion over at least 30 minutes. Two weeks following the initial dose, individuals receive a maintenance dose of 15 mg/kg by intravenous infusion over at least 15 minutes, with ongoing treatment administered every two weeks thereafter. IMAAVY™ is provided in a 1,200 mg/6.5 mL (185 mg/mL) single dose vial. A 300 mg/1.62 mL (185 mg/mL) single dose vial is anticipated to become commercially available in early 2026.

CMS Final HCPCS Coding Determination

1. Establish a new HCPCS Level II code J9256, “Injection, nipocalimab-aahu, 3 mg”

2. Discontinue HCPCS Level II code C9305, “Injection nipocalimab-aahu, 3 mg”

CMS has a long-standing convention to assign dose descriptors 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. This framework explains the distinction between the applicant's proposed dosage of 1 mg and the HCPCS Level II code J9256 designation of 3 mg.

EMRELIS™ - HCP250626PUDWT

Topic/Issue

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

Applicant's suggested language: JXXXX, “Emrelis (telisotuzumab vedotin-tllv), for injection, for intravenous use, per 1 mg”

Summary of Applicant's Submission

AbbVie submitted a request to establish a new HCPCS Level II code to identify EMRELIS™ (telisotuzumab vedotin-tllv). EMRELIS™ was approved by the Food and Drug Administration (FDA) under a 351(a) Biologics License Application (BLA) on May 14, 2025. EMRELIS™ is indicated for the treatment of adults with locally advanced or metastatic non-squamous non-small cell lung cancer with high mesenchymal-epithelial transition factor (c-Met) protein overexpression who have received a prior systemic therapy. EMRELIS™ is a c-Met-directed antibody and microtubule inhibitor conjugate. The recommended dosage of EMRELIS™ is 1.9 mg/kg, administered as an intravenous infusion over 30 minutes, every 2 weeks, until disease progression or unacceptable toxicity occurs. The dosage may be modified for adverse reactions. EMRELIS™ is supplied as a sterile, preservative-free, white to off-white lyophilized powder for reconstitution, packaged in a glass single-dose vial and available in cartons containing one 20 mg vial or one 100 mg vial.

CMS Final HCPCS Coding Determination

1. Establish a new HCPCS Level II code J9326, “Injection, telisotuzumab vedotin-tllv, 1 mg”

2. Discontinue HCPCS Level II code C9306, “Injection telisotuzumab vedotin-tllv, 1 mg”

AlexiGuard SL-T - HCP250701JVQ7A

Topic/Issue

Request to establish a new HCPCS Level II code to identify AlexiGuard SL-T.

Applicant's suggested language: XXXXX, “AlexiGuard SL-T Single Layer Textured Amniotic Barrier, per sq cm”

Summary of Applicant's Submission

AlexiGen BioTech submitted a request to establish a new HCPCS Level II code to identify AlexiGuard SL-T. AlexiGuard SL-T 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 to serve as a “barrier” and “provide protective coverage from the surrounding environment.” AlexiGuard SL-T is a single-layer textured amniotic barrier, minimally manipulated, human tissue-based allograft that contains the extracellular matrix of the amniotic membrane from a human placenta. The amniotic membrane grafts contain cytokines and growth factors to enhance chronic wound healing. AlexiGuard SL-T is intended for use as a wound covering that provides a barrier or protective coverage to acute and chronic wounds. AlexiGuard SL-T is applied over the wound after preparation of the wound (e.g., excision and debridement). AlexiGuard SL-T 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, AlexiGuard SL-T, “when intended to serve as a barrier and provide protective coverage from the surrounding environment, 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 Q4415, “Alexiguard sl-t, per square centimeter (add-on, list separately in addition to primary procedure)”

This coding determination applies to the AlexiGuard SL-T product described in the application and accompanying FDA TRG letter dated May 13, 2025, when intended to serve as a “barrier” and “provide protective coverage.”

AlexiGuard TL-T - HCP250701AH4NB

Topic/Issue

Request to establish a new HCPCS Level II code to identify AlexiGuard TL-T.

Applicant's suggested language: XXXXX, “AlexiGuard TL-T Triple Layer Textured Amniotic Barrier”

Summary of Applicant's Submission

AlexiGen BioTech submitted a request to establish a new HCPCS Level II code to identify AlexiGuard TL-T. AlexiGuard TL-T 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 to serve as a “barrier” and “provide protective coverage from the surrounding environment.” The AlexiGuard TL-T is a triple-layer textured amniotic barrier, minimally manipulated, human tissue-based allograft that contains the extracellular matrix of the amniotic membrane from a human placenta. Amniotic membrane grafts contain cytokines and growth factors to enhance chronic wound healing. AlexiGuard TL-T is intended to be used as a wound covering that provides a barrier or protective coverage to acute and chronic wounds. AlexiGuard TL-T is applied over the wound after preparation of the wound (e.g., excision and debridement). AlexiGuard TL-T 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, AlexiGuard TL-T, “when intended to serve as a barrier and provide protective coverage from the surrounding environment, 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 Q4416, “Alexiguard tl-t, per square centimeter (add-on, list separately in addition to primary procedure)”

This coding determination applies to the AlexiGuard TL-T product described in the application and accompanying FDA TRG letter dated May 13, 2025, when intended to serve as a “barrier” and “provide protective coverage.”

AlexiGuard DL-T - HCP250701MY27Q

Topic/Issue

Request to establish a new HCPCS Level II code to identify AlexiGuard DL-T.

Applicant's suggested language: XXXXX, “AlexiGuard DL-T Dual Layer Textured Amniotic Barrier, per sq cm”

Summary of Applicant's Submission

AlexiGen BioTech submitted a request to establish a new HCPCS Level II code to identify AlexiGuard DL-T. AlexiGuard DL-T 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 to serve as a “barrier” and “provide protective coverage from the surrounding environment.” AlexiGuard DL-T is a dual-layer textured amniotic barrier, minimally manipulated, human tissue-based allograft that contains the extracellular matrix of the amniotic membrane from a human placenta. Amniotic membrane grafts contain cytokines and growth factors to enhance chronic wound healing. AlexiGuard DL-T is intended to be used as a wound covering that provides a barrier or protective coverage to acute and chronic wounds. AlexiGuard DL-T is applied over the wound after preparation of the wound (e.g., excision and debridement). AlexiGuard DL-T 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, AlexiGuard DL-T, “when intended to serve as a barrier and provide protective coverage from the surrounding environment, 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 Q4417, “Alexiguard dl-t, per square centimeter (add-on, list separately in addition to primary procedure)”

This coding determination applies to the AlexiGuard DL-T product described in the application and accompanying FDA TRG letter dated May 13, 2025, when intended to serve as a “barrier” and “provide protective coverage.”

XWRAP 2.0® - HCP250626Y1HDK

Topic/Issue

Request to establish a new HCPCS Level II code to identify XWRAP 2.0®.

Applicant's suggested language: QXXXX, “XWRAP 2.0®, per square centimeter”

Summary of Applicant's Submission

Applied Biologics submitted a request to establish a new HCPCS Level II code to identify XWRAP 2.0®. XWRAP 2.0® is regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) solely under section 361 of the Public Health Service (PHS) Act and 21 CFR part 1271 when intended for use as a “protective barrier and wound covering.” XWRAP 2.0® is a dehydrated, single-layer, chorion-free amniotic membrane allograft. XWRAP 2.0® is intended for homologous use as a wound barrier or cover applied to partial and full thickness acute and chronic wounds such as diabetic, venous, arterial, pressure and other ulcers, including those with exposed tendon, muscle, bone, or other vital structures, as well as traumatic and complex wounds, burns, surgical and Mohs surgery sites. XWRAP 2.0® is available in various sizes and configurations. XWRAP 2.0® is packaged individually and aseptically inside two sterile peel pouches for individual/one-time use only. Packaging includes a tissue tracking card, identification labels for billing, and a package insert.

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, XWRAP 2.0®, “when intended for use as a ‘protective barrier and wound covering’ 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 Q4402, “Xwrap 2.0, per square centimeter (add-on, list separately in addition to primary procedure)”

This coding determination applies to the XWRAP 2.0® product described in the application and accompanying FDA TRG letter dated June 17, 2025, when intended for use as a “protective barrier and wound covering.”

XWRAP Dual Plus® - HCP250626MX715

Topic/Issue

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

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

Summary of Applicant's Submission

Applied Biologics submitted a request to establish a new HCPCS Level II code to identify XWRAP Dual Plus®. XWRAP Dual Plus® is regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) solely under section 361 of the Public Health Service (PHS) Act and 21 CFR part 1271 when intended for use as a “protective barrier and wound covering.” XWRAP Dual Plus® is a dehydrated, double-layer, chorion-free amniotic membrane allograft. XWRAP Dual Plus® is intended for homologous use as a wound barrier or cover applied to partial and full thickness acute and chronic wounds such as diabetic, venous, arterial, pressure and other ulcers, including those with exposed tendon, muscle, bone, or other vital structures, as well as traumatic and complex wounds, burns, surgical and Mohs surgery sites. XWRAP Dual Plus® is available in various sizes and configurations. XWRAP Dual Plus® is packaged individually and aseptically inside two sterile peel pouches for individual one-time use only. Packaging includes a tissue tracking card, identification labels for billing, and a package insert.

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, XWRAP Dual Plus®, “when intended for use as a ‘protective barrier and wound covering’ 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 Q4403, “Xwrap dual plus, per square centimeter (add-on, list separately in addition to primary procedure)”

This coding determination applies to the XWRAP Dual Plus® product described in the application and accompanying FDA TRG letter dated June 17, 2025, when intended for use as a “protective barrier and wound covering.”

XWRAP Hydro Plus®- HCP250626NXMVE

Topic/Issue

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

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

Summary of Applicant's Submission

Applied Biologics submitted a request to establish a new HCPCS Level II code to identify XWRAP Hydro Plus®. XWRAP Hydro Plus® is regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) solely under section 361 of the Public Health Service (PHS) Act and 21 CFR part 1271 when intended for use as a “protective barrier and wound covering.” XWRAP Hydro Plus® is a hydrated, single-layer, chorion-free amniotic membrane allograft. XWRAP Hydro Plus® is intended for homologous use as a wound barrier or cover applied to partial and full thickness acute and chronic wounds such as diabetic, venous, arterial, pressure and other ulcers, including those with exposed tendon, muscle, bone, or other vital structures, as well as traumatic and complex wounds, burns, surgical and Mohs surgery sites. XWRAP Hydro Plus® is available in various sizes and configurations. XWRAP Hydro Plus® is packaged individually and aseptically inside two sterile peel pouches for individual/one-time use only. Packaging includes a tissue tracking card, identification labels for billing, and a package insert.

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, XWRAP Hydro Plus®, “when intended for use as a ‘protective barrier and wound covering’ 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 Q4404, “Xwrap hydro plus, per square centimeter (add-on, list separately in addition to primary procedure)”

This coding determination applies to the XWRAP Hydro Plus® product described in the application and accompanying FDA TRG letter dated June 17, 2025, when intended for use as a “protective barrier and wound covering.”

XWRAP Fenestra Plus®- HCP250626BP621

Topic/Issue

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

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

Summary of Applicant's Submission

Applied Biologics submitted a request to establish a new HCPCS Level II code to identify XWRAP Fenestra Plus®. XWRAP Fenestra Plus® is regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) solely under section 361 of the Public Health Service (PHS) Act and 21 CFR part 1271 when intended for use as a “protective barrier and wound covering.” XWRAP Fenestra Plus® is a dehydrated, single-layer, chorion-free amniotic membrane allograft. XWRAP Fenestra Plus® is intended for homologous use as a wound barrier or cover applied to partial and full thickness acute and chronic wounds such as diabetic, venous, arterial, pressure and other ulcers, including those with exposed tendon, muscle, bone, or other vital structures, as well as traumatic and complex wounds, burns, surgical and Mohs surgery sites. XWRAP Fenestra Plus® is available in various sizes and configurations. XWRAP Fenestra Plus® is packaged individually and aseptically inside two sterile peel pouches for individual/one-time use only. Packaging includes a tissue tracking card, identification labels for billing, and a package insert.

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, XWRAP Fenestra Plus®, “when intended for use as a ‘protective barrier and wound covering’ 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 Q4405, “Xwrap fenestra plus, per square centimeter (add-on, list separately in addition to primary procedure)”

This coding determination applies to the XWRAP Fenestra Plus® product described in the application and accompanying FDA TRG letter dated June 17, 2025, when intended for use as a “protective barrier and wound covering.”

XWRAP Fenestra® - HCP250502BMEKL

Topic/Issue

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

Applicant's suggested language: QXXXX, “XWRAP Fenestra®, per square centimeter”

Summary of Applicant's Submission

Applied Biologics submitted a request to establish a new HCPCS Level II code to identify XWRAP Fenestra®. XWRAP Fenestra® is regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) solely under section 361 of the Public Health Service (PHS) Act and 21 CFR part 1271 when intended for use as a “protective barrier and wound covering.” XWRAP Fenestra® is a fenestrated, single-layer, chorion-free amniotic membrane allograft. XWRAP Fenestra® is intended for homologous use as a wound barrier or cover applied to partial and full thickness acute and chronic wounds such as diabetic, venous, arterial, pressure and other ulcers, including those with exposed tendon, muscle, bone, or other vital structures, as well as traumatic and complex wounds, burns, surgical and Mohs surgery sites. XWRAP Fenestra® is available in various sizes and configurations. XWRAP Fenestra® is packaged individually and aseptically inside two sterile peel pouches for individual/one-time use only. Packaging includes a tissue tracking card, identification labels for billing, and a package insert.

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, XWRAP Fenestra®, “when intended for use as a ‘protective barrier and wound covering’ 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 Q4406, “Xwrap fenestra, per square centimeter (add-on, list separately in addition to primary procedure)”

This coding determination applies to the XWRAP Fenestra® product described in the application and accompanying FDA TRG letter dated April 25, 2025, when intended for use as a “protective barrier and wound covering.”

XWRAP Tribus® - HCP250502G25AX

Topic/Issue

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

Applicant's suggested language: QXXXX, “XWRAP Tribus®, per square centimeter”

Summary of Applicant's Submission

Applied Biologics submitted a request to establish a new HCPCS Level II code to identify XWRAP Tribus®. XWRAP Tribus® is regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) solely under section 361 of the Public Health Service (PHS) Act and 21 CFR part 1271 when intended for use as a “protective barrier and wound covering.” XWRAP Tribus® is a triple-layer, chorion-free amniotic membrane allograft. XWRAP Tribus® is intended for homologous use as a wound barrier or cover applied to partial and full thickness acute and chronic wounds such as diabetic, venous, arterial, pressure and other ulcers, including those with exposed tendon, muscle, bone, or other vital structures, as well as traumatic and complex wounds, burns, surgical and Mohs surgery sites. XWRAP Tribus® is available in various sizes and configurations. XWRAP Tribus® is packaged individually and aseptically inside two sterile peel pouches for individual/one-time use only. Packaging includes a tissue tracking card, identification labels for billing, and a package insert.

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, XWRAP Tribus®, “when intended for use as a ‘protective barrier and wound covering,’ 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 Q4407, “Xwrap tribus, per square centimeter (add-on, list separately in addition to primary procedure)”

This coding determination applies to the XWRAP Tribus® product described in the application and accompanying FDA TRG letter dated April 25, 2025, when intended for use as a “protective barrier and wound covering.”

XWRAP Hydro® - HCP250502F49JF

Topic/Issue

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

Applicant's suggested language: QXXXX, “XWRAP Hydro®, per square centimeter”

Summary of Applicant's Submission

Applied Biologics submitted a request to establish a new HCPCS Level II code to identify XWRAP Hydro®. XWRAP Hydro® is regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) solely under section 361 of the Public Health Service (PHS) Act and 21 CFR part 1271 when intended for use as a “protective barrier and wound covering.” XWRAP Hydro® is a hydrated, single-layer, chorion-free amniotic membrane allograft. XWRAP Hydro® is intended for homologous use as a wound barrier or cover applied to partial and full thickness acute and chronic wounds such as diabetic, venous, arterial, pressure and other ulcers, including those with exposed tendon, muscle, bone, or other vital structures, as well as traumatic and complex wounds, burns, surgical and Mohs surgery sites. XWRAP Hydro® is available in various sizes and configurations. XWRAP Hydro® is packaged individually and aseptically inside two sterile peel pouches for individual/one-time use only. Packaging includes a tissue tracking card, identification labels for billing, and a package insert.

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, XWRAP Hydro®, “when intended for use as a ‘protective barrier and wound covering,’ 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 Q4408, “Xwrap hydro, per square centimeter (add-on, list separately in addition to primary procedure)”

This coding determination applies to the XWRAP Hydro® product described in the application and accompanying FDA TRG letter dated April 25, 2025, when intended for use as a “protective barrier and wound covering.”

AmchoMatrixDL - HCP250625417NY

Topic/Issue

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

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

Summary of Applicant's Submission

Cellution Biologics Inc. submitted a request to establish a new HCPCS Level II code to identify AmchoMatrixDL. AmchoMatrixDL 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” or “barrier.” AmchoMatrixDL is a minimally manipulated, dehydrated, dual-layer amnion membrane allograft intended for homologous use. It acts as a barrier and provides protective coverage from the surrounding environment for acute and chronic wounds. Smaller sizes can be applied as a cover to the ocular surface following repair or reconstruction procedures. AmchoMatrixDL is processed using aseptic techniques and terminally sterilized by gamma irradiation. The dosage is based on the size of the injury or site of application and measured per square centimeter. AmchoMatrixDL must be stored in a clean, dry environment at an ambient room temperature before application. AmchoMatrixDL is available in a variety of sizes and configurations.

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, AmchoMatrixDL, “when intended for use as a cover or barrier for acute and chronic wounds and for the ocular surface following repair or reconstruction procedures, 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 Q4410, “Amchomatrixdl, per square centimeter (add-on, list separately in addition to primary procedure)”

This coding determination applies to the AmchoMatrixDL product described in the application and accompanying FDA TRG letter dated May 30, 2025, when intended for use as a “cover” and “barrier.”

Summit AC - HCP250701R05G7

Topic/Issue

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

The applicant did not submit any suggested language.

Summary of Applicant's Submission

Legacy Medical Consultants submitted a request to establish a new HCPCS Level II code to identify Summit AC. Summit 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 "covering" or "barrier." Summit AC is a dual-layer amnion/chorion membrane allograft. Summit AC is a sterile, single use, dehydrated resorbable allograft derived from donated human placental birth tissue. Summit AC is applied over the wound and serves as a barrier and protective covering to acute and chronic wounds. Summit AC allografts are processed using aseptic techniques. Each allograft is packaged in a primary foil pouch and a secondary Tyvek® pouch and sterilized. The irradiation label indicates that the product has been irradiated by a validated protocol. The processing and sterilization methods maintain the mechanical integrity of the tissue. A single sterile, double-pouched membrane is provided in a solid bleached sulfate paperboard box. Summit AC must be stored at an ambient temperature of 15-30°C (59-86°F) before application. It may be stored for up to 5 years. Summit AC must be ordered and used by a licensed healthcare professional.

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 AC, "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 Q4398, "Summit ac, per square centimeter (add-on, list separately in addition to primary procedure)"

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

Summit FX- HCP2507017UCB0

Topic/Issue

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

The applicant did not submit any suggested language.

Summary of Applicant's Submission

Legacy Medical Consultants submitted a request to establish a new HCPCS Level II code to identify Summit FX. Summit FX 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 FX is a fenestrated dual-layer amnion/amnion membrane allograft. Summit FX is a sterile, single-use, dehydrated resorbable allograft derived from donated human placental birth tissue. Summit FX is applied over the wound and serves as a barrier and protective covering to acute and chronic wounds. Summit FX allografts are processed using aseptic techniques. Each allograft is packaged in a primary foil pouch and a secondary Tyvek® pouch and sterilized. The irradiation label indicates that the product has been irradiated by a validated protocol. The processing and sterilization methods maintain the mechanical integrity of the tissue. A single sterile, double-pouched membrane is provided in a solid bleached sulfate paperboard box. Summit FX must be stored at an ambient temperature of 15-30°C (59-86°F) before application. It may be stored for up to 5 years. Summit FX must be ordered and used by a licensed healthcare professional.

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 FX, "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 Q4399, "Summit fx, per square centimeter (add-on, list separately in addition to primary procedure)"

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

SimpliChor - HCP250701GEFPX

Topic/Issue

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

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

Summary of Applicant's Submission

Xtant Medical submitted a request to establish a new HCPCS Level II code to identify SimpliChor. SimpliChor 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 to serve as a “barrier” and “provide protective coverage from the surrounding environment.” SimpliChor is an amnion and chorion membrane allograft obtained from healthy deliveries following informed consent. SimpliChor is intended to serve as a barrier and provide protective coverage from the surrounding environment when topically applied to chronic and acute wounds. SimpliChor is dehydrated, packaged in various sheet sizes, and terminally sterilized by e-beam irradiation.

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, SimpliChor, “when intended to serve as a barrier and provide protective coverage from the surrounding environment, SimpliChor 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 Q4414, “Simplichor, per square centimeter (add-on, list separately in addition to primary procedure)”

This coding determination applies to the SimpliChor product described in the application and accompanying FDA TRG letter dated October 23, 2023, when intended to serve as a “barrier” and “provide protective coverage from the surrounding environment.”

CHORIOFIX™ - HCP250625N69RD

Topic/Issue

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

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

Summary of Applicant's Submission

MiMedx submitted a request to establish a new HCPCS Level II code to identify CHORIOFIX™. CHORIOFIX™ is regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) solely under section 361 of the Public Health Service (PHS) Act and 21 CFR part 1271 when intended for use as a “barrier, to provide a protective environment in acute and chronic wounds.” CHORIOFIX™ is a dehydrated, dual-layered chorion membrane. CHORIOFIX™ is a lyophilized human placental allograft that includes two layers of chorion with an attached intermediate layer. The PURION® process preserves multiple extracellular matrix components and other proteins present in amniotic membrane tissue. Processing the placental tissue includes separation of the chorion and amnion membranes, followed by cleaning, rinsing, placing the chorion membrane in a dual-layer configuration, dehydration, cutting to size, and sterilization using irradiation. CHORIOFIX™ is intended for use as a barrier to provide a protective environment in acute and chronic wounds and is available in four different sizes. It is recommended that CHORIOFIX™ grafts be applied weekly until wound epithelialization is achieved. However, clinician discretion should be used based on the individual and wound condition/progress. Clinicians can apply CHORIOFIX™ without consideration of orientation, wet or dry to the wound site, within the wound margins. CHORIOFIX™ can be hydrated while on the wound site with sterile saline solution, if desired. The allograft can be secured to the application site or itself using staples or tissue adhesive. CHORIOFIX™ should be covered with a non-adherent contact layer and appropriate moisture management dressings at the site. CHORIOFIX™ is individually packaged in a labeled and sealed carton containing the product provided in a sterile inner pouch inside a non-permeable labeled outer pouch that can be opened using aseptic technique to access the sterile inner pouch. The package contains six individual labels used for tissue tracking, a tissue utilization record card for tissue tracking, and an instruction for use package insert. CHORIOFIX™ allografts should be stored in a clean, dry environment between 2-30°C before further distribution or transplant.

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

Establish a new HCPCS Level II code Q4412, “Choriofix, per square centimeter (add-on, list separately in addition to primary procedure)”

This coding determination applies to the CHORIOFIX™ product described in the application and accompanying FDA TRG letter dated January 17, 2025, when intended for use as a "barrier, to provide a protective environment in acute and chronic wounds."

AmnioMatrixF4X - HCP25062579QMB

Topic/Issue

Request to establish a new HCPCS Level II code to identify AmnioMatrixF4X.

Applicant's suggested language: XXXXX, “AmnioMatrixF4X, per square centimeter”

Summary of Applicant's Submission

Cellution Biologics Inc. submitted a request to establish a new HCPCS Level II code to identify AmnioMatrixF4X. AmnioMatrixF4X 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 for acute and chronic wounds.” AmnioMatrixF4X is a minimally manipulated, dehydrated, four-layer amnion membrane allograft. AmnioMatrixF4X 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, trauma wounds, and draining wounds. It is restricted to homologous use. AmnioMatrixF4X is processed using aseptic techniques and terminally sterilized by gamma irradiation. The dosage is based on the size of the injury or site of application and measured per square centimeter. AmnioMatrixF4X must be stored in a clean, dry environment at ambient room temperature before application. AmnioMatrixF4X is available in a variety of sizes and configurations.

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, AmnioMatrixF4X, “when intended for use as a cover and barrier for acute and chronic wounds, appears to meet the criteria for regulation solely under section 361 of the PHS Act and the regulations in 21 CFR part 1271.” As a result of our review of the TRG’s feedback, CMS has decided to:

Establish a new HCPCS Level II code Q4411, “Amniomatrixf4x, per square centimeter (add-on, list separately in addition to primary procedure)”

This coding determination applies to the AmnioMatrixF4X product described in the application and accompanying FDA TRG letter dated May 30, 2025, when intended for use as a “barrier and cover for acute and chronic wounds.”

AmnioMatrixF3X - HCP250625286PD

Topic/Issue

Request to establish a new HCPCS Level II code to identify AmnioMatrixF3X.

Applicant's suggested language: XXXXX, “AmnioMatrixF3X, per square centimeter”

Summary of Applicant's Submission

Cellution Biologics Inc. submitted a request to establish a new HCPCS Level II code to identify AmnioMatrixF3X. AmnioMatrixF3X 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 for acute and chronic wounds.” AmnioMatrixF3X is a minimally manipulated, dehydrated, tri-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. It acts as a barrier and provides protective coverage from the surrounding environment for acute and chronic wounds. AmnioMatrixF3X is processed using aseptic techniques and terminally sterilized by gamma irradiation. The dosage is based on the size of the injury or site of application, measured per square centimeter, and it can be reapplied as needed. AmnioMatrixF3X must be stored in a clean, dry environment at ambient room temperature before application. AmnioMatrixF3X sheets are supplied in various sizes and configurations.

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, AmnioMatrixF3X, “when intended for use as a cover and barrier for acute and chronic wounds, appears to meet the criteria for regulation solely under section 361 of the PHS Act and the regulations in 21 CFR part 1271.” As a result of our review of the TRG’s feedback, CMS has decided to:

Establish a new HCPCS Level II code Q4409, “Amniomatrixf3x, per square centimeter (add-on, list separately in addition to primary procedure)”

This coding determination applies to the AmnioMatrixF3X product described in the application and accompanying FDA TRG letter dated May 30, 2025, when intended for use as a “cover and barrier for acute and chronic wounds.”

CYGNUS Solo - HCP250625Y4CVY

Topic/Issue

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

Applicant's suggested language: Q4XXX, “CYGNUS Solo, per square centimeter”

Summary of Applicant's Submission

Vivex Biologics submitted a request to establish a new HCPCS Level II code to identify CYGNUS Solo. CYGNUS Solo 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 “tissue barrier” or “wound covering.” CYGNUS Solo is a single-layer allograft derived from the amnion layer of the placental membrane and is manufactured using proprietary Integrity Processing™ Methodology, which helps to maintain the inherent levels of key extracellular matrices, including proteins, carbohydrates, growth factors, and cytokines. CYGNUS Solo retains the structural and functional characteristics of the membrane to provide a barrier or covering, protecting injured tissue from the external environment. The intended use of CYGNUS Solo is to serve as a tissue barrier or covering, protecting injured tissue from the external environment. CYGNUS Solo is most often used for acute and chronic complex wounds and burns. It is available in a variety of sizes. CYGNUS Solo is shipped in a single-use package with one unit per package and must be stored at room temperature for up to 5 years. It is the responsibility of the end-user to store tissues in appropriate storage conditions before further distribution or transplant and to track expiration dates accordingly. It is not necessary to reconstitute CYGNUS Solo before implantation. Once the package seal is broken, the allograft must be used within 24 hours.

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, CYGNUS Solo, “when intended for use as a tissue barrier or wound covering, 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 Q4413, “Cygnus solo, per square centimeter (add-on, list separately in addition to primary procedure)”

This coding determination applies to the CYGNUS Solo product described in the application and accompanying FDA TRG letter dated April 7, 2021, when intended for use as a “tissue barrier” or “wound covering.”

Dual Layer PalinGen® X-Membrane - HCP250609C0V3M

Topic/Issue

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

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

Summary of Applicant's Submission

Amnio Technology submitted a request to establish a new HCPCS Level II code to identify Dual Layer PalinGen® X-Membrane. Dual Layer PalinGen® X-Membrane is regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) solely under section 361 of the Public Health Service (PHS) Act and 21 CFR part 1271 when intended for use as a “barrier.” Dual Layer PalinGen® X-Membranes are dehydrated, cross-linked, human allografts derived from dual layers of amniotic membrane of the placenta. They are minimally manipulated, preserving many of the natural growth factors normally present in amniotic tissue. Dual Layer PalinGen® X-Membrane products can be utilized for all age groups with non-healing acute and chronic wounds (diabetic, venous, mixed venous-arterial, pressure ulcers), complex and/or open surgical wounds. Dual Layer PalinGen® X-Membrane is intended to act as a barrier to protect the wound during healing and maintain a moist wound environment. The size of the membrane is determined by the physician and should be large enough to completely cover the wound. After preparation of the wound site, the human amnion allograft is applied to the wound surface, extended beyond the wound margins, and secured in place using the clinician’s choice of fixation. As determined by the physician, reapplication may be necessary. Dual Layer PalinGen® X-Membrane is supplied in various sizes. Dual Layer PalinGen® X-Membrane is packaged in a Mangar pouch as the primary packaging and sealed inside two outer plastic trays and enclosed in a box.

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, Dual Layer PalinGen® X-Membrane, “when intended for use as ‘a barrier’, meets 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:

Revise existing HCPCS Level II code Q4354, “Palingen dual-layer membrane, per square centimeter,” to instead read “Palingen dual-layer membrane and dual-layer palingen x-membrane, per square centimeter (add-on, list separately in addition to primary procedure)” to describe Dual Layer PalinGen® X-Membrane.

This coding determination applies to the Dual Layer PalinGen® X-Membrane product described in the application and accompanying FDA TRG letter dated February 8, 2022, when intended for use as a “barrier.”

Polygon3 Membrane - HCP2506105F4FN

Topic/Issue

Request to establish a new HCPCS Level II code to identify Polygon3 Membrane.

Applicant's suggested language: XXXXX, “Polygon3 Membrane per square centimeter”

Summary of Applicant's Submission

Amnio Technology submitted a request to establish a new HCPCS Level II code to identify Polygon3 Membrane. Polygon3 Membrane is regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) solely under section 361 of the Public Health Service (PHS) Act and 21 CFR part 1271 when intended for use as a “covering,” a “barrier,” and “to protect the wound.” Polygon3 Membrane is dehydrated, human allografts derived from the placenta, consisting of two layers of amniotic membrane with a chorionic layer in the middle. They are minimally manipulated, preserving many of the natural growth factors normally present in amniotic tissue. Polygon3 Membrane products can be utilized for all age groups with non-healing acute and chronic wounds (diabetic, venous, mixed venous-arterial, pressure ulcers), complex and/or open surgical wounds. Polygon3 Membrane is intended to act as a covering, a barrier, and to protect the wound. The size of the membrane is determined by the physician and should be large enough to completely cover the wound. After preparation of the wound site, the human amnion allograft is applied to the wound surface, extended beyond the wound margins, and secured in place using the clinician’s choice of fixation. As determined by the physician, reapplication may be necessary. Polygon3 Membrane is supplied in various sizes. Polygon3 Membrane is packaged in a Mangar pouch as the primary packaging and sealed inside two outer plastic trays and enclosed in a box.

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, Polygon3 Membrane, “when intended for use as a ‘covering,’ a ‘barrier,’ and ‘to protect the wound,’ it 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 Q4400, “Polygon3 membrane, per square centimeter (add-on, list separately in addition to primary procedure)”

This coding determination applies to the Polygon3 Membrane product described in the application and accompanying FDA TRG letter dated June 2, 2025, when intended for use as a “covering,” a “barrier,” and “to protect the wound.”

Absolv3 Membrane - HCP250610CGMC9

Topic/Issue

Request to establish a new HCPCS Level II code to identify Absolv3 Membrane.

Applicant's suggested language: XXXXX, “Absolv3 Membrane; per square centimeter”

Summary of Applicant's Submission

Amnio Technology submitted a request to establish a new HCPCS Level II code to identify Absolv3 Membrane. Absolv3 Membrane is regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) solely under section 361 of the Public Health Service (PHS) Act and 21 CFR part 1271 when intended for use as a “covering,” a “barrier,” and “to protect the wound.” Absolv3 Membrane is an amniotic/chorionic/amniotic membrane product used as a wound covering and to act as a barrier for full and partial-thickness, chronic and acute wounds. The size of the membrane is determined by the physician and should be large enough to completely cover the wound. After preparation of the wound site, the human allograft is applied to the wound surface, extended beyond the wound margins, and secured in place using the clinician’s choice of fixation. As determined by the physician, reapplication may be necessary. Absolv3 Membrane is supplied in various sizes, and the membranes are packaged in a primary Mangar pouch and then sealed into two different plastic trays with a Tyvek® lid.

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, Absolv3 Membrane, “when intended for use as a ‘covering,’ a ‘barrier,’ and ‘to protect the wound,’ it 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 Q4401, “Absolv3 membrane, per square centimeter (add-on, list separately in addition to primary procedure)”

This coding determination applies to the Absolv3 Membrane product described in the application and accompanying FDA TRG letter dated June 2, 2025, when intended for use as a “covering,” a “barrier,” and “to protect the wound.”

NuForm™ - HCP250613B3W98

Topic/Issue

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

Applicant's suggested language: XXXXX, “NuForm, per square inch”

Summary of Applicant's Submission

Organogenesis Inc. submitted a request to establish a new HCPCS Level II code to identify NuForm™. NuForm™ is regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) solely under section 361 of the Public Health Service (PHS) Act and 21 CFR part 1271 when intended for “use as a protective barrier.” NuForm™ is a human allograft tissue product composed of amnion and chorion, derived from donated birth tissue, that is meshed to allow for better conformability and drainage of exudative wounds. It functions as a protective barrier in the management of acute and chronic wounds as well as surgical procedures. NuForm™ may be applied to protect a variety of partial- and full-thickness acute and chronic wounds, such as dermal ulcers, and wounds with exposed tendon, muscle, joint capsule, and bone. The dosage is based on the size of the wound being protected. NuForm™ is available in multiple sizes. NuForm™ is administered by applying or implanting the allograft in a dry state or hydrated in lactated ringers, normal saline, or other normal physiologic solution containing antibiotics of the clinician’s preference. The chorion layer is placed in contact with the wound bed or surgical implantation site, and the allograft is anchored using the physician's preferred fixation method, such as sutures or adhesive strips. NuForm™ is processed gently in a manner that retains its native extracellular matrix scaffolding and proteins. NuForm™ is dehydrated and provided sterile for individual, single use only.

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, NuForm™, “when intended for ‘use as a protective 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 Q4420, “Nuform, per square centimeter (add-on, list separately in addition to primary procedure)”

This coding determination applies to the NuForm™ product described in the application and accompanying FDA TRG letter dated May 30, 2025, when intended for “use as a protective barrier.”

Discontinuation of Existing HCPCS Level II Codes - IHC2503232KXMT

CMS has been conducting a comprehensive review of the HCPCS Level II code set for drugs and biological products to ensure the coding system remains current, accurate, and reflects products that are actively available in the United States market. As part of this ongoing maintenance effort, CMS will discontinue HCPCS Level II codes for products that meet specific criteria: those with no active products listed in the Red Book[2] (the pharmaceutical pricing reference), products not found in the Red Book database, products listed as discontinued in the Food and Drug Administration's (FDA's) Orange Book[3], products not sold in the United States (U.S.), or products that have been discontinued by manufacturers. This systematic review helps maintain the integrity of the HCPCS Level II coding system, ensures accurate billing and reimbursement for Medicare and other insurers, reduces administrative burden on healthcare providers, and eliminates outdated codes that no longer serve a functional purpose in healthcare billing and documentation. By removing inactive or unavailable product codes, CMS supports more efficient healthcare operations while maintaining accurate records of covered drugs and biological products for beneficiaries.

CMS intends to continue this review in subsequent HCPCS Level II quarterly cycles to ensure the HCPCS Level II code set remains up-to-date and reflects the current pharmaceutical marketplace.

CMS Final HCPCS Coding Determination

Discontinue 57 existing HCPCS Level II codes.

See Appendix A for a complete list of HCPCS Level II codes that we are discontinuing. We will also address these coding determinations at an upcoming HCPCS Level II Public Meeting, consistent with our usual practice for public requests to discontinue a code.

[2] https://www.micromedexsolutions.com/micromedex2/librarian

[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.

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 thirteen new HCPCS Level II codes and discontinue one HCPCS Level II code 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 B 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 at an upcoming biannual public meeting.

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[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: Discontinuation of Existing HCPCS Level II Codes

HCPCS Code[6]	Long Descriptor	Trade Name	CMS' Rational
J0190	Injection, biperiden lactate, per 2 mg	Akineton	No active products per Red Book; product discontinued per Orange Book
J0200	Injection, alatrofloxacin mesylate, 100 mg	TROVAN	No active products per Red Book; product discontinued per Orange Book
J0205	Injection, alglucerase, per 10 units	Ceredase	No active products per Red Book
J0215	Injection, alefacept, 0.5 mg	Amevive	No active products per Red Book
J0288	Injection, amphotericin B cholesteryl sulfate complex, 10 mg		No active products per Red Book
J0350	Injection, anistreplase, per 30 units	Eminase	No active products per Red Book
J0365	Injection, aprotonin, 10,000 kiu	Trasylol	No active products per Red Book
J0380	Injection, metaraminol bitartrate, per 10 mg		No active products per Red Book
J0395	Injection, arbutamine hcl, 1 mg	GENESA	No active products per Red Book; product discontinued per Orange Book
J0710	Injection, cephapirin sodium, up to 1 gm		No active products per Red Book; product discontinued per Orange Book
J0715	Injection, ceftizoxime sodium, per 500 mg	CEFIZOX	No active products per Red Book; product discontinued per Orange Book
J0795	Injection, corticorelin ovine triflutate, 1 microgram		No active products per Red Book
J1267	Injection, doripenem, 10 mg	Doribax	No active products per Red Book; product discontinued per Orange Book
J1330	Injection, ergonovine maleate, up to 0.2 mg		No active products per Red Book

[6] Updated on January 7~~6~~, 2026 to not discontinue existing HCPCS Level II code J1572~~5~~, "Injection, immune globulin, (flebogamma/flebogamma dif), intravenous, non-lyophilized (e.g., liquid), 500 mg" as the manufacturer has reactivated the previously discontinued NDCs. This HCPCS Level II will remain effective until further notice.

HCPCS Code[6]	Long Descriptor	Trade Name	CMS' Rational
J1452	Injection, fomivirsen sodium, intraocular, 1.65 mg	Vitavene	No active products per Red Book; product discontinued per Orange Book
J1457	Injection, gallium nitrate, 1 mg	GANITE	No active products per Red Book; product discontinued per Orange Book
J1562	Injection, immune globulin (vivaglobin), 100 mg	VIVAGLOBIN	No active products per Red Book
J1620	Injection, gonadorelin hydrochloride, per 100 mcg	FACTREL	No active products per Red Book; product discontinued per Orange Book
J1655	Injection, tinzaparin sodium, 1000 iu	INNOHEP	No active products per Red Book; product discontinued per Orange Book
J1710	Injection, hydrocortisone sodium phosphate, up to 50 mg		No active products per Red Book; product discontinued per Orange Book
J1945	Injection, lepirudin, 50 mg		No active products per Red Book
J2504	Injection, pegademase bovine, 25 iu	ADAGEN	No active products per Red Book; product discontinued per Orange Book
J2513	Injection, pentastarch, 10% solution, 100 ml		No active products per Red Book
J2910	Injection, aurothioglucose, up to 50 mg	Solganal	No active products per Red Book
J2940	Injection, somatrem, 1 mg		No active products per Red Book
J2995	Injection, streptokinase, per 250,000 iu		No active products per Red Book
J3280	Injection, thiethylperazine maleate, up to 10 mg	Torecan	No active products per Red Book; product discontinued per Orange Book
J3305	Injection, trimetrexate glucuronate, per 25 mg	NEUTREXIN	No active products per Red Book; product discontinued per Orange Book
J3320	Injection, spectinomycin dihydrochloride, up to 2 gm	Trobicin	No active products per Red Book; product

HCPCS Code[6]	Long Descriptor	Trade Name	CMS' Rational
			discontinued per Orange Book
J3355	Injection, urofollitropin, 75 iu		No active products per Red Book
J3364	Injection, urokinase, 5000 iu vial	KINLYTIC	No active products per Red Book; product discontinued per Orange Book
J3365	Injection, iv, urokinase, 250,000 i.u. vial	KINLYTIC	No active products per Red Book; product discontinued per Orange Book
J3400	Injection, trifluprom azine hcl, up to 20 mg	VESPRIN	No active products per Red Book; product discontinued per Orange Book
J7309	Methyl aminolevulinate (mal) for topical administration,16.8%, 10 mg	METVIXIA	No active products per Red Book; product discontinued per Orange Book
J7310	Ganciclovir, 4.5 mg, long-acting implant	Vitrasert	No active products per Red Book; product discontinued per Orange Book
J7505	Muromonab-cd3, parenteral, 5 mg	Muromonab-CD3, also known as OKT3	Product discontinued
J7513	Daclizumab, parenteral, 25 mg	Zinbryta	Product discontinued
J8562	Fludarabine phosphate, oral, 10 mg	Oforta	No active products per Red Book
J8650	Nabilone, oral, 1 mg	CESAMET	No active products per Red Book; product discontinued per Orange Book
J9019	Injection, asparaginase (erwinaze), 1,000 iu	Erwinaze	No active products per Red Book
J9020	Injection, asparaginase, 10,000 units, not otherwise specified		No active products per Red Book
J9098	Injection, cytarabine liposome, 10 mg		No active products per Red Book
J9151	Injection, daunorubicin citrate, liposomal formulation, 10 mg	DAUNOXOME	No active products per Red Book; product discontinued per Orange Book
J9165	Injection, diethylstilbestrol diphosphate, 250 mg		No active products per Red Book; product

HCPCS Code[6]	Long Descriptor	Trade Name	CMS' Rational
			discontinued per Orange Book
J9212	Injection, interferon alfacon-1, recombinant, 1 microgram	Infergen	No active products per Red Book
J9270	Injection, plicamycin, 2.5 mg		No active products per Red Book
Q0174	Thiethylperazine maleate, 10 mg, oral, fda approved prescription anti-emetic, for use as a complete therapeutic substitute for an iv anti-emetic at the time of chemotherapy treatment, not to exceed a 48 hour dosage regimen	TORECAN	No active products per Red Book; product discontinued per Orange Book
Q5109	Injection, infliximab-qbtx, biosimilar, (ixifi), 10 mg	Ixifi	Not sold in the U.S.
J1443	Injection, ferric pyrophosphate citrate solution (triferic), 0.1 mg of iron	triferic	Product discontinued; product discontinued per Orange Book
J1444	Injection, ferric pyrophosphate citrate powder, 0.1 mg of iron		Product discontinued
J1445	Injection, ferric pyrophosphate citrate solution (triferic avnu), 0.1 mg of iron	Triferic Avnu	Product discontinued; product discontinued per Orange Book
Q2017	Injection, teniposide, 50 mg	VUMON	Product discontinued; product discontinued per Orange Book
J3310	Injection, perphenazine, up to 5 mg		Not found in the Red Book
J0889	Daprodustat, oral, 1 mg, (for esrd on dialysis)	JESDUVROQ	Product discontinued
Q4106	Dermagraft, per square centimeter	DERMAGRAFT®	Product discontinued
J0172	Injection, aducanumab-avwa, 2 mg	Aduhelm	Product discontinued

Appendix B: 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[7]	Action	Long Descriptor
J0013	Add	Esketamine, nasal spray, 1 mg
J0654	Add	Injection, liothyronine, 1 mcg
J1073	Add	Testosterone pellet, implant, 75 mg
J1837	Add	Injection, posaconazole, 1 mg
J2516	Add	Injection, pentamidine isethionate, 1 mg
J2711	Add	Injection, neostigmine methylsulfate 0.1 mg and glycopyrrolate 0.02 mg
J2596	Add	Injection, vasopressin (long grove), not therapeutically equivalent to j2598, 1 unit
J3291	Add	Injection, tranexamic acid in sodium chloride, 5 mg
J3376	Add	Injection, vancomycin hcl (hikma), not therapeutically equivalent to j3373, 10 mg
J3379	Add	Injection, valproate sodium, 5 mg
J3387	Add	Injection, elivaldogene autotemcel, per treatment
J7528	Add	Mycophenolate mofetil, for suspension, oral, 100 mg
S0080	Delete	Injection, pentamidine isethionate, 300 mg
S0013[8]	Delete	Esketamine, nasal spray, 1 mg
S0189[9]	Delete	Testosterone pellet, 75 mg

[7] Updated on November 14, 2025, to remove the establishment of HCPCS Level II code J3377, "Injection, vancomycin hcl (tyzavan), 10 mg" as the product falls under the same NDA as all the Xellia National Drug Codes listed under HCPCS Level II code J3375.
[8] Updated on November 14, 2025 to discontinue HCPCS Level II code S0013, as it is being replaced with HCPCS Level II code J0013.
[9] Updated on November 20, 2025 to discontinue HCPCS Level II code S0189, as it is being replaced with HCPCS Level II code J1073.