DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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Baltimore, Maryland 21244-1850

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

Second Quarter, 2024 HCPCS Coding Cycle

This document presents a summary of each HCPCS Level II code application and CMS' coding decision for each application processed in CMS' Second Quarter 2024 Drug and Biological HCPCS Level II code application review cycle. Each individual summary includes the request number; topic/issue; summary of the applicant's submission as written by the applicant with occasional non-substantive editorial changes made by CMS; and CMS' final HCPCS Level II coding decision. All new coding actions will be effective October 1, 2024, unless otherwise indicated.

The HCPCS Level II coding decisions below will also be included in the October 2024 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, and a unique code is warranted based on the statutory definition of "single source drug" in section 1847A(c)(6) of the Social Security Act, CMS will further distinguish a new code by using the brand name or manufacturer name. CMS generally creates codes for products themselves, without specifying a route of administration in the code descriptor, as there might be multiple routes of administration for the same product. Drugs that fall under this category should be billed with either JA modifier for the intravenous infusion of the drug or billed with JB modifier for subcutaneous injection of the drug. The dose descriptors assigned to codes established in this quarterly coding cycle are in alignment with these policies.

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Final Determinations for the Second Quarter 2024 Drug and Biological HCPCS Applications.

DOCIVYX - HCP2404019VBU5

Topic/Issue

Request to revise existing HCPCS Level II code J9172, “Injection, docetaxel (ingenus) not therapeutically equivalent to j9171, 1 mg” to change the manufacturer from Ingenus to Avyxa.

Applicant's suggested language: J9172, “Injection, docetaxel (Avyxa) not therapeutically equivalent to J9171, 1 mg”

Summary of Applicant's Submission

Avyxa Holdings, LLC submitted a request to revise HCPCS Level II code J9172 that describes DOCIVYX (docetaxel) injection. DOCIVYX was approved by the Food and Drug Administration (FDA) under a 505(b)(2) New Drug Application (NDA) on November 22, 2022. DOCIVYX was assigned the J code, J9172, and descriptor, “Injection, docetaxel (ingenus) not therapeutically equivalent to j9171, 1 mg,” effective January 1, 2024. In January 2024, Ingenus Pharmaceuticals, LLC transferred the NDA for DOCIVYX to Avyxa Holdings, LLC and therefore is requesting a J code descriptor change to "Injection, docetaxel (Avyxa) not therapeutically equivalent to J9171, 1 mg" to account for the product transfer.

CMS Final HCPCS Coding Decision

Revise existing HCPCS Level II code J9172, “Injection, docetaxel (ingenus) not therapeutically equivalent to j9171, 1 mg” to instead read “Injection, docetaxel (avyxa) not therapeutically equivalent to j9171, 1 mg.”

AURLUMYN™ - HCP240325L8NKG

Topic/Issue

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

Applicant's suggested language: XXXXX, “AURLUMYN™ (iloprost) injection, for intravenous use, 100mcg per 1mL”

Summary of Applicant's Submission

Eicos Sciences, Inc. submitted a request to establish a new HCPCS Level II code to identify AURLYMYN™ (iloprost) injection. AURLUMYN™ was approved by the Food and Drug Administration (FDA) under a 505(b)(2) New Drug Application (NDA) on February 13, 2024. AURLYMYN™ is intended to treat severe frostbite, a cold injury caused by exposure to freezing temperatures. AURLYMYN™ is a prostacyclin mimetic indicated for adults with severe frostbite to reduce the risk of digit amputations. AURLYMYN™ is a vasodilator and inhibits platelet aggregation. AURLYMYN™ is administered as a continuous intravenous infusion over 6 hours each day for up to a maximum of 8 consecutive days. The initial infusion is started on day 1 at a rate of 0.5 ng/kg/minute and increased in increments of 0.5 ng/kg/minute every 30 minutes according to tolerability up to 2 ng/kg/minute. Dosage is based on actual patient body weight. Dose titration steps are repeated on day 2 and day 3. From day 4 onward, the infusion is started at the highest tolerated dose from the previous day, and rate is adjusted as needed, based on tolerability. AURLYMYN™ is a clear, colorless sterile solution supplied as 100 mcg per mL single-dose glass vial per carton.

CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code J1749, “Injection, iloprost, 0.1 mcg”

XENOVIEW™ - HCP240401VRF9K

Topic/Issue

Request to establish a new HCPCS Level II to identify the procedure of preparation, measurement, and administration of an inhaled hyperpolarized contrast agent XENOVIEW™ for magnetic resonance imaging.

Applicant's suggested language: XXXXX, "Magnetic resonance imaging with inhaled hyperpolarized xenon-129 contrast agent, chest, including preparation and administration of agent"

Summary of Applicant's Submission

Polarean Inc. submitted a request to establish a new HCPCS Level II code to identify the procedure of preparation, measurement, and administration of an inhaled hyperpolarized contrast agent XENOVIEW™ for magnetic resonance imaging (MRI). A HCPCS Level II code for this new service would be used for reporting the costs and work performed as a service to patients in place of service (POS) 11, 19, 49 and 81. XENOVIEW™ (xenon Xe 129 hyperpolarized) for oral inhalation and the HPX Hyperpolarization System (HPX Gas Handling Manifold, the HPX Hyperpolarizer, HPX Polarization Measurement Station, and the XENOVIEW Dose Delivery Bag (DDB)) received the Food and Drug Administration's (FDA's) New Drug Application (NDA) approval on December 23, 2022. The corresponding XENOVIEW™ 3T Chest Coil and the XENOVIEW™ VDP Software was approved by the FDA under the 510(k) pathway. The FDA granted XENOVIEW™ the status of a New Chemical Entity designation. It has designated a five-year market exclusivity period. XENOVIEW™ is a hyperpolarized (HP) contrast agent indicated for use with MRI for evaluation of lung ventilation in adults and pediatric patients aged 12 years and older. XENOVIEW™ is produced on site by the HPX Hyperpolarization System from the isotopically enriched xenon Xe 129 Gas Blend. Xenon Xe 129 Gas Blend for preparation of XENOVIEW™ is supplied as a compressed gas under high pressure in aluminum cylinders with a volume of 6,350 L. The Gas Blend cylinder distributed by Polarean Inc. contains xenon (1%), nitrogen (10%), and helium (89%). XENOVIEW™ is prepared by trained personnel using the HPX Hyperpolarizer in the HPX Hyperpolarization System applying the FDA approved method. The HPX Hyperpolarizer transforms the inert gas, xenon Xe 129, into a HP state leaving the gases chemically unchanged, yet their nuclei are magnetically aligned. Inhaled XENOVIEW™ becomes distributed throughout the lung. HP Xe 129 nuclei are directly detected by a Xe 129 MRI Chest coil. XENOVIEW™ MRI provides measurement of regional lung function in patients undergoing evaluation of lung ventilation. XENOVIEW™ MRIs are analyzed to quantify normalized xenon intensity and used by clinicians to assist in the interpretation and numerical classification of HP Xe 129 ventilation MRIs. XENOVIEW™ is distilled into a 1,000 mL XENOVIEW™ DDB. The dosage for patient 12 years and older is 75 mL to 100 mL dose equivalent of HP Xe 129.

In September 2023, CMS established HCPCS Level II code C9791, "Magnetic resonance imaging with inhaled hyperpolarized xenon-129 contrast agent, chest, including preparation and administration of agent" for use by healthcare providers in POS 21, 22, or 24. C9791 is assigned to Ambulatory Payment Classifications (APC) 1551 with payment of $1,250.50, and based on CMS' Hospital Outpatient Prospective Payment System (OPPS) final rule, it is not suitable for CMS 1500 claim form. Several centers want to use XENOVIEW™ MRI in POS

11 and 19. A new HCPCS Level II code is requested to allow patient access to XENOVIEW™ MRI in imaging centers delivering patient care outside of the OPPS setting."

CMS Final HCPCS Coding Decision

1. Establish a new HCPCS Level II code A9610, "Xenon xe-129 hyperpolarized gas, diagnostic, per study dose" to describe the inhaled hyperpolarized contrast agent, XENOVIEW™.

   Effective 10/1/2024

2. Discontinue HCPCS Level II code C9150, "Xenon xe-129 hyperpolarized gas, diagnostic, per study dose"

   Effective 9/30/2024

CMS believes that the procedure of a MRI with inhaled hyperpolarized contrast agent, XENOVIEW™ would be typically described by a HCPCS Level I Current Procedural Terminology (CPT®) code. CMS encourages the applicant to engage with the American Medical Association about potential HCPCS Level I CPT® coding.

COMBOGESIC® IV - HCP240227APXX2

Topic/Issue

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

Applicant's suggested language:
First option: JXXXX, “COMBOGESIC IV (acetaminophen 1000mg, ibuprofen 300mg)”
Second option: JXXXX, “Inj. COMBOGSC acetaminophen/ibuprofen”

Summary of Applicant's Submission

Hikma Pharmaceuticals USA Inc. submitted a request to establish a new HCPCS Level II code to identify COMBOGESIC® IV (acetaminophen and ibuprofen) injection, for intravenous use. COMBOGESIC® IV was approved by the Food and Drug Administration (FDA) under a 505(b)(2) New Drug Application (NDA) on October 17, 2023. COMBOGESIC® IV is indicated in adults (over age 18), where an intravenous route of administration is considered clinically necessary for the relief of mild to moderate pain and the management of moderate to severe pain as an adjunct to opioid analgesics. COMBOGESIC® IV is limited in use and only indicated for short-term use of five days or less. COMBOGESIC® IV contains acetaminophen and ibuprofen as active drug substances. Acetaminophen is a non-opiate, non-salicylate analgesic. The precise mechanism of action of the analgesic properties of acetaminophen is not established but it is thought to primarily involve central actions. Ibuprofen is a nonsteroidal anti-inflammatory drug (NSAID). Its mechanism of action for analgesia, like that of other NSAIDs, is not completely understood either, but it involves inhibition of cyclooxygenase (COX-1 and COX-2). Ibuprofen is also a potent inhibitor of prostaglandin synthesis in vitro. Prostaglandins sensitize afferent nerves and potentiate the action of bradykinin in inducing pain in animal models, and are mediators of inflammation. Because ibuprofen is an inhibitor of prostaglandin synthesis, its mode of action may be due to a decrease of prostaglandins in peripheral tissues. Do not exceed the maximum total daily dose of COMBOGESIC® IV (4,000 mg acetaminophen, and 1,200 mg ibuprofen) in 24 hours or a total daily dose of 4,000 mg (4 g) of acetaminophen from all drug sources, including any other acetaminophen-containing over-the-counter, and prescription products. For adult patients weighing greater than or equal to 50 kg (actual body weight), the recommended dosage is 1,000 mg of acetaminophen, and 300 mg of ibuprofen, administered as a 15-minute IV infusion, every 6 hours, as necessary. For adult patients weighing less than 50 kg (actual body weight), the recommended dosage is 15 mg/kg acetaminophen, and 4.5 mg/kg ibuprofen, administered as a 15-minute IV infusion, every 6 hours, as necessary. COMBOGESIC® IV injection is supplied in a solution in a single-dose vial (10 vials/carton).

CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code J0138, “Injection, acetaminophen 10 mg and ibuprofen 3 mg”

Paclitaxel Protein-Bound Particles for Injectable Suspension (albumin-bound) - HCP24032960DYC

Topic/Issue

Request to discontinue an existing HCPCS Level II code J9258, “Injection, paclitaxel protein-bound particles (teva) not therapeutically equivalent to j9264, 1 mg.”

Summary of Applicant's Submission

Teva Pharmaceuticals Industries Ltd. (Teva) seeks to discontinue HCPCS Level II code J9258, “Injection, paclitaxel protein-bound particles (teva) not therapeutically equivalent to j9264, 1 mg.” Teva’s paclitaxel (paclitaxel protein-bound particles for injectable suspension albumin-bound), was approved by the Food and Drug Administration (FDA) under a 505(b)(2) New Drug Application (NDA) on February 12, 2024, as AB-rated and therapeutic equivalent to ABRAXANE® (paclitaxel bound protein particles for injectable suspension, albumin bound) by Bristol Meyers Squibb. Teva’s AB-rated and therapeutically equivalent paclitaxel product (National Drug Code, 00480-3290-01, 100 mg), should be billed under HCPCS Level II code J9264. Again, Teva’s paclitaxel product is now considered as a multi-source drug to be billed under ABRAXANE®'s existing HCPCS Level II code J9264. This drug is physician administered. It is a microtubule inhibitor indicated for the treatment of, metastatic breast cancer, after failure of combination chemotherapy for metastatic disease or relapse within 6 months of adjuvant chemotherapy, locally advanced or metastatic non-small cell lung cancer , as first-line treatment in combination with carboplatin, in patients who are not candidates for curative surgery or radiation therapy, and metastatic adenocarcinoma of the pancreas as first-line treatment, in combination with gemcitabine.

CMS Final HCPCS Coding Decision

Discontinue existing HCPCS Level II code J9258, “Injection, paclitaxel protein-bound particles (teva) not therapeutically equivalent to j9264, 1 mg.”

Effective 9/30/2024

It is believed that HCPCS Level II code J9258 is no longer needed, and keeping it would create confusion for payers and providers due to CMS’ coding guidelines for AB-rated drugs listed in the Orange Book.

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

JUBBONTI and WYOST - HCP24032826DXD

Topic/Issue

Request to establish a new HCPCS Level II code to identify JUBBONTI and WYOST.

Applicant's suggested language: QXXXX, “Injection, denosumab-bbdz, biosimilar, (Jubbonti/Wyost), 1 mg”

Summary of Applicant's Submission

Sandoz Inc. submitted a request to establish a new HCPCS Level II code to identify JUBBONTI and WYOST. JUBBONTI and WYOST (denosumab-bbdz) were approved by the Food and Drug Administration (FDA) under section 351(k) of the Public Health Service Act (PHSA) as biosimilars to PROLIA®/XGEVA® (denosumab) on March 5, 2024. JUBBONTI and WYOST are RANK ligand (RANKL) inhibitors with two different indications. Each indication is marketed with different trade names. JUBBONTI is indicated to treat postmenopausal women with osteoporosis at high risk for fracture; increase bone mass in men with osteoporosis at high risk for fracture; treat patients with glucocorticoid-induced osteoporosis at high risk for fracture; increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer; and increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer. WYOST is indicated to prevent skeletal-related events in patients with multiple myeloma and in patients with bone metastases from solid tumors; treat adults and skeletally-mature adolescents with giant cell tumors of bone that are unresectable or where surgical resection is likely to result in severe morbidity; and treat hypercalcemia of malignancy refractory to bisphosphonate therapy. JUBBONTI injection is a sterile, preservative-free, clear to slightly opalescent and colorless to slightly yellowish to slightly brownish solution for subcutaneous use and is supplied as one 60 mg/mL in a single-dose prefilled syringe per carton. Each 1 mL single-dose prefilled syringe of JUBBONTI contains 60 mg denosumab-bbdz (60 mg/mL solution), glacial acetic acid (1.021 mg), polysorbate 20 (0.1 mg), sodium hydroxide (0.499 mg), sorbitol (47 mg), and Water for Injection (USP) with a pH of 5.2. JUBBONTI is administered as a single subcutaneous injection in the upper arm, upper thigh, or abdomen, once every six months. WYOST injection is a sterile, preservative-free, clear to slightly opalescent and colorless to slightly yellowish to slightly brownish solution for subcutaneous use and is supplied as one 120 mg/1.7 mL (70 mg/mL) single-dose vial per carton. Each single-dose vial of WYOST contains 120 mg denosumab-bbdz, glacial acetic acid (1.85 mg), polysorbate 20 (0.17 mg), sodium hydroxide (0.91 mg), sorbitol (78.9 mg), and Water for Injection (USP) with a pH of 5.2. WYOST is administered as a subcutaneous injection every 4 weeks in the upper arm, upper thigh, or abdomen.

CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code Q5136, “Injection, denosumab-bbdz (jubbonti/wyost), biosimilar, 1 mg”

TYENNE® - HCP240328BVKV4

Topic/Issue

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

Applicant's suggested language: QXXXX, “Injection, tocilizumab-aazg, biosimilar, (tyenne), 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 the Biologics License Application (BLA) pathway on March 5, 2024. TYENNE® is an interleukin-6 (IL-6) receptor antagonist indicated for treatment of adult patients with moderate to severe active rheumatoid arthritis who have had an inadequate response to one or more Disease-Modifying Anti-Rheumatic Drugs (DMARDs), adult patients with giant cell arteritis, patients 2 years of age and older with active polyarticular juvenile idiopathic arthritis, and patients 2 years of age and older with active systemic juvenile idiopathic arthritis. Tocilizumab products bind to both soluble and membrane-bound IL-6 receptors (sIL-6R and mIL-6R) and have been shown to inhibit IL-6-mediated signaling through these receptors. IL-6 is a pleiotropic pro-inflammatory cytokine produced by a variety of cell types including T- and B-cells, lymphocytes, monocytes and fibroblasts. IL-6 has been shown to be involved in diverse physiological processes such as T-cell activation, induction of immunoglobulin secretion, initiation of hepatic acute phase protein synthesis, and stimulation of hematopoietic precursor cell proliferation and differentiation. IL-6 is also produced by synovial and endothelial cells leading to local production of IL-6 in joints affected by inflammatory processes such as rheumatoid arthritis. TYENNE® can be administered intravenously and subcutaneously and the dosing is weight based and varies by indication. TYENNE® for intravenous infusion use is available as 80 mg/4 mL, 200 mg/10 mL, 400 mg/20 mL in single-dose vials for further dilution prior to administration. Also, TYENNE® for subcutaneous injection is available as 162 mg/0.9 mL in a single-dose prefilled syringe or single-dose prefilled autoinjector.

CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code Q5135, “Injection, tocilizumab-aazg (tyenne), biosimilar, 1 mg”

TEVIMBRA - HCP240325X20D8

Topic/Issue

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

Applicant's suggested language: JXXXX, “tislelizumab-jsgr injection, for intravenous use, 1 mg”

Summary of Applicant's Submission

BeiGene USA, Inc. submitted a request to establish a new HCPCS Level II code to identify TEVIMBRA (tislelizumab-jsgr) injection, for intravenous use. TEVIMBRA was approved by the Food & Drug Administration (FDA) under the Biologics License Application (BLA) pathway on March 13, 2024. Orphan Drug Designation was granted previously in 2019. TEVIMBRA is a programmed death receptor-1 (PD-1) blocking antibody indicated as monotherapy for the treatment of adult patients with unresectable or metastatic esophageal squamous cell carcinoma (ESCC) after prior systemic chemotherapy that did not include a PD-(L)1 inhibitor. TEVIMBRA is a uniquely designed humanized immunoglobulin G4 (IgG4) anti-PD-1 monoclonal antibody with high affinity and binding specificity against PD-1. It is designed to minimize binding to Fc-gamma (Fcγ) receptors on macrophages, helping to aid the body’s immune cells to detect and fight tumors. Globally, esophageal cancer (EC) is the sixth most common cause of cancer-related deaths. Additionally, ESCC is the most common histologic subtype, accounting for nearly 90% of ECs. EC is a rapidly fatal disease. More than two-thirds of patients with EC have advanced metastatic disease at the time of diagnosis. TEVIMBRA injection is supplied in a carton containing one 100 mg/10 mL (10 mg/mL) single-dose vial. The recommended dose of TEVIMBRA is 200 mg administered as an intravenous infusion once every 3 weeks, until disease progression or unacceptable toxicity. The initial infusion should be administered over 60 minutes. If tolerated, subsequent infusions may be administered over 30 minutes.

CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code J9329, “Injection, tislelizumab-jsgr, 1 mg”

KISUNLA™ - HCP240205U0BNH

Topic/Issue

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

Applicant's suggested language: JXXXX, "Injection, donanemab-azbt, 350 mg, intravenous"

Applicant's Summary

Lilly submitted a request to establish a new HCPCS Level II code to identify KISUNLA™ (donanemab-azbt). KISUNLA™ was approved by the Food and Drug Administration (FDA) under the Biologics License Application (BLA) pathway on July 2, 2024. KISUNLA™ is an amyloid beta-directed antibody indicated for the treatment of Alzheimer's disease. Treatment with KISUNLA™ should be initiated in patients with mild cognitive impairment or mild dementia stage of disease, the population in which treatment was initiated in the clinical trials. KISUNLA™ is a humanized IgG1 monoclonal antibody directed against insoluble N-truncated pyroglutamate amyloid beta. The accumulation of amyloid beta plaques in the brain is a defining pathophysiological feature of Alzheimer's disease. KISUNLA™ reduces amyloid beta plaques. The recommended dosage of KISUNLA™ is 700 mg every four weeks for three doses, then 1400 mg every four weeks administered by intravenous infusion over at least 30 minutes. KISUNLA™ is supplied in one single-dose vial per carton in a concentration of 350 mg/20 mL.

CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code J0175, "Injection, donanemab-azbt, 2 mg"

The effective date aligns with the date when KISUNLA™ received traditional FDA approval and aided CMS in efficiently implementing National Coverage Determination (NCD) 200.3.

Effective July 2, 2024

Baxter's Vasopressin in Sodium Chloride Injection - HCP2403180K0BN

Topic/Issue

Request to establish a new HCPCS Level II code to identify Baxter's Vasopressin in Sodium Chloride Injection.

Applicant's suggested language: JXXXX, "Injection, Vasopressin in Sodium Chloride (Baxter), 1 unit"

Summary of Applicant's Submission

Baxter Healthcare Corporation submitted a request to establish a new HCPCS Level II code to identify Baxter's Vasopressin in Sodium Chloride Injection. Baxter's Vasopressin in Sodium Chloride Injection was approved by the Food and Drug Administration (FDA) under the 505(b)(2) New Drug Application (NDA) pathway on September 29, 2023. Baxter's Vasopressin in Sodium Chloride Injection is indicated to increase blood pressure in adults with vasodilatory shock who remain hypotensive despite fluids and catecholamines. Baxter's Vasopressin in Sodium Chloride Injection contains vasopressin, a polypeptide hormone. Vasopressin causes vasoconstriction by binding to V1 receptors on vascular smooth muscle, releasing intracellular calcium. In addition, vasopressin stimulates antidiuresis via the stimulation of V2 receptors. The recommended starting dose is 0.03 units/minute by intravenous infusion for post-cardiotomy shock and 0.01 units/minute for septic shock, titrating up by 0.005 units/minute at 10- to 15-minute intervals until the target blood pressure is reached. After the target blood pressure has been maintained for 8 hours without using catecholamines, taper vasopressin injection by 0.005 units/minute every hour as tolerated to maintain target blood pressure. Baxter's Vasopressin in Sodium Chloride Injection is supplied as a clear, sterile, colorless aqueous solution of synthetic arginine vasopressin for intravenous administration in single-dose 100 mL ready-to-use containers. Each 100 mL container contains 20 units (0.2 units/mL) or 40 units (0.4 units/mL) of vasopressin. Each 100 mL contains 900 mg sodium chloride, 33.6 mg sodium dl-lactate, and water for injection.

CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code J2601, "Injection, vasopressin (baxter), 1 unit"

Tri-Membrane Wrap™ - HCP240325E32XN

Topic/Issue

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

Applicant's suggested language: XXXXX, “Tri-Membrane Wrap™ product”

Summary of Applicant's Submission

BioLab submitted a request to establish a new HCPCS Level II code to identify Tri-Membrane Wrap™. Tri-Membrane 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 to provide protective cover.” Tri-Membrane Wrap™ is indicated for chronic and acute wounds. After preparation of the wound site, the human amnion allograft is applied to the wound surface by a licensed health care provider and secured in place with their choice of fixation. Reapplication is determined by the clinician. The route of administration is topical, applying the product over the wound. Tri-Membrane Wrap™ serves as a protective covering from the surrounding environment around the wound. Tri-Membrane Wrap™ 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. Tri-Membrane Wrap™ is available in various sizes.

CMS Final HCPCS Coding Decision

After review of the Food and Drug Administration’s (FDA’s) Tissue Reference Group (TRG) letter submitted by the applicant, “Tri-Membrane Wrap™…, when intended to be used as a ‘barrier’ and to provide ‘protective cover,’ appear to meet all the criteria for regulation solely under section 361of 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 Q4344, “Tri-membrane wrap, per square centimeter”

This coding decision applies to the Tri-Membrane Wrap ™ product described in the application and accompanying FDA TRG Letter dated July 12, 2023, when intended as “barrier and to provide protective cover.”

Dermacyte® AC Matrix Amniotic Membrane Allograft - HCP2404019QDCC

Topic/Issue

Request to establish a new HCPCS Level II code to identify Dermacyte® AC Matrix Amniotic Membrane Allograft.

Applicant's suggested language: XXXXX, “Dermacyte® AC Matrix Amniotic Membrane Allograft, per square centimeter”

Summary of Applicant's Submission

Merakris Therapeutics, Inc. submitted a request to establish a new HCPCS Level II code to identify Dermacyte® AC Matrix Amniotic Membrane Allograft. Dermacyte® AC Matrix Amniotic Membrane Allograft is regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) solely under section 361 of the Public Health Service (PHS) Act and 21 CFR Part 1271 when intended for use as a “protective covering or barrier.”

CMS Final HCPCS Coding Decision

After review of the Food and Drug Administration’s (FDA’s) Tissue Reference Group (TRG) letter submitted by the applicant, “Dermacyte® AC Matrix Amniotic Membrane Allograft, when intended for use as a ‘protective covering or barrier,’ appears to meet the criteria for regulation solely under section 361 of the PHS Act and the regulations in 21 CFR part 1271.” As a result of our review of the TRG’s feedback, CMS has decided to:

Establish a new HCPCS Level II code Q4343, “Dermacyte ac matrix amniotic membrane allograft, per square centimeter”

This coding decision applies to the Dermacyte® AC Matrix Amniotic Membrane Allograft product described in the application and accompanying FDA TRG Letter dated January 2, 2024, when intended as “protective covering or barrier.”

TheraMend - HCP240328G54T6

Topic/Issue

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

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

Summary of Applicant's Submission

Lux Therapeutics submitted a request to establish a new HCPCS Level II code to identify TheraMend. TheraMend is regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) solely under section 361 of the Public Health Service (PHS) Act and 21 CFR Part 1271 when intended for use as a “covering or barrier.” TheraMend is a patch product made from minimally processed, dehydrated amniotic membrane obtained from donated human tissue and is sterilized via gamma irradiation. TheraMend is for single-patient, one-time, homologous use only. Indications for use include topical wound covering or barrier for acute or chronic wounds. TheraMend is applied directly to the wound and can be meshed or fenestrated as needed for drainage. The decision to alter the product for wound drainage is to be made by the healthcare practitioner and done in such a way to maintain sterility of the product. TheraMend is intended to be applied to the moist wound environment and can be hydrated with sterile saline if the healthcare practitioner deems it necessary for appropriate application. TheraMend may be applied for the duration of the wound or in an interval approved by the health care practitioner. The dose or sizing of the selected TheraMend is dependent on the wound size. TheraMend is packaged in single, one-time-use pouch, which is heat sealed to maintain a secure barrier and sterilized by gamma irradiation to meet a sterility assurance level of 10-6. Once opened, TheraMend should be used immediately or discarded to prevent contamination. TheraMend can be stored in the sealed packaging at ambient temperature.

CMS Final HCPCS Coding Decision

After review of the Food and Drug Administration’s (FDA’s) Tissue Reference Group (TRG) letter submitted by the applicant, “TheraMend product, when intended to serve as a ‘covering or barrier,’ appears to meet all the criteria for regulation solely under section 361 of the PHS Act and the regulations in 21 CFR part 1271.” As a result of our review of the TRG’s feedback, CMS has decided to:

Establish a new HCPCS Level II code Q4342, “Theramend, per square centimeter”

This coding decision applies to the TheraMend product described in the application and accompanying FDA TRG Letter dated February 26, 2024, when intended to serve as a “covering or barrier.”

Matrix HD Allograft Dermis - HCP240328G61LY

Topic/Issue

Request to establish a new HCPCS Level II code to identify Matrix HD Allograft Dermis.

Applicant's suggested language: XXXXX, “Matrix HD Allograft Dermis, per square centimeter”

Summary of Applicant's Submission

Royal Wound-X, Inc, RTI Surgical, Inc submitted a request to establish a new HCPCS Level II code to identify Matrix HD Allograft Dermis. Matrix HD Allograft Dermis Matrix is regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) solely under section 361 of the Public Health Service (PHS) Act and 21 CFR Part 1271 when intended for use as a “wound cover for various wounds including diabetic foot ulcers and burns.” Matrix HD Allograft Dermis is intended as a wound cover to help repair, replace, reconstruct, or supplement damaged soft tissue in acute and chronic wounds including diabetic foot ulcers and burns. Matrix HD Allograft Dermis is available in multiple sizes. Matrix HD Allograft Dermis can be applied directly to the wound. Matrix HD Allograft Dermis is a single-use product, packaged in a primary film-Tyvek® pouch and a secondary film-Tyvek® pouch.

CMS Final HCPCS Coding Decision

After review of the Food and Drug Administration’s (FDA’s) Tissue Reference Group (TRG) letter submitted by the applicant, “Matrix HD Allograft Dermis, when intended to for use as a ‘wound cover for various wounds including diabetic foot ulcers and burns’, appears to be regulated 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 Q4345, “Matrix hd allograft dermis, per square centimeter”

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

Artacent C- HCP240313L2GV0

Topic/Issue

Request to establish a new HCPCS Level II code to identify Artacent C.

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

Summary of Applicant's Submission

Tides Medical submitted a request to establish a new HCPCS Level II code to identify Artacent C. Artacent C 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.” Artacent C is a single use, dehydrated, sterilized, human amniotic allograft (single layer chorion membrane) intended for use as a protective wound covering for acute and chronic wounds.

CMS Final HCPCS Coding Decision

After review of the Food and Drug Administration’s (FDA’s) Tissue Reference Group (TRG) letter submitted by the applicant, “Artacent C, when intended to for use as a ‘wound covering,’ appears to be regulated 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 Q4336, “Artacent c, per square centimeter”

This coding decision applies to the Artacent C product described in the application and accompanying FDA TRG Letter dated February 7, 2024, when intended to use as a “wound covering.”

Artacent Trident- HCP24031361EJA

Topic/Issue

Request to establish a new HCPCS Level II code to identify Artacent Trident.

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

Summary of Applicant's Submission

Tides Medical submitted a request to establish a new HCPCS Level II code to identify Artacent Trident. Artacent Trident 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.” Artacent Trident is a single use, dehydrated, sterilized, triple layer human amniotic membrane allograft intended for use as a wound covering for acute and chronic wounds.

CMS Final HCPCS Coding Decision

After review of the Food and Drug Administration’s (FDA’s) Tissue Reference Group (TRG) letter submitted by the applicant, “Artacent Trident, when intended to for use as a ‘wound covering,’ appears to be regulated 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 Q4337, “Artacent trident, per square centimeter”

This coding decision applies to the Artacent Trident product described in the application and accompanying FDA TRG Letter dated February 7, 2024, when intended to use as a “wound covering.”

Artacent Velos - HCP240313ACBRA

Topic/Issue

Request to establish a new HCPCS Level II code to identify Artacent Velos.

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

Summary of Applicant's Submission

Tides Medical submitted a request to establish a new HCPCS Level II code to identify Artacent Velos. Artacent Velos 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.” Artacent Velos is a single use, dehydrated, sterilized, dual layer human amniotic membrane allograft intended for use as a wound covering for acute and chronic wounds.

CMS Final HCPCS Coding Decision

After review of the Food and Drug Administration’s (FDA’s) Tissue Reference Group (TRG) letter submitted by the applicant, “Artacent Velos, when intended to for use as a ‘wound covering,’ appears to be regulated 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 Q4338, “Artacent velos, per square centimeter”

This coding decision applies to the Artacent Velos product described in the application and accompanying FDA TRG Letter dated February 5, 2024, when intended to use as a “wound covering.”

Artacent VeriClen - HCP240313YJ0JT

Topic/Issue

Request to establish a new HCPCS Level II code to identify Artacent VeriClen.

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

Summary of Applicant's Submission

Tides Medical submitted a request to establish a new HCPCS Level II code to identify Artacent VeriClen. Artacent VeriClen 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.” Artacent VeriClen is a single use, dehydrated, sterilized, human amnion-chorion membrane allograft intended for use as a wound covering for acute and chronic wounds.

CMS Final HCPCS Coding Decision

After review of the Food and Drug Administration’s (FDA’s) Tissue Reference Group (TRG) letter submitted by the applicant, “Artacent Vericlen, when intended to for use as a ‘wound covering,’ appears to be regulated 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 Q4339, “Artacent vericlen, per square centimeter”

This coding decision applies to the Artacent VeriClen product described in the application and accompanying FDA TRG Letter dated February 7, 2024, when intended to use as a “wound covering.”

AmnioPlast 1™ - HCP240322PUNEV

Topic/Issue

Request to establish a new HCPCS Level II code to identify AmnioPlast 1™.

Applicant's suggested language: XXXXX, “AmnioPlast 1™, per square centimeter”

Summary of Applicant's Submission

LifeCell International Pvt Ltd. submitted to establish a new HCPCS Level II code to identify AmnioPlast 1™. AmnioPlast 1™ is regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) solely under section 361 of the Public Health Service (PHS) Act and 21 CFR Part 1271 when intended for use as a “covering or barrier [to be] applied to the ocular surface.” AmnioPlast 1™ is a minimally manipulated, sterile, dehydrated mono-layered human amnion membrane allograft for homologous use. It is intended to be used as a protective barrier and cover that offers protection from surrounding environment in repair or reconstruction procedures of ocular diseases and/or abnormalities.

CMS Final HCPCS Coding Decision

After review of the Food and Drug Administration’s (FDA’s) Tissue Reference Group (TRG) letter submitted by the applicant, “AmnioPlast 1™, when intended for use as a ‘covering or barrier [to be] applied to the ocular surface’ 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 new HCPCS Level II code Q4334, “Amnioplast 1, per square centimeter"

This coding decision applies to the AmnioPlast 1™ product described in the application and accompanying FDA TRG Letter dated January 19, 2024, when intended to when intended for use as a “covering or barrier [to be] applied to the ocular surface.”

AmnioPlast 2™ - HCP2403238LNW4

Topic/Issue

Request to establish a new HCPCS Level II code to identify AmnioPlast 2™.

Applicant's suggested language: XXXXX, “AmnioPlast 2™, per square centimeter”

Summary of Applicant's Submission

LifeCell International Pvt Ltd submitted to establish a new HCPCS Level II code to identify AmnioPlast 2™. AmnioPlast 2™ is regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) solely under section 361 of the Public Health Service (PHS) Act and 21 CFR Part 1271 when intended for use as a “covering or barrier [to be] applied to the ocular surface.” AmnioPlast 2™ is a sterile, minimally manipulated, non-viable cellular amnion chorion membrane allograft for homologous use. It is intended to be used as a protective barrier and cover that offers protection from the surrounding environment in repair or reconstruction procedures of ocular diseases and/or abnormalities. Allograft must be stored in a clean and dry environment at ambient room temperature prior to patient application. The allograft is processed using aseptic techniques and terminally sterilized by gamma radiation. AmnioPlast 2® is packaged in a single-use primary aluminum polyester pouch and a secondary aluminum pouch. AmnioPlast 2® is available in various sizes.

CMS Final HCPCS Coding Decision

After review of the Food and Drug Administration’s (FDA’s) Tissue Reference Group (TRG) letter submitted by the applicant, “AmnioPlast 2 ™, when intended for use as a ‘covering or barrier [to be] applied to the ocular surface’ 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 new HCPCS Level II code Q4335, “Amnioplast 2, per square centimeter"

This coding decision applies to the AmnioPlast 2™ product described in the application and accompanying FDA TRG Letter dated January 19, 2024, when intended to when intended for use as a “covering or barrier [to be] applied to the ocular surface.”

SimpliMax - HCP240401DRKPF

Topic/Issue

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

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

Summary of Applicant's Submission

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

CMS Final HCPCS Coding Decision

After review of the Food and Drug Administration’s (FDA’s) Tissue Reference Group (TRG) letter submitted by the applicant, “SimpliMax, when intended to serve as a barrier and provide protective coverage from the surrounding environment, SimpliMax 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 new HCPCS Level II code Q4341, “Simplimax, per square centimeter"

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

SimpliGraft - HCP240401Q41EW

Topic/Issue

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

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

Summary of Applicant's Submission

Xtant Medical submitted a request to establish a HCPCS Level II code to identify SimpliGraft. SimpliGraft 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 protective coverage from the surrounding environment.” SimpliGraft is single-layer amniotic membrane obtained from healthy deliveries following informed consent. SimpliGraft is intended to serve as a barrier and provide protective coverage from the surrounding environment when topically applied to chronic and acute wounds.

CMS Final HCPCS Coding Decision

After review of the Food and Drug Administration’s (FDA’s) Tissue Reference Group (TRG) letter submitted by the applicant, “SimpliGraft, when intended to serve as a barrier and provide protective coverage from the surrounding environment, SimpliGraft 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 new HCPCS Level II code Q4340, “Simpligraft, per square centimeter"

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

HCPCS Level II Codes for Various FDA Approvals under the 505(b)(2) or Biologics License Application (BLA) Pathways and Products "Not Otherwise Classified" - HCP220517FAENJ

CMS has been reviewing its approach for establishing HCPCS Level II codes to identify products approved under the 505(b)(2) New Drug Application (NDA) or the Biologics License Application (BLA) pathways after October 2003. These products are not rated as therapeutically equivalent to their reference listed drug in the Food and Drug Administration's (FDA) Orange Book[1], and are therefore considered single source products. Also, this effort will help reduce use of the not otherwise classified (NOC) codes.

In order to conform with the general approach used for the assignment of products paid under section 1847A of the Social Security Act (the Act) to HCPCS Level II codes as described at the following CMS link: https://www.cms.gov/files/document/frequently-asked-questions-single-source-drugs-and-biologicals.pdf. CMS is making several code changes, including manufacturer specific codes to identify products approved under separate 505(b)(2) NDA or BLA pathways. Since the products are approved under separate 505(b)(2) NDAs and are not rated as therapeutically equivalent by the FDA in the Orange Book, they are single source drugs based on the statutory definition of "single source drug" in section 1847A(c)(6) of the Act. Because these are single source drugs, there is a programmatic need for each product to have a unique billing and payment code.

In cases where certain products meet the statutory definition of "multiple source drug" in section 1847A(c)(6) of the Act, CMS will remove the brand name of the drug from any existing HCPCS Level II code as needed as it will accommodate any associated generic product(s), if approved and marketed, that are rated as therapeutically equivalent.

Due to the complexity and nuanced nature of the differences between each product, we encourage providers to rely on the Average Sales Price (ASP) HCPCS-National Drug Code (NDC) crosswalk[2] to identify the correct billing and payment code for each applicable product.

CMS Final HCPCS Coding Decision

Establish eight new HCPCS Level II codes, revise one HCPCS Level II code, and discontinue four HCPCS Level II codes to 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.

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

[1] 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.

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

CMS intends to continue our review in subsequent HCPCS Level II code application quarterly cycles to separately identify products approved under the 505(b)(2) NDA or the BLA pathways after October 2003, and not rated as therapeutically equivalent to a reference listed product in an existing code, as well as products that have been “not otherwise classified.”

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

HCPCS Code	Action	Long Descriptor
J1170*	delete	Injection, hydromorphone, up to 4 mg
J1171	add	Injection, hydromorphone, 0.1 mg
J2001*	delete	Injection, lidocaine hcl for intravenous infusion, 10 mg
J2002	add	Injection, lidocaine hcl in 5% dextrose, 1 mg
J2003	add	Injection, lidocaine hydrochloride, 1 mg
J2004	add	injection, lidocaine hcl with epinephrine, 1 mg
J2251	revise	Injection, midazolam in 0.9% sodium chloride, intravenous, not therapeutically equivalent to J2250, 1 mg
J2252	add	Injection, midazolam in 0.8% sodium chloride, intravenous, not therapeutically equivalent to J2250, 1 mg
J2253	add	Injection, midazolam (seizalam), 1 mg
J8520*	delete	Capecitabine, oral, 150 mg
J8521*	delete	Capecitabine, oral, 500 mg
J8522	add	Capecitabine, oral, 50 mg
J8541	add	Dexamethasone (hemady), oral, 0.25 mg

* The effective date for the discontinuation of this code is September 30, 2024.