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

Fourth Quarter, 2025 HCPCS Coding Cycle

This document presents a summary of each HCPCS Level II code application and CMS' coding determination for each application processed in CMS' Fourth 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 April 1, 2026, unless otherwise indicated.

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

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

LEQEMBI® - HCP250829V87GP

Topic/Issue

Request to revise existing HCPCS Level II code J0174, “Injection, lecanemab-irmb, 1 mg” to differentiate LEQEMBI® injection for intravenous infusion from LEQEMBI® IQLIK™ (lecanemab-irmb) subcutaneous autoinjector for weekly self-administered maintenance dose.

Applicant’s suggested language: J0174, “Injection, lecanemab-irmb, intravenous, 1 mg”

Summary of Applicant’s Submission

Eisai Inc. submitted a request to revise existing HCPCS Level II code J0174, “Injection, lecanemab-irmb, 1 mg” to make it clear that this code is specific to LEQEMBI® injection for intravenous infusion. LEQEMBI® (lecanemab-irmb) was approved by the Food and Drug Administration (FDA) under a 351(k) Biologics License Application (BLA) on January 6, 2023. LEQEMBI® is an amyloid beta-directed antibody indicated for the treatment of Alzheimer’s disease. Treatment with LEQEMBI® should be initiated in individuals with mild cognitive impairment or mild dementia stage of disease. The recommended initial dosage is 10 mg/kg every 2 weeks administered as an intravenous infusion. After 18 months, the regimen of 10 mg/kg every 2 weeks may be continued, or a transition to the maintenance dosage of 10 mg/kg every 4 weeks as an intravenous infusion or subcutaneous maintenance dosage of 360 mg weekly using the LEQEMBI® IQLIK™ autoinjector may be considered. LEQEMBI® is supplied in a single-dose vial of 500 mg/5 mL and 200 mg/2 mL.

CMS Final HCPCS Coding Determination

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. However, LEQEMBI® was approved by the Food and Drug Administration (FDA) under its own unique BLA, 761269, and must be distinguished from LEQEMBI® IQLIK™, which also has a unique BLA, 761375. As such, CMS will:

Revise existing HCPCS Level II code J0174, "Injection, lecanemab-irmb, 1 mg" to instead read "Lecanemab-irmb, for intravenous injection, 1 mg” to describe LEQEMBI® injection for intravenous infusion.

Ascor® - HCP250724EPY4V

Topic/Issue

Request to establish a new HCPCS Level II to identify Ascor®.

The applicant did not submit any suggested language.

Summary of Applicant's Submission

McGuff Pharmaceuticals, Inc. submitted a request to establish a new HCPCS Level II code to identify Ascor® (ascorbic acid injection). Ascor® was approved by the Food and Drug Administration (FDA) under a 505(b)(2) New Drug Application (NDA) on October 2, 2017. Ascor® is indicated for the short term (up to 1 week) treatment of individuals aged 5 months and older with scurvy whom oral administration is not possible, insufficient, or contraindicated. Ascor® is not indicated for vitamin C deficiency without scurvy. Ascor® must be diluted prior to slow intravenous infusion by a healthcare professional. The recommended doses vary by the individual's age as follows: 50 mg once daily for ages 5 months to 12 months, 100 mg once daily for ages 1 year to 11 years, and 200 mg once daily for ages 11 years and older. Ascor® is supplied as a pharmacy bulk package intended for admixture in a clean air compounding area and for use within 4 hours of puncture. Each 50 mL vial of Ascor® contains 25,000 mg of ascorbic acid (500 mg/mL) in either a single vial or a tray of 25 vials.

CMS Final HCPCS Coding Determination

It is our understanding that Ascor® would generally be used in a procedure reported with a HCPCS Level I Current Procedural Terminology (CPT®) code. Additionally, for Medicare, drugs administered during an inpatient hospital setting are paid as part of the Diagnosis Related Group payment. We have not identified a specific need for this item to be separately paid, since we believe that a particular payer may elect to pay for the service in which this product is used. As such, CMS is denying the applicant's request to establish a new HCPCS Level II code to identify Ascor®.

CYKLX - HCP250923RB8P1

Topic/Issue

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

Applicant's suggested language: JXXXX, “Articaine ophthalmic solution 8%, 1mg”

Summary of Applicant's Submission

American Genomics, LLC submitted a request to establish a new HCPCS Level II code for CYKLX (articaine ophthalmic solution 8%). CYKLX was approved by the Food and Drug Administration (FDA) under a 505(b)(2) New Drug Application (NDA) on August 15, 2025. CYKLX is an amide local anesthetic indicated for individuals prior to ocular procedures and/or intraocular injections. Articaine ophthalmic solution 8%, the active ingredient in CYKLX, acts as a local anesthetic which blocks the generation and conduction of nerve impulses, presumably by increasing the threshold for electrical excitation in the nerve, by slowing the propagation of the nerve impulse, and by reducing the rate of rise of the action potential. The recommended dose and route of administration of CYKLX is 2 drops applied topically, 30 seconds apart to the ocular surface of the eye. CYKLX is not intended for self-administration, but rather administered under the direct supervision of a healthcare provider. CYKLX is packaged as an aseptically prepared, sterile, clear and colorless solution contained in a single-dose vial, with each vial containing 32 mg per 0.4 mL of articaine ophthalmic solution.

CMS Final HCPCS Coding Determination[1]

Establish a new HCPCS Level II code J1098, “Articaine ophthalmic, 8% solution, 0.4 ml”

[1] Updated on February 13, 2026 to revise our final determination from stating that CYKLX, a local anesthetic, would generally be included in the payment for the procedure and instead establishing a new HCPCS Level II code J1098.

INLEXZO™ - HCP250918DWVLU

Topic/Issue

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

Applicant's suggested language: JXXXX, “225 mg gemcitabine per intravesical system, each”

Summary of Applicant's Submission

Johnson & Johnson Healthcare Systems Inc. submitted a request to establish a new HCPCS Level II code for INLEXZO™ (gemcitabine intravesical system). INLEXZO™ was approved by the Food and Drug Administration (FDA) under a 505(b)(2) New Drug Application (NDA) on September 9, 2025. INLEXZO™ is a nucleoside metabolic inhibitor-containing intravesical system, indicated for the treatment of adults with Bacillus Calmette-Guerin unresponsive, non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ with or without papillary tumors. Gemcitabine kills cells undergoing deoxyribonucleic acid (DNA) synthesis and blocks the progression of cells. After the gemcitabine nucleotide is incorporated into DNA, only one additional nucleotide is added to the growing DNA strands, which eventually results in the initiation of apoptotic cell death. Each 225 mg dose of INLEXZO™ provides a prolonged release of gemcitabine into the bladder urine, with approximately 77% released by day 7 and approximately 99% released by day 21. INLEXZO™ is inserted into the bladder once every 3 weeks for up to 6 months (8 doses), followed by once every 12 weeks for up to 18 months, or until persistent or recurrent NMIBC, disease progression, or unacceptable toxicity. INLEXZO™ is intended to be removed after each 3-week indwelling period throughout the 2 years of therapy. INLEXZO™ contains 225 mg gemcitabine and is for intravesical administration using the co-packaged sterile urinary catheter and a sterile stylet only packaged together in a pouch. No other route of administration is appropriate.

CMS Final HCPCS Coding Determination

Establish a new HCPCS Level II code J9183, “Gemcitabine intravesical system, 225 mg”

KEYTRUDA QLEX™ - HCP250930A1LYA

Topic/Issue

Request to establish a new HCPCS Level II code to specifically identify KEYTRUDA QLEX™

Applicant's suggested language: JXXXX, “Injection, pembrolizumab, 1 mg and berahyaluronidase alfa-pmph”

Summary of Applicant's Submission

Merck submitted a request to establish a new HCPCS Level II code to identify KEYTRUDA QLEX™ (pembrolizumab and berahyaluronidase alfa-pmph). KEYTRUDA QLEX™ was approved by the Food and Drug Administration (FDA) under a 351(a) Biologics License Application (BLA) on September 19, 2025. KEYTRUDA QLEX™ is indicated for the treatment of certain individuals with the following tumor types: melanoma, non-small cell lung cancer, malignant pleural mesothelioma, head and neck squamous cell cancer, urothelial cancer, microsatellite instability-high or mismatch repair deficient cancer, microsatellite instability-high or mismatch repair deficient colorectal cancer, gastric cancer, esophageal cancer, cervical cancer, hepatocellular carcinoma, biliary tract cancer, Merkel cell carcinoma, renal cell carcinoma, endometrial carcinoma, tumor mutational burden-high cancer, cutaneous squamous cell carcinoma, and triple-negative breast cancer. For individuals aged 12 years and older who weigh greater than 40 kg, the doses are given either every 3-weeks or every 6-weeks. The 3-week dose is 2.4 mL containing 395 mg pembrolizumab and 4,800 units berahyaluronidase alfa, and the 6-week dose is 4.8 mL containing 790 mg pembrolizumab and 9,600 units berahyaluoronidase alfa. KEYTRUDA QLEX™ is administered by a healthcare provider as a subcutaneous injection into the thigh or abdomen, and the injections may be provided in various sites of care (i.e., it need not be given in an infusion clinic). KEYTRUDA QLEX™ is supplied in single-dose vials providing either 2.4 mL (165 mg/ 2,000 units per mL) or 4.8 mL (165 mg/ 2,000 units per mL).

CMS Final HCPCS Coding Determination

Establish a new HCPCS Level II code J9277, “Injection, pembrolizumab, 1 mg and berahyaluronidase alfa-pmph”

CAMCEVI ETM® - HCP250929Y18QL

Topic/Issue

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

Applicant's suggested language: JXXXX, "Leuprolide inj, camcevi etm, 1 mg"

Summary of Applicant's Submission

Accord Biopharma, Inc. submitted a request to establish a new HCPCS Level II code to identify CAMCEVI ETM® (leuprolide mesylate). CAMCEVI ETM® was approved by the Food and Drug Administration (FDA) under a 505(b)(2) New Drug Application (NDA) on August 25, 2025. CAMCEVI ETM® is indicated for the treatment of individuals with advanced prostate cancer. CAMCEVI ETM® is a sterile, off-white to pale yellow, viscous, and opalescent injectable emulsion supplied in a kit as a single-dose, ready-to-use pre-filled syringe with a sterile 18-gauge SurGuard®3 safety needle. CAMCEVI ETM® is designed to deliver approximately 21 mg of leuprolide over 3 months. Leuprolide, a gonadotropin-releasing hormone agonist, acts as an inhibitor of gonadotropin secretion. CAMCEVI ETM® must be administered by a healthcare provider. By using a proprietary delivery system, the stability of the depot formulation allows the final drug product to be manufactured and supplied in a ready-to-use syringe with suitable shelf-life for shipping and storage.

CMS Final HCPCS Coding Determination

Establish a new HCPCS Level II code J9003, “Leuprolide injectable (camcevi etm), 1 mg”

AUKELSO™ and BOSAYA™ - HCP25092969CND

Topic/Issue

Request to establish a new HCPCS Level II code to identify AUKELSO™ and BOSAYA™.

Applicant's suggested language: QXXXX, “Injection, denosumab-kyqq (aukelso/bosaya), biosimilar, 1 mg”

Summary of Applicant's Submission

Biocon Biologics Inc. submitted a request to establish a new HCPCS Level II code to identify AUKELSO™ (denosumab-kvqq) and BOSAYA™ (denosumab-kvqq). AUKELSO™ and BOSAYA™ were approved by the Food and Drug Administration (FDA) under a 351(k) Biologics License Application (BLA) on September 16, 2025, as biosimilars to their respective biological reference products, XGEVA® and PROLIA®. Both AUKELSO™ and BOSAYA™ are human monoclonal antibody receptor activators that target and bind to the receptor activator of nuclear factor-kappa-B ligand (RANKL). AUKELSO™ is approved for multiple indications, including for the prevention of skeletal-related events in individuals with multiple myeloma, and in individuals with bone metastases from solid tumors. It is also indicated for the treatment of adults and skeletally-mature adolescents with giant cell tumor of bone that is unresectable, or where surgical resection is likely to result in severe morbidity. Another indication is for the treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy. BOSAYA™ is also approved for multiple indications, including for the treatment of postmenopausal individuals with osteoporosis at high risk for fracture, and for the increase in bone mass in individuals with osteoporosis at high risk for fracture. It is also indicated for the treatment of glucocorticoid-induced osteoporosis in individuals at high risk for fracture, and for the increase in bone mass in individuals at high risk for fracture receiving androgen deprivation therapy used for nonmetastatic prostate cancer. Another indication is for the increase in bone mass in individuals at high risk for fracture receiving adjuvant aromatase inhibitor therapy used for breast cancer. The recommended dosage of AUKELSO™ varies by indication. The recommended dose of BOSAYA™ is 60 mg once every 6 months. Both AUKELSO™ and BOSAYA™ are administered via subcutaneous injection.

CMS Final HCPCS Coding Determination

Establish a new HCPCS Level II code Q5161, “Injection, denosumab-kyqq (aukelso/bosaya), biosimilar, 1 mg”

BILDYOS® and BILPREVDA® - HCP250923ND1Q6

Topic/Issue

Request to establish a new HCPCS Level II code to identify BILDYOS® and BILPREVDA®.

Applicant's suggested language: QXXXX, “Injection, biosimilar, (BILDYOS/BILPREVDA), 1 mg”

Summary of Applicant's Submission

Organon LLC submitted a request to establish a new HCPCS Level II code to identify BILDYOS® (denosumab-nxxp) and BILPREVDA® (denosumab-nxxp). BILDYOS® and BILPREVDA® were approved by the Food and Drug Administration (FDA) under a 351(k) Biologics License Application (BLA) on August 29, 2025, as biosimilars to their respective biological reference products, PROLIA® and XGEVA®. BILDYOS® and BILPREVDA® are both receptor activator of nuclear factor-kappa-B (RANK) ligand inhibitors. BILDYOS® is indicated for the treatment of postmenopausal individuals with osteoporosis at high risk for fracture, and for the treatment to increase bone mass in individuals with osteoporosis at high risk for fracture. It is also indicated for the treatment of glucocorticoid-induced osteoporosis in individuals at high risk for fracture. Further indications also include, for the treatment to increase bone mass in individuals at high risk for fracture receiving androgen deprivation therapy used for nonmetastatic prostate cancer, and for the treatment to increase bone mass in individuals at high risk for fracture receiving adjuvant aromatase inhibitor therapy used for breast cancer. BILPREVDA® is indicated for the prevention of skeletal-related events in individuals with multiple myeloma, and in individuals with bone metastases from solid tumors. Another indication is for the treatment of adults and skeletally-mature adolescents with giant cell tumor of bone that is unresectable, or where surgical resection is likely to result in severe morbidity. It is also indicated for the treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy. The recommended dosage of BILDYOS® is a single subcutaneous injection of 60 mg, administered once every 6 months. The recommended dose of BILPREVDA® for multiple myeloma and bone metastases from solid tumors is 120 mg, administered as a subcutaneous injection every 4 weeks. The recommended dose of BILPREVDA® for giant cell tumor of bone and hypercalcemia of malignancy is 120 mg, administered as a subcutaneous injection every 4 weeks, with additional 120 mg doses on days 8 and 15 of the first month of therapy. BILDYOS® and BILPREVDA® are clear to slightly opalescent, colorless to slightly yellow solutions that are supplied in a single-dose prefilled syringe for manual use. Each BILDYOS® single-dose prefilled syringe contains 60 mg/mL of denosumab in a 1 mL single-dose syringe, with a 29-gauge 1/2-inch needle with a BD UltraSafe Plus™ passive safety guard. Each BILDYOS® single-dose vial contains 60 mg/mL of denosumab in a 2 mL vial. BILPREVDA® is provided as a single-dose vial containing 120 mg/1.7 mL of denosumab.

CMS Final HCPCS Coding Determination

Establish a new HCPCS Level II code Q5162, “Injection, denosumab-nxxp (bildyos/bilprevda), biosimilar, 1 mg”

TYENNE® - HCP2509304W5H2

Topic/Issue

Request to establish a new HCPCS Level II code to identify a new treatment indication of TYENNE® for COVID-19.

Applicant's suggested language: QXXXX, “Injection, tocilizumab-aazg, for hospitalized adult patients with covid-19 who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ecmo) only, 1 mg”

Summary of Applicant's Submission

Fresenius Kabi submitted a request to establish a new HCPCS Level II code to identify TYENNE® (tocilizumab-aazg). TYENNE® was approved by the Food and Drug Administration (FDA) under a 351(k) Biologics License Application (BLA) on February 28, 2025, and is a biosimilar to ACTEMRA® (tocilizumab). TYENNE® is indicated for intravenous administration in hospitalized adults with COVID-19 who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation.

CMS Final HCPCS Coding Determination

1. Establish a new HCPCS Level II code Q0238, “Injection, tocilizumab-aazg, for hospitalized adult patients with covid-19 who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ecmo) only, 1 mg”

2. Establish a new HCPCS Level II code M0233, “Intravenous infusion, tocilizumab-aazg, for hospitalized adult patients with covid-19 who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ecmo) only, includes infusion and post administration monitoring, first dose”

3. Establish a new HCPCS Level II code M0234, “Intravenous infusion, tocilizumab-aazg, for hospitalized adult patients with covid-19 who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ecmo) only, includes infusion and post administration monitoring, second dose”

TYENNE® (tocilizumab-aazg), a biosimilar to ACTEMRA® (tocilizumab), is approved for the treatment of rheumatoid arthritis, giant cell arteritis, polyarticular juvenile idiopathic arthritis, systemic juvenile idiopathic arthritis, and coronavirus disease 2019 (COVID-19). Effective October 1, 2024, CMS established HCPCS Level II code Q5135, “Injection, tocilizumab-aazg (tyenne), biosimilar, 1 mg”, to describe TYENNE®, which is payable under Medicare Part B at a rate of average sales price (ASP) plus 6%. In 2020, CMS established payment policies for monoclonal antibody (mAb) products with an indication for post-exposure prophylaxis or treatment of COVID-19 to be paid under the Medicare Part B preventive vaccine benefit at 95% of the average wholesale price through the end of the

calendar year in which the Emergency Use Authorization (EUA) declaration under section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) ends. To date, the EUA declaration under section 564 of the FD&C Act remains in effect. Effective January 1 of the year following the year in which the EUA declaration for drugs and biological products ends, CMS will pay for COVID-19 mAb products used for the treatment or for post-exposure prophylaxis of COVID-19 as biological products paid under section 1847A of the Social Security Act (the Act), typically at ASP plus 6%; healthcare providers and practitioners will be paid under the applicable payment system, and using the appropriate coding and payment rates, for administering COVID-19 mAb therapies similar to the way they are paid for administering other complex biological products.

Typically, CMS does not establish new HCPCS Level II codes for drug and biological products to distinguish an indication; however, the HCPCS Level II code Q5135 for TYENNE® would not be suitable for the treatment of COVID-19 based on CMS' current payment policies, similar to what has been done for prior mAb products with this indication (such as HCPCS Level II code Q0249 for ACTEMRA®) for appropriate Medicare Part B payment. As such, CMS is establishing HCPCS Level II code Q0238 to describe TYENNE® for post-exposure prophylaxis or treatment of COVID-19 to align with the appropriate Medicare payment policies. These codes would be effective through the end of the calendar year in which the EUA declaration under section 564 of the FD&C Act ends. At that time, COVID-19 mAb products used for the treatment or for post-exposure prophylaxis of COVID-19 as biological products will be paid under section 1847A of the Act and the appropriate HCPCS Level II code Q5135 should be billed for these indications.

PAPZIMEOS™ - HCP250922UX1V9

Topic/Issue

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

Applicant's suggested language: XXXXX, "Injection, zopapogene imadenovec-drba suspension, 0.1 mL"

Summary of Applicant's Submission

Precigen, Inc. submitted a request to establish a new HCPCS Level II code to identify PAPZIMEOS™ (zopapogene imadenovec-drba) suspension for subcutaneous injection. PAPZIMEOS™ was approved by the Food and Drug Administration (FDA) under a 351(a) Biologics License Application (BLA) on August 14, 2025. PAPZIMEOS™ is a non-replicating adenoviral vector-based immunotherapy. PAPZIMEOS™ is indicated for the treatment of adults with recurrent respiratory papillomatosis, a chronic disease caused by persistent Human Papillomavirus (HPV) 6 and HPV 11 infection. PAPZIMEOS™ addresses the root cause of the disease by inducing HPV specific T-cell responses to eliminate infected cells and reduce recurrence. This enables immune-mediated clearance of papilloma lesions, reducing the need for surgical interventions. The recommended dosage is 5 x 10^{11} particle units (PU) per injection administered subcutaneously four times over a 12 week interval.

CMS Final HCPCS Coding Determination

Establish a new HCPCS Level II code J3404, "Injection, zopapogene imadenovec-drba suspension, per therapeutic dose"

LYNOZYFIC™ - HCP250702NDLHT

Topic/Issue

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

Applicant's suggested language: JXXXX, “Injection, linvoseltamab-gcpt, 1 mg”

Summary of Applicant's Submission

Regeneron Pharmaceuticals, Inc. submitted a request to establish a new HCPCS Level II code to identify LYNOZYFIC™ (linvoseltamab-gcpt). LYNOZYFIC™ was approved by the Food and Drug Administration (FDA) under a 351(a) Biologics License Application (BLA) on July 2, 2025. LYNOZYFIC™ is a bispecific B-cell maturation antigen (BCMA)-directed CD3 T-cell engager indicated for the treatment of adults with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody. LYNOZYFIC™ is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the LYNOZYFIC™ REMS. LYNOZYFIC™ is a bispecific T-cell engaging antibody that binds to the CD3 receptor expressed on the surface of T-cells and BCMA expressed on the surface of multiple myeloma cells and some healthy B-lineage cells. LYNOZYFIC™ is administered only as an intravenous infusion after dilution in 0.9% sodium chloride injection. The recommended dosage of LYNOZYFIC™ is step-up doses of 5 mg, 25 mg, and 200 mg, followed by 200 mg weekly for 10 doses, and then 200 mg every two weeks. LYNOZYFIC™ should be administered by a healthcare provider with immediate access to emergency equipment and appropriate medical support to manage severe reactions such as cytokine release syndrome (CRS), infusion-related reactions, and neurologic toxicity, including immune effector cell-associated neurotoxicity syndrome (ICANS). Due to the risk of CRS and neurologic toxicity, including ICANS, individuals should be hospitalized for 24 hours after administration of the first step-up dose and for 24 hours after administration of the second step-up dose.

CMS Final HCPCS Coding Determination

1. Establish a new HCPCS Level II code J9601, “Injection, linvoseltamab-gcpt, 1 mg”
2. Discontinue HCPCS Level II code C9307, “Injection, linvoseltamab-gcpt, 1 mg”

APONVIE® - HCP2509269DK33

Topic/Issue

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

Applicant's suggested language: JXXXX, “Injection, aprepitant (APONVIE®), 1 mg”

Summary of Applicant's Submission

Heron Therapeutics, Inc. submitted a request to establish a new HCPCS Level II code to identify APONVIE® (aprepitant). APONVIE® was approved by the Food and Drug Administration (FDA) under a 505(b)(2) New Drug Application (NDA) on September 16, 2022. APONVIE® is indicated for adults to prevent postoperative nausea and vomiting. APONVIE® is an intravenous injectable emulsion formulation of the antiemetic agent aprepitant, which is a Substance P/neurokinin 1 receptor antagonist indicated for the prevention of postoperative nausea and vomiting. APONVIE® injectable emulsion is supplied as an opaque, off-white to amber emulsion in a single-dose glass vial for intravenous use. Each vial contains 32 mg aprepitant in 4.4 mL of emulsion. APONVIE® dose is 32 mg administered as a 30-second intravenous injection before the induction of anesthesia.

CMS Final HCPCS Coding Determination

1. Establish a new HCPCS Level II code J8502, “Injection, aprepitant (aponvie), 1 mg”

2. Discontinue HCPCS Level II code C9145, “Injection, aprepitant, (aponvie), 1 mg”

KYXATA™ - HCP250929HQXUD

Topic/Issue

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

Applicant's suggested language: JXXXX, “Injection, carboplatin (KYXATA), 1 mg”

Summary of Applicant's Submission

AVYXA Pharma, LLC submitted a request to establish a new HCPCS Level II code to identify KYXATA™ (carboplatin). KYXATA™ was approved by the Food and Drug Administration (FDA) under a 505(b)(2) New Drug Application (NDA) on August 8, 2025. KYXATA™ is indicated as part of a combination regimen for the initial treatment of advanced ovarian carcinoma, and as a single agent for the treatment of ovarian carcinoma recurrent after prior chemotherapy. KYXATA™ is a platinum-based drug that binds to deoxyribonucleic acid (DNA) and forms DNA crosslinks. These crosslinks inhibit DNA replication and transcription and trigger cytotoxic processes that lead to cell death. KYXATA™ is for intravenous use only, and dosing is dependent on the indication. KYXATA™ is supplied as a clear to pale yellow solution in multiple-dose vials available in two strengths: 80 mg/8 mL (10 mg/mL) and 500 mg/50 mL (10 mg/mL).

CMS Final HCPCS Coding Determination

1. Establish a new HCPCS Level II code J9278, “Injection, carboplatin (avyxa), 1 mg”

2. Discontinue HCPCS Level II code C9308, “Injection, carboplatin (avyxa), 1 mg”

InstaGraft - HCP251001WN7E1

Topic/Issue

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

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

Summary of Applicant's Submission

Xtant Medical submitted a request to establish a new HCPCS Level II code to identify InstaGraft. InstaGraft is regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) solely under section 361 of the Public Health Service (PHS) Act and 21 CFR part 1271 when intended for use as a “barrier” and “to provide protective coverage from the surrounding environment.” InstaGraft is a textured, dual-layer amniotic membrane obtained from healthy deliveries following informed consent. InstaGraft is intended to serve as a barrier and provide protective coverage from the surrounding environment when topically applied to chronic and acute wounds. InstaGraft 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, InstaGraft, “when intended to serve as a barrier and to provide protective coverage from the surrounding environment, 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 Q4439, “Instagraft, per square centimeter (add-on, list separately in addition to primary procedure)”

This coding determination applies to the InstaGraft product described in the application and accompanying FDA TRG letter dated July 10, 2025, when intended for use as a “barrier” and “to provide protective coverage from the surrounding environment.”

Revive FT - HCP250929NG0L6

Topic/Issue

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

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

Summary of Applicant's Submission

Acesso Biologics LLC dba Dynamic Medical Services submitted a request to establish a new HCPCS Level II code to identify Revive FT. Revive FT is regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) solely under section 361 of the Public Health Service (PHS) Act and 21 CFR part 1271 when intended for use as a “barrier” or “cover.” Revive FT Membrane is a sterile, single-use, dehydrated resorbable allograft derived from donated human placental birth tissue. Revive FT is a full-thickness amnion/chorion membrane. The allograft is processed using aseptic techniques and terminally sterilized by electron beam. An 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. Each allograft is packaged in a primary foil pouch and a secondary Tyvek® pouch. Revive FT is restricted to use by a licensed healthcare professional. Revive FT provides an extracellular matrix scaffold intended for use as a protective wound covering and barrier in acute and chronic wounds. Revive FT is applied directly to the wound. A single sterile, double-pouched membrane is provided in a solid bleached sulfate paperboard box. Revive FT must be stored at an ambient temperature of 15-30°C (59-86°F) before application and may be stored for up to 5 years.

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

Establish a new HCPCS Level II code Q4424, “Revive ft, per square centimeter (add-on, list separately in addition to primary procedure)”

This coding determination applies to the Revive FT product described in the application and accompanying FDA TRG letter dated July 10, 2025, when intended for use as a “barrier” or “cover.”

DermaBind TL + - HCP2509249FYKF

Topic/Issue

Request to establish a new HCPCS Level II code to identify DermaBind TL +.

Applicant's suggested language: QXXXX, “DermaBind TL + per sq cm”

Summary of Applicant's Submission

HealthTech Wound Care submitted a request to establish a new HCPCS Level II code to identify DermaBind TL +. DermaBind TL + is regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) solely under section 361 of the Public Health Service (PHS) Act and 21 CFR part 1271 when intended for use as a “wound covering” and “to protect those wounds from the environment.” DermaBind TL + is a dehydrated human full-thickness placental membrane comprised of an extracellular matrix that is rich in collagen, fibrin, and elastin fibers native to the tissue. DermaBind TL + is a wound covering designed for application directly to acute and chronic wounds, is flexible, and is a conforming cover that adheres to complex anatomies. DermaBind TL + membrane protects the wound from the external environment and maintains a moist environment. Before application, ensure the wound and/or skin is debrided, is clean, and free of infection. To apply DermaBind TL +, place the membrane onto the wound surface with the amnion (epithelial) side facing the wound. Smooth the membrane with non-toothed forceps. To discourage membrane displacement following transplantation, DermaBind TL + may be affixed to the site using aseptic technique with a variety of wound closure mechanisms, including absorbable sutures, non-absorbable sutures, non-adhesive wrapping, adhesive wrapping, and/or tissue adhesive appropriate for the procedure type. The membrane will be easier to suture before hydration. DermaBind TL + can be rehydrated using sterile water if hydrated before securing it to the wound, by wound exudate if applied before hydration to a lightly exuding wound, and by hydrating with sterile water after the membrane is applied to the wound. DermaBind TL + is packaged in a double peel-pouch packaging configuration. The outer pouch is not sterile. The inner pouch that contains the DermaBind TL + membrane is sterile unless the pouch is damaged or compromised. The product package includes the full-thickness triple-layer membrane covering, tissue utilization record, packaging list, product labels, and instructions for use.

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, DermaBind TL +, “when intended for use ‘as a wound covering’ and ‘to protect those wounds from the 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 Q4426, “Dermabind tl + or dermabind tl x, per square centimeter (add-on, list separately in addition to primary procedure)”

This coding determination applies to the DermaBind TL + product described in the application and accompanying FDA TRG letter dated April 24, 2025, when intended for use as a “wound covering” and “to protect those wounds from the environment.”

DermaBind TL X - HCP250924WN5FW

Topic/Issue

Request to establish a new HCPCS Level II code to identify DermaBind TL X.

Applicant's suggested language: QXXXX, “DermaBind TL X per sq cm”

Summary of Applicant's Submission

HealthTech Wound Care submitted a request to establish a new HCPCS Level II code to identify DermaBind TL X. DermaBind TL X is regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) solely under section 361 of the Public Health Service (PHS) Act and 21 CFR part 1271 when intended for use as a “wound covering” and “to protect those wounds from the environment.” DermaBind TL X is a dehydrated human full-thickness placental membrane comprised of an extracellular matrix that is rich in collagen, fibrin, and elastin fibers native to the tissue. DermaBind TL X is a wound covering designed for application directly to acute and chronic wounds, is flexible, and is a conforming cover that adheres to complex anatomies. DermaBind TL X membrane protects the wound from the external environment and maintains a moist environment. Before application, ensure the wound and/or skin is debrided, is clean, and free of infection. To apply DermaBind TL X, place the membrane onto the wound surface with the amnion (epithelial) side facing the wound. Smooth the membrane with non-toothed forceps. To discourage membrane displacement following transplantation, DermaBind TL X may be affixed to the site using aseptic technique with a variety of wound closure mechanisms, including absorbable sutures, non-absorbable sutures, non-adhesive wrapping, adhesive wrapping, and/or tissue adhesive appropriate for the procedure type. The membrane will be easier to suture before hydration. DermaBind TL X can be rehydrated using sterile water if hydrated before securing it to the wound, by wound exudate if applied before hydration to a lightly exuding wound, and by hydrating with sterile water after the membrane is applied to the wound. DermaBind TL X is packaged in a double peel-pouch packaging configuration. The outer pouch is not sterile. The inner pouch that contains the DermaBind TL X membrane is sterile unless the pouch is damaged or compromised. The product package includes the full-thickness triple-layer membrane covering, tissue utilization record, packaging list, product labels, and instructions for use.

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, DermaBind TL X, “when intended for use ‘as a wound covering’ and ‘to protect those wounds from the 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 Q4426, “Dermabind tl + or dermabind tl x, per square centimeter (add-on, list separately in addition to primary procedure)”

This coding determination applies to the DermaBind TL X product described in the application and accompanying FDA TRG letter dated April 24, 2025, when intended for use as a “wound covering” and “to protect those wounds from the environment.”

DermaBind DL N - HCP250924YVKBC

Topic/Issue

Request to establish a new HCPCS Level II code to identify DermaBind DL N.

Applicant's suggested language: QXXXX, “DermaBind DL N per sq cm”

Summary of Applicant's Submission

HealthTech Wound Care submitted a request to establish a new HCPCS Level II code to identify DermaBind DL N. DermaBind DL N is regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) solely under section 361 of the Public Health Service (PHS) Act and 21 CFR part 1271 when intended for use as a “wound covering” and “to protect those wounds from the environment.” DermaBind DL N is a dehydrated human double-layer amnion/chorion membrane comprised of an extracellular matrix that is rich in collagen, fibrin, and elastin fibers native to the tissue. It is designed as a wound covering. DermaBind DL N is a wound covering designed for application directly to acute and chronic wounds, is flexible, and is a conforming cover that adheres to complex anatomies. DermaBind DL N membrane protects the wound from the external environment and maintains a moist environment. Before application, ensure the wound and/or skin is debrided, is clean, and free of infection. To apply DermaBind DL N, place the membrane onto the wound surface with the amnion (epithelial) side facing the wound. Smooth the membrane with non-toothed forceps. To discourage membrane displacement following transplantation, DermaBind DL N may be affixed to the site using aseptic technique with a variety of wound closure mechanisms, including absorbable sutures, non-absorbable sutures, non-adhesive wrapping, adhesive wrapping, and/or tissue adhesive appropriate for the procedure type. The membrane will be easier to suture before hydration. DermaBind DL N can be rehydrated using sterile water if hydrated before securing it to the wound, by wound exudate if applied before hydration to a lightly exuding wound, and by hydrating with sterile water after the membrane is applied to the wound. DermaBind DL N is packaged in a double peel-pouch packaging configuration. The outer pouch is not sterile. The inner pouch that contains the DermaBind DL N membrane is sterile unless the pouch is damaged or compromised. The product package includes a double-layer amnion/chorion membrane covering, tissue utilization record, packaging list, product labels, and instructions for use.

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, DermaBind DL N, “when intended for use ‘as a wound covering’ and ‘to protect those wounds from the 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 Q4427, “Dermabind dl n or dermabind dl + or dermabind dl x, per square centimeter (add-on, list separately in addition to primary procedure)”

This coding determination applies to the DermaBind DL N product described in the application and accompanying FDA TRG letter dated April 24, 2025, when intended for use as a “wound covering” and “to protect those wounds from the environment.”

DermaBind DL + - HCP250924WWBGW

Topic/Issue

Request to establish a new HCPCS Level II code to identify DermaBind DL +.

Applicant's suggested language: QXXXX, “DermaBind DL + per sq cm”

Summary of Applicant's Submission

HealthTech Wound Care submitted a request to establish a new HCPCS Level II code to identify DermaBind DL +. DermaBind DL + is regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) solely under section 361 of the Public Health Service (PHS) Act and 21 CFR part 1271 when intended for use as a “wound covering” and “to protect those wounds from the environment.” DermaBind DL + is a dehydrated human amnion/chorion membrane comprised of an extracellular matrix that is rich in collagen, fibrin, and elastin fibers native to the tissue. DermaBind DL + is a wound covering designed for application directly to acute and chronic wounds, is flexible, and is a conforming cover that adheres to complex anatomies. DermaBind DL + membrane protects the wound from the external environment and maintains a moist environment. Before application, ensure the wound and/or skin is debrided, is clean, and free of infection. To apply DermaBind DL +, place the membrane onto the wound surface with the amnion (epithelial) side facing the wound. Smooth the membrane with non-toothed forceps. To discourage membrane displacement following transplantation, DermaBind DL + may be affixed to the site using aseptic technique with a variety of wound closure mechanisms, including absorbable sutures, non-absorbable sutures, non-adhesive wrapping, adhesive wrapping, and/or tissue adhesive appropriate for the procedure type. The membrane will be easier to suture before hydration. DermaBind DL + can be rehydrated using sterile water if hydrated before securing it to the wound, by wound exudate if applied before hydration to a lightly exuding wound, and by hydrating with sterile water after the membrane is applied to the wound. DermaBind DL + is packaged in a double peel-pouch packaging configuration. The outer pouch is not sterile. The inner pouch that contains the DermaBind DL + membrane is sterile unless the pouch is damaged or compromised. The product package includes the dehydrated human double-layer amnion/chorion layer membrane covering, tissue utilization record, packaging list, product labels, and instructions for use.

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, DermaBind DL +, “when intended for use ‘as a wound covering’ and ‘to protect those wounds from the 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 Q4427, “Dermabind dl n or dermabind dl + or dermabind dl x, per square centimeter (add-on, list separately in addition to primary procedure)”

This coding determination applies to the DermaBind DL + product described in the application and accompanying FDA TRG letter dated April 24, 2025, when intended for use as a “wound covering” and “to protect those wounds from the environment.”

DermaBind DL X - HCP250924BWD4H

Topic/Issue

Request to establish a new HCPCS Level II code to identify DermaBind DL X.

Applicant's suggested language: QXXXX, “DermaBind DL X per sq cm”

Summary of Applicant's Submission

HealthTech Wound Care submitted a request to establish a new HCPCS Level II code to identify DermaBind DL X. DermaBind DL X is regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) solely under section 361 of the Public Health Service (PHS) Act and 21 CFR part 1271 when intended for use as a “wound covering” and “to protect those wounds from the environment.” DermaBind DL X is a dehydrated human double-layer amnion/chorion membrane comprised of an extracellular matrix that is rich in collagen, fibrin, and elastin fibers native to the tissue. DermaBind DL X is a wound covering designed for application directly to acute and chronic wounds, is flexible, and is a conforming cover that adheres to complex anatomies. DermaBind DL X membrane protects the wound from the external environment and maintains a moist environment. Before application, ensure the wound and/or skin is debrided, is clean, and free of infection. To apply DermaBind DL X, place the membrane onto the wound surface with the amnion (epithelial) side facing the wound. Smooth the membrane with non-toothed forceps. To discourage membrane displacement following transplantation, DermaBind DL X may be affixed to the site using aseptic technique with a variety of wound closure mechanisms, including absorbable sutures, non-absorbable sutures, non-adhesive wrapping, adhesive wrapping, and/or tissue adhesive appropriate for the procedure type. The membrane will be easier to suture before hydration. DermaBind DL X can be rehydrated using sterile water if hydrated before securing it to the wound, by wound exudate if applied before hydration to a lightly exuding wound, and by hydrating with sterile water after the membrane is applied to the wound. DermaBind DL X is packaged in a double peel-pouch packaging configuration. The outer pouch is not sterile. The inner pouch that contains the DermaBind DL X membrane is sterile unless the pouch is damaged or compromised. The product package includes the dehydrated human double-layer amnion/chorion layer membrane covering, tissue utilization record, packaging list, product labels, and instructions for use.

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, DermaBind DL X, “when intended for use ‘as a wound covering’ and ‘to protect those wounds from the 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 Q4427, “Dermabind dl n or dermabind dl + or dermabind dl x, per square centimeter (add-on, list separately in addition to primary procedure)”

This coding determination applies to the DermaBind DL X product described in the application and accompanying FDA TRG letter dated April 24, 2025, when intended for use as a “wound covering” and “to protect those wounds from the environment.”

DermaBind SL N - HCP250924RLCLJ

Topic/Issue

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

Applicant's suggested language: QXXXX, “DermaBind SL N per sq cm”

Summary of Applicant's Submission

HealthTech Wound Care submitted a request to establish a new HCPCS Level II code to identify DermaBind SL N. DermaBind SL N is regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) solely under section 361 of the Public Health Service (PHS) Act and 21 CFR part 1271 when intended for use as a “wound covering” and “to protect those wounds from the environment.” DermaBind SL N is a dehydrated human single-layer amnion membrane comprised of an extracellular matrix that is rich in collagen, fibrin, and elastin fibers native to the tissue. It is designed as a wound covering. DermaBind SL N is a wound covering designed for application directly to acute and chronic wounds, is flexible, and is a conforming cover that adheres to complex anatomies. DermaBind SL N membrane protects the wound from the external environment and maintains a moist environment. Before application, ensure the wound and/or skin is debrided, is clean, and free of infection. To apply DermaBind SL N, place the membrane onto the wound surface with the amnion (epithelial) side facing the wound. Smooth the membrane with non-toothed forceps. To discourage membrane displacement following transplantation, DermaBind SL N may be affixed to the site using aseptic technique with a variety of wound closure mechanisms, including absorbable sutures, non-absorbable sutures, non-adhesive wrapping, adhesive wrapping, and/or tissue adhesive appropriate for the procedure type. The membrane will be easier to suture before hydration. DermaBind SL N can be rehydrated using sterile water if hydrated before securing it to the wound, by wound exudate if applied before hydration to a lightly exuding wound, and by hydrating with sterile water after the membrane is applied to the wound. DermaBind SL N is packaged in a double peel-pouch packaging configuration. The outer pouch is not sterile. The inner pouch that contains the DermaBind SL N membrane is sterile unless the pouch is damaged or compromised. The product package includes a single-layer amnion membrane covering, tissue utilization record, packaging list, product labels, and instructions for use.

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, DermaBind SL N, “when intended for use ‘as a wound covering’ and ‘to protect those wounds from the 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 Q4428, “Dermabind sl n or dermabind sl + or dermabind sl x, per square centimeter (add-on, list separately in addition to primary procedure)”

This coding determination applies to the DermaBind SL N product described in the application and accompanying FDA TRG letter dated April 24, 2025, when intended for use as a “wound covering” and “to protect those wounds from the environment.”

DermaBind SL X - HCP250924CFT5U

Topic/Issue

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

Applicant's suggested language: QXXXX, “DermaBind SL X per sq cm”

Summary of Applicant's Submission

HealthTech Wound Care submitted a request to establish a new HCPCS Level II code to identify DermaBind SL X. DermaBind SL X is regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) solely under section 361 of the Public Health Service (PHS) Act and 21 CFR part 1271 when intended for use as a “wound covering” and “to protect those wounds from the environment.” DermaBind SL X is a dehydrated human single-layer amnion membrane comprised of an extracellular matrix that is rich in collagen, fibrin, and elastin fibers native to the tissue. It is designed as a wound covering. DermaBind SL X is a wound covering designed for application directly to acute and chronic wounds, is flexible, and is a conforming cover that adheres to complex anatomies. DermaBind SL X membrane protects the wound from the external environment and maintains a moist environment. Before application, ensure the wound and/or skin is debrided, is clean, and free of infection. To apply DermaBind SL X, place the membrane onto the wound surface with the amnion (epithelial) side facing the wound. Smooth the membrane with non-toothed forceps. To discourage membrane displacement following transplantation, DermaBind SL X may be affixed to the site using aseptic technique with a variety of wound closure mechanisms, including absorbable sutures, non-absorbable sutures, non-adhesive wrapping, adhesive wrapping, and/or tissue adhesive appropriate for the procedure type. The membrane will be easier to suture before hydration. DermaBind SL X can be rehydrated using sterile water if hydrated before securing it to the wound, by wound exudate if applied before hydration to a lightly exuding wound, and by hydrating with sterile water after the membrane is applied to the wound. DermaBind SL X is packaged in a double peel-pouch packaging configuration. The outer pouch is not sterile. The inner pouch that contains the DermaBind SL X membrane is sterile unless the pouch is damaged or compromised. The product package includes a single-layer amnion membrane covering, tissue utilization record, packaging list, product labels, and instructions for use.

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, DermaBind SL X, “when intended for use ‘as a wound covering’ and ‘to protect those wounds from the 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 Q4428, “Dermabind sl n or dermabind sl + or dermabind sl x, per square centimeter (add-on, list separately in addition to primary procedure)”

This coding determination applies to the DermaBind SL X product described in the application and accompanying FDA TRG letter dated April 24, 2025, when intended for use as a “wound covering” and “to protect those wounds from the environment.”

DermaBind SL + - HCP250924E0UYM

Topic/Issue

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

Applicant's suggested language: QXXXX, “DermaBind SL + per sq cm”

Summary of Applicant's Submission

HealthTech Wound Care submitted a request to establish a new HCPCS Level II code to identify DermaBind SL +. DermaBind SL + is regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) solely under section 361 of the Public Health Service (PHS) Act and 21 CFR part 1271 when intended for use as a “wound covering” and “to protect those wounds from the environment.” DermaBind SL + is a dehydrated human single-layer amnion membrane comprised of an extracellular matrix that is rich in collagen, fibrin, and elastin fibers native to the tissue. It is designed as a wound covering. DermaBind SL + is a wound covering designed for application directly to acute and chronic wounds, is flexible, and is a conforming cover that adheres to complex anatomies. DermaBind SL + membrane protects the wound from the external environment and maintains a moist environment. Before application, ensure the wound and/or skin is debrided, is clean, and free of infection. To apply DermaBind SL +, place the membrane onto the wound surface with the amnion (epithelial) side facing the wound. Smooth the membrane with non-toothed forceps. To discourage membrane displacement following transplantation, DermaBind SL + may be affixed to the site using aseptic technique with a variety of wound closure mechanisms, including absorbable sutures, non-absorbable sutures, non-adhesive wrapping, adhesive wrapping, and/or tissue adhesive appropriate for the procedure type. The membrane will be easier to suture before hydration. DermaBind SL + can be rehydrated using sterile water if hydrated before securing it to the wound, by wound exudate if applied before hydration to a lightly exuding wound, and by hydrating with sterile water after the membrane is applied to the wound. DermaBind SL + is packaged in a double peel-pouch packaging configuration. The outer pouch is not sterile. The inner pouch that contains the DermaBind SL + membrane is sterile unless the pouch is damaged or compromised. The product package includes a single-layer amnion membrane covering, tissue utilization record, packaging list, product labels, and instructions for use.

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, DermaBind SL +, “when intended for use ‘as a wound covering’ and ‘to protect those wounds from the 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 Q4428, “Dermabind sl n or dermabind sl + or dermabind sl x, per square centimeter (add-on, list separately in addition to primary procedure)”

This coding determination applies to the DermaBind SL + product described in the application and accompanying FDA TRG letter dated April 24, 2025, when intended for use as a “wound covering” and “to protect those wounds from the environment.”

DermaBind CH N - HCP2509242UP9A

Topic/Issue

Request to establish a new HCPCS Level II code to identify DermaBind CH N.

Applicant's suggested language: QXXXX, “DermaBind CH N per sq cm”

Summary of Applicant's Submission

HealthTech Wound Care submitted a request to establish a new HCPCS Level II code to identify DermaBind CH N. DermaBind CH N is regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) solely under section 361 of the Public Health Service (PHS) Act and 21 CFR part 1271 when intended for use as a “wound covering” and “to protect those wounds from the environment.” DermaBind CH N is a dehydrated human single-layer chorion membrane comprised of an extracellular matrix that is rich in collagen, fibrin, and elastin fibers native to the tissue. It is designed as a wound covering. DermaBind CH N is a wound covering designed for application directly to acute and chronic wounds, is flexible, and is a conforming cover that adheres to complex anatomies. DermaBind CH N membrane protects the wound from the external environment and maintains a moist environment. Before application, ensure the wound and/or skin is debrided, is clean, and free of infection. To apply DermaBind CH N, place the membrane onto the wound surface with the amnion (epithelial) side facing the wound. Smooth the membrane with non-toothed forceps. To discourage membrane displacement following transplantation, DermaBind CH N may be affixed to the site using aseptic technique with a variety of wound closure mechanisms, including absorbable sutures, non-absorbable sutures, non-adhesive wrapping, adhesive wrapping, and/or tissue adhesive appropriate for the procedure type. The membrane will be easier to suture before hydration. DermaBind CH N can be rehydrated using sterile water if hydrated before securing it to the wound, by wound exudate if applied before hydration to a lightly exuding wound, and by hydrating with sterile water after the membrane is applied to the wound. DermaBind CH N is packaged in a double peel-pouch packaging configuration. The outer pouch is not sterile. The inner pouch that contains the DermaBind CH N membrane is sterile unless the pouch is damaged or compromised. The product package includes a single-layer chorion membrane covering, tissue utilization record, packaging list, product labels, and instructions for use.

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, DermaBind CH N, “when intended for use ‘as a wound covering’ and ‘to protect those wounds from the 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 Q4429, “Dermabind ch n or dermabind ch x, per square centimeter (add-on, list separately in addition to primary procedure)”

This coding determination applies to the DermaBind CH N product described in the application and accompanying FDA TRG letter dated April 24, 2025, when intended for use as a “wound covering” and “to protect those wounds from the environment.”

DermaBind CH X - HCP250924V469G

Topic/Issue

Request to establish a new HCPCS Level II code to identify DermaBind CH X.

Applicant's suggested language: QXXXX, “DermaBind CH X per sq cm”

Summary of Applicant's Submission

HealthTech Wound Care submitted a request to establish a new HCPCS Level II code to identify DermaBind CH X. DermaBind CH X is regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) solely under section 361 of the Public Health Service (PHS) Act and 21 CFR part 1271 when intended for use as a “wound covering” and “to protect those wounds from the environment.” DermaBind CH X is a dehydrated human single-layer chorion membrane comprised of an extracellular matrix that is rich in collagen, fibrin, and elastin fibers native to the tissue. It is designed as a wound covering. DermaBind CH X is a wound covering designed for application directly to acute and chronic wounds, is flexible, and is a conforming cover that adheres to complex anatomies. DermaBind CH X membrane protects the wound from the external environment and maintains a moist environment. Before application, ensure the wound and/or skin is debrided, is clean, and free of infection. To apply DermaBind CH X, place the membrane onto the wound surface with the amnion (epithelial) side facing the wound. Smooth the membrane with non-toothed forceps. To discourage membrane displacement following transplantation, DermaBind CH X may be affixed to the site using aseptic technique with a variety of wound closure mechanisms, including absorbable sutures, non-absorbable sutures, non-adhesive wrapping, adhesive wrapping, and/or tissue adhesive appropriate for the procedure type. The membrane will be easier to suture before hydration. DermaBind CH X can be rehydrated using sterile water if hydrated before securing it to the wound, by wound exudate if applied before hydration to a lightly exuding wound, and by hydrating with sterile water after the membrane is applied to the wound. DermaBind CH X is packaged in a double peel-pouch packaging configuration. The outer pouch is not sterile. The inner pouch that contains the DermaBind CH X membrane is sterile unless the pouch is damaged or compromised. The product package includes a single-layer chorion membrane covering, tissue utilization record, packaging list, product labels, and instructions for use.

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, DermaBind CH X, “when intended for use ‘as a wound covering’ and ‘to protect those wounds from the 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 Q4429, “Dermabind ch n or dermabind ch x, per square centimeter (add-on, list separately in addition to primary procedure)”

This coding determination applies to the DermaBind CH X product described in the application and accompanying FDA TRG letter dated April 24, 2025, when intended for use as a “wound covering” and “to protect those wounds from the environment.”

BioLab Membrane Wrap -Lite Flow™ - HCP250903R17F6

Topic/Issue

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

The applicant did not submit any suggested language.

Summary of Applicant's Submission

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

CMS Final HCPCS Coding Determination

After review of the Food and Drug Administration's (FDA's) Tissue Reference Group (TRG) letter submitted by the applicant, BioLab Membrane Wrap -Lite Flow™, "when intended to be used as a 'cover' and 'barrier,' appear[s] to meet the criteria for regulation solely under section 361 of the PHS Act and the regulations in 21 CFR part 1271." As a result of our review of the TRG's feedback, CMS has decided to:

Establish a new HCPCS Level II code Q4419, "Biolab membrane wrap lite flow, per square centimeter (add-on, list separately in addition to primary procedure)"

This coding determination applies to the BioLab Membrane Wrap -Lite Flow™ product described in the application and accompanying FDA TRG letter dated July 10, 2025, when intended for use as a "cover" and "barrier."

BioLab Membrane Wrap- Solo™ - HCP250904JD3NP

Topic/Issue

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

The applicant did not submit any suggested language.

Summary of Applicant's Submission

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

CMS Final HCPCS Coding Determination

After review of the Food and Drug Administration's (FDA's) Tissue Reference Group (TRG) letter submitted by the applicant, BioLab Membrane Wrap- Solo™, "when intended to be used as a 'cover' and 'barrier,' appear[s] to meet the criteria for regulation solely under section 361 of the PHS Act and the regulations in 21 CFR part 1271." As a result of our review of the TRG's feedback, CMS has decided to:

Establish a new HCPCS Level II code Q4421, "Biolab membrane wrap solo, per square centimeter (add-on, list separately in addition to primary procedure)"

This coding determination applies to the BioLab Membrane Wrap- Solo™ product described in the application and accompanying FDA TRG letter dated July 10, 2025, when intended for use as a "cover" and "barrier."

BioLab Membrane Wrap Flow™ - HCP250827PKD8N

Topic/Issue

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

The applicant did not submit any suggested language.

Summary of Applicant's Submission

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

CMS Final HCPCS Coding Determination

After review of the Food and Drug Administration's (FDA's) Tissue Reference Group (TRG) letter submitted by the applicant, BioLab Membrane Wrap Flow™, "when intended to be used as a 'cover' and 'barrier,' appear[s] to meet the criteria for regulation solely under section 361 of the PHS Act and the regulations in 21 CFR part 1271." As a result of our review of the TRG's feedback, CMS has decided to:

Establish a new HCPCS Level II code Q4418, "Biolab membrane wrap flow, per square centimeter (add-on, list separately in addition to primary procedure)"

This coding determination applies to the BioLab Membrane Wrap Flow™ product described in the application and accompanying FDA TRG letter dated July 10, 2025, when intended for use as a "cover" and "barrier."

A/C Wrap™ - HCP250904U2VT0

Topic/Issue

Request to establish a new HCPCS Level II code to identify A/C Wrap™.

The applicant did not submit any suggested language.

Summary of Applicant's Submission

BioLab Holdings submitted a request to establish a new HCPCS level II code to identify A/C Wrap™. A/C Wrap™ is regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) solely under section 361 of the Public Health Service (PHS) Act and 21 CFR part 1271 when intended for use as a "barrier" and "provide coverage from the surrounding environment." A/C Wrap™ dosage is per square centimeter. This product is indicated for chronic and acute wounds. After preparation of the wound site, the human dual-layer amnion and chorion allograft is applied to the wound surface by a licensed healthcare provider and secured in place by their choice of fixation. Reapplication is determined by the clinician. The route of administration is topical, applying the product to the wound base. A/C Wrap™ serves as a protective covering from the surrounding environment. It is available in various sizes to be used by the clinician. The product comes in a double pouch for aseptic presentation of the packaged product onto the sterile field. The inner pouch is both sterile and a moisture barrier. The outer pouch is a peel pouch for aseptic presentation to the sterile field, and it is transparent on one side to allow for visualization of the contents.

CMS Final HCPCS Coding Determination

After review of the Food and Drug Administration's (FDA's) Tissue Reference Group (TRG) letter submitted by the applicant, A/C Wrap™, "when intended to be used as a barrier and provide 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 Q4422, "A/c wrap, per square centimeter (add-on, list separately in addition to primary procedure)"

This coding determination applies to the A/C Wrap™ product described in the application and accompanying FDA TRG letter dated July 10, 2025, when intended for use as a "barrier" and "provide coverage from the surrounding environment."

Renati Membrane - HCP250930A3HMB

Topic/Issue

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

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

Summary of Applicant's Submission

Pinnacle Transplant Technologies submitted a request to establish a new HCPCS level II code to identify Renati Membrane. Renati 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 “wound covering” and “to act as a barrier to protect the wound.” Renati Membrane is a sterile, single-use, dehydrated allograft derived from donated human placental birth tissue. Renati Membrane is comprised of amniotic membrane. Renati Membrane is intended for use as a wound covering and acts as a barrier for full and partial-thickness, chronic and acute wounds. The product is prescribed and applied by a qualified health care professional. Renati Membrane is available in multiple sizes. The allograft is processed using aseptic techniques and terminally sterilized. Each allograft is packaged in a primary foil pouch and a secondary Tyvek® pouch and sterilized. A single sterile, double-pouched membrane is provided in a solid bleached sulfate paperboard box. Renati Membrane must be stored at an ambient temperature of 15-30°C (59-86°F) before application and may be stored up to 5 years.

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, Renati Membrane, “when intended to for use as a wound covering and to act as a barrier to protect the wound, 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 Q4435, “Renati membrane, per square centimeter (add-on, list separately in addition to primary procedure)”

This coding determination applies to the Renati Membrane product described in the application and accompanying FDA TRG letter dated August 8, 2025, when intended for use as a “wound covering” and “to act as a barrier to protect the wound.”

Renati AC Membrane - HCP250930QA3VR

Topic/Issue

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

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

Summary of Applicant's Submission

Pinnacle Transplant Technologies submitted a request to establish a new HCPCS level II code to identify Renati AC Membrane. Renati AC 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 “wound covering” and “to act as a barrier to protect the wound.” Renati AC Membrane is a sterile, single-use, dehydrated resorbable allograft derived from donated human placental birth tissue. Renati AC Membrane is comprised of amniotic membrane. Renati AC Membrane is intended for use as a wound covering and acts as a barrier for full and partial-thickness, chronic and acute wounds. The product is prescribed and applied by a qualified health care professional. Renati AC Membrane is available in multiple sizes. The allograft is processed using aseptic techniques and terminally sterilized. Each allograft is packaged in a primary foil pouch and a secondary Tyvek® pouch and sterilized. A single sterile, double-pouched membrane is provided in a solid bleached sulfate paperboard box. Renati AC Membrane must be stored at an ambient temperature of 15-30°C (59-86°F) before application and may be stored for up to 5 years.

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, Renati AC Membrane, “when intended to for use as a wound covering and to act as a barrier to protect the wound, 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 Q4436, “Renati ac membrane, per square centimeter (add-on, list separately in addition to primary procedure)”

This coding determination applies to the Renati AC Membrane product described in the application and accompanying FDA TRG letter dated August 8, 2025, when intended for use as a “wound covering” and “to act as a barrier to protect the wound.”

Revive TL - HCP250929CLEUF

Topic/Issue

Request to establish a new HCPCS Level II code to identify Revise TL.

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

Summary of Applicant's Submission

Acesso Biologics LLC dba Dynamic Medical Services submitted a request to establish a new HCPCS level II code to identify Revive TL. Revive TL is regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) solely under section 361 of the Public Health Service (PHS) Act and 21 CFR part 1271 when intended for use as a “barrier” or “cover.” Revive TL membrane is a sterile, single-use, dehydrated resorbable allograft derived from donated human placental birth tissue. Revive TL is a triple-layer amnion membrane. Revive TL provides wound covering and barrier for acute and chronic wounds. The product is prescribed and administered by a qualified healthcare professional. Revive TL is designed for easy handling capabilities and allows for fixation to the wound when medically necessary. The allograft is processed using aseptic techniques and terminally sterilized by electron beam. Each allograft is packaged in a primary foil pouch and a secondary Tyvek® pouch. A single sterile, double-pouched membrane is provided in a solid bleached sulfate paperboard box. Revive TL must be stored at an ambient temperature of 15-30°C (59-86°F) before application and may be stored for up to 5 years.

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

Establish a new HCPCS Level II code Q4425, “Revive tl, per square centimeter (add-on, list separately in addition to primary procedure)”

This coding determination applies to the Revive TL product described in the application and accompanying FDA TRG letter dated July 10, 2025, when intended for use as a “barrier” or “cover.”

BioLab Tri-Membrane Wrap Flow™ - HCP250827D23U2

Topic/Issue

Request to establish a new HCPCS Level II code to identify BioLab Tri-Membrane Wrap Flow™.

The applicant did not submit any suggested language.

Summary of Applicant's Submission

BioLab Holdings submitted a request to establish a new HCPCS level II code to identify BioLab Tri-Membrane Wrap Flow™. BioLab Tri-Membrane Wrap Flow™ 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." BioLab Tri-Membrane Wrap Flow™ dosage is per square centimeter. The route of administration is topical, with the allograft applied to the wound base. The product is indicated for chronic and acute wounds. After preparation of the wound site, a human amnion tri-layer allograft is applied to the wound surface by a licensed healthcare provider and secured in place using their preferred method of fixation. Reapplication is determined by the clinician. BioLab Tri-Membrane Wrap Flow™ serves as a protective covering from the surrounding environment. It is available in various sizes. BioLab Tri-Membrane Wrap Flow™ is aseptically packaged in a double pouch. The inner pouch is both sterile and a moisture barrier. The outer pouch is a peel pouch for aseptic presentation to the sterile field, and it is transparent on one side to allow for visualization of the contents.

CMS Final HCPCS Coding Determination

After review of the Food and Drug Administration's (FDA's) Tissue Reference Group (TRG) letter submitted by the applicant, BioLab Tri-Membrane Wrap Flow™, "when intended to be used as a 'cover' and 'barrier,' appear[s] to meet the criteria for regulation solely under section 361 of the PHS Act and the regulations in 21 CFR part 1271." As a result of our review of the TRG's feedback, CMS has decided to:

Establish a new HCPCS Level II code Q4423, "Biolab tri-membrane wrap flow, per square centimeter (add-on, list separately in addition to primary procedure)"

This coding determination applies to the BioLab Tri-Membrane Wrap Flow™ product described in the application and accompanying FDA TRG letter dated July 10, 2025, when intended for use as a "cover" and "barrier."

CuraMatrix - HCP251001YYUV6

Topic/Issue

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

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

Summary of Applicant's Submission

Xtant Medical submitted a request to establish a new HCPCS Level II code to identify CuraMatrix. CuraMatrix is regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) solely under section 361 of the Public Health Service (PHS) Act and 21 CFR part 1271 when intended for use as a “barrier” and “to provide protective coverage from the surrounding environment.” CuraMatrix is a sterile, dehydrated, textured, single-layer amniotic membrane obtained from healthy deliveries following informed consent. CuraMatrix is intended to serve as a barrier and provide protective coverage from the surrounding environment when topically applied to chronic and acute wounds. CuraMatrix is available in a variety of sizes. Dosage is per square centimeter, based on the size of the wound. CuraMatrix is topically applied and positioned as needed to completely contact the entire surface of the wound bed and adheres to the wound bed without fixation. CuraMatrix is 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, CuraMatrix, “when intended to serve as a barrier and to provide protective coverage from the surrounding environment, 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 Q4440, “Curamatrix, per square centimeter (add-on, list separately in addition to primary procedure)”

This coding determination applies to the CuraMatrix product described in the application and accompanying FDA TRG letter dated July 10, 2025, when intended for use as a “barrier” and “to provide protective coverage from the surrounding environment.”

Pretect - HCP25100165A61

Topic/Issue

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

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

Summary of Applicant's Submission

Stimlabs LLC submitted a request to establish a new HCPCS Level II code to identify Pretect. Pretect 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 membrane or wound covering” and “not intended for wound healing.” Pretect is comprised of dehydrated human amniotic membrane obtained from donated placental tissue. This allograft contains non-viable cells and is intended for use as a barrier membrane or protective wound covering to protect wounds from the surrounding environment. The processed membrane is dehydrated, cut into various sizes, and presented in a sterilized, dehydrated sheet graft form. Pretect is indicated for use over acute and chronic wounds, such as dermal wounds and surgical defects. Pretect is not intended for use in pediatric populations or for ocular use. Pretect is cleaned, rinsed with sterile water or sterile saline, soaked in a proprietary solution that contains a sterilizing agent, and is again thoroughly rinsed with sterile water and or sterile saline. Pretect is a dehydrated human amniotic membrane that preserves all layers of the placental membrane and maintains the 3D physiological architecture of the natural barrier membrane. This complete barrier membrane, containing amnion, intermediate layer, and chorion, protects the surrounding environment when used as a surgical barrier membrane or wound covering. Pretect is for single use only. Pretect is offered in a variety of sheet sizes. The amount of Pretect used will be determined by the treating healthcare provider based on the size of the wound being treated. Pretect can be applied over the wound area, wet or dry. If rehydration is preferred, utilize sterile saline solution to hydrate the graft after placement. Apply several drops of sterile solution at one-to-two-minute intervals until the desired level of rehydration is achieved. Alternative methods for rehydration may be considered based upon end-user needs. To enhance contact with the wound, affix Pretect to the surgical site using aseptic technique with the preferred method of fixation. Pretect should be maintained in its original packaging and stored at ambient temperature (0°C to 38°C) until ready to use. Pretect is packaged as individual sheets. When stored properly in the original packaging, the allografts are shelf-stable for up to 5 years.

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, Pretect, “when intended for use as a barrier membrane or wound covering and ‘not intended for wound healing,’ 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 Q4438, “Pretect, per square centimeter (add-on, list separately in addition to primary procedure)”

This coding determination applies to the Pretect product described in the application and accompanying FDA TRG letter dated April 21, 2022, when intended for use as a “barrier membrane or wound covering” and “not intended for wound healing.”

REVIVAL™AC - HCP250909004YA

Topic/Issue

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

Applicant's suggested language: QXXXX, “REVIVAL™ AC, per sq cm”

Summary of Applicant's Submission

Samaritan Biologics LLC submitted a request to establish a new HCPCS Level II code to identify REVIVAL™ AC. REVIVAL™ AC is regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) solely under section 361 of the Public Health Service (PHS) Act and 21 CFR part 1271 when intended for use as a “barrier” or “cover for acute and chronic wounds.” REVIVAL™ AC is an amnion-chorion derived allograft to serve as a barrier and provide protective coverage from the surrounding environment to acute and chronic wounds. REVIVAL™AC is a sterile, single-use, dehydrated allograft derived from donated human amnion chorion membrane. REVIVAL™AC allograft provides a physical barrier to the wound. The product dosage is per square centimeter, depending on the size of the wound. REVIVAL™AC is intended for external application, and the graft can be reapplied as needed. Following standard wound preparation, REVIVAL™AC is applied directly to the wound. REVIVAL™AC adheres to the wound bed with or without fixation. REVIVAL™AC does not have to be removed from the wound bed. REVIVAL™AC is supplied sterile in a variety of 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, REVIVAL™ AC, “when intended for use as a barrier or cover for acute and chronic wounds, it appears to meet the criteria for regulation solely under section 361 of the 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 Q4437, “Revival ac, per square centimeter (add-on, list separately in addition to primary procedure)”

This coding determination applies to the REVIVAL™ AC product described in the application and accompanying FDA TRG letter dated July 10, 2025, when intended for use as a “barrier” or “cover for acute and chronic wounds.”

HCPCS Level II Codes for Various FDA Approvals under a 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 a 505(b)(2) New Drug Application (NDA) or a BLA 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[2], 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. 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[3] to identify the correct billing and payment code for each applicable product.

CMS Final HCPCS Coding Determination

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

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

[2] 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.

[3] 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 a 505(b)(2) NDA or a BLA after October 2003, and not rated as therapeutically equivalent to a reference listed product in an existing code, as well as products that have been “not otherwise classified.

Appendix A: HCPCS Level II Codes for Products Approved by the FDA Under a 505(b)(2) NDA or BLA and Products "Not Otherwise Classified"

HCPCS Code	Action	Long Descriptor
J0463	Add	Injection, atropine sulfate (fresenius and therapeutically equivalent), 0.01 mg
J1164	Add	Injection, diltiazem hydrochloride in 0.72% sodium chloride, 0.5 mg
J1553	Add	Injection, immune globulin (yimmugo), 100 mg