



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

Third Quarter, 2026 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' Third Quarter 2026 Drug and Biological HCPCS Level II code application review cycle. Each individual summary includes the request number; topic/issue; summary of the applicant's submission as written by the applicant with occasional non-substantive editorial changes made by CMS; and CMS' final HCPCS Level II coding determination. All new coding actions will be effective January 1, 2027, unless otherwise indicated.

The HCPCS Level II coding determinations below will also be included in the January 2027 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 Original Medicare 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 descriptors assigned to codes established in this quarterly coding cycle are in alignment with these policies.

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AVTOZMA® Intravenous - HCP260701XWEUC

Topic/Issue

Request to revise existing HCPCS Level II code Q5156, “Injection, tocilizumab-anoh (avtozma), biosimilar, 1 mg” to further identify AVTOZMA® intravenous (IV) injection.

Applicant's suggested language: Q5156, “Injection, tocilizumab-anoh (avtozma), intravenous, 1 mg”

Summary of Applicant's Submission

Celltrion USA, Inc. submitted a request to revise existing HCPCS Level II code Q5156 to remove the word biosimilar, and add IV to the descriptor to further identify AVTOZMA® (tocilizumab-anoh) IV injection. AVTOZMA® IV was originally approved by the Food and Drug Administration (FDA) under a 351(k) Biologics License Application (BLA) on January 24, 2025, under BLA 761420. On January 21, 2026, the FDA approved the prefilled syringe for subcutaneous (SC) use, and prefilled autoinjector for SC use under a new BLA 761498. Since AVTOZMA® SC injection was approved under a new, separate and unique BLA 761498, it should be distinguished from the original AVTOZMA® IV. Additionally, on January 21, 2026, the FDA revoked approval to manufacture and market AVTOZMA® for SC use under BLA 761420. AVTOZMA® is a biosimilar to ACTEMRA® (tocilizumab), and an interleukin-6 (IL-6) receptor antagonist. AVTOZMA® IV is indicated for the treatment of rheumatoid arthritis, giant cell arteritis, polyarticular juvenile idiopathic arthritis, systemic juvenile idiopathic arthritis, cytokine release syndrome, and Coronavirus Disease 2019. It is a preservative-free, sterile clear to slightly opalescent, colorless to pale yellow solution. For IV infusion, it is supplied in 80 mg/4 mL (20 mg/mL), 200 mg/10 mL (20 mg/mL), 400 mg/20 mL (20 mg/mL) single-dose vials.

CMS Final HCPCS Coding Determination

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, AVTOZMA® IV was approved by the FDA under its own unique BLA, 761420, and must be distinguished from AVTOZMA® SC which also has a unique BLA, 761498. As such, CMS will:

Revise existing HCPCS Level II code Q5156, “Injection, tocilizumab-anoh (avtozma), biosimilar, 1 mg”, to instead read, “Injection, tocilizumab-anoh, biosimilar, intravenous, 1 mg”.

AVTOZMA® Subcutaneous - HCP260701JMDYL

Topic/Issue

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

Applicant's suggested language: QXXXX, "Injection, tocilizumab-anoh (avtozma), subcutaneous, 1 mg"

Summary of Applicant's Submission

Celltrion USA, Inc. submitted a request to establish a new HCPCS Level II code to identify AVTOZMA® (tocilizumab-anoh) SC injection. AVTOZMA® was originally approved by the Food and Drug Administration (FDA) under a 351(k) Biologics License Application (BLA) on January 24, 2025, under BLA 761420. On January 21, 2026, the FDA approved the prefilled syringe for subcutaneous use, and prefilled autoinjector for SC use under a new BLA 761498. Due to the fact that AVTOZMA® SC injection was approved under a new, separate and unique BLA 761498, it should be distinguished from the original AVTOZMA® intravenous (IV). Additionally, on January 21, 2026, the FDA revoked approval to manufacture and market AVTOZMA® for SC use under BLA 761420. AVTOZMA® is a biosimilar to ACTEMRA® (tocilizumab), and an interleukin-6 (IL-6) receptor antagonist. AVTOZMA® SC is indicated for the treatment of rheumatoid arthritis (RA), giant cell arteritis (GCA), polyarticular juvenile idiopathic arthritis (PJIA), and systemic juvenile idiopathic arthritis (SJIA). Tocilizumab products bind to both soluble and membrane-bound IL-6 receptors, and have been shown to inhibit IL-6-mediated signaling through these receptors. Dosing varies based on diagnosis. For SC dosing in RA, it is weight-based. For individuals at or above 162 kg weight, the dose is 162 mg administered SC weekly. For individuals weighing less than 162 kg, 162 mg is administered SC every other week, followed by an increase to every week based on clinical response. In GCA, the dose for adults is 162 mg given weekly in an SC injection in combination with a tapering course of glucocorticoids. In PJIA, the dose is also weight-based. For individuals less than 30 kg weight, the dose is 162 mg once every 3 weeks SC. For individuals at or above 30 kg, the dose is weekly SC. For all indications, when transitioning from AVTOZMA® IV therapy to SC administration, administer the first SC dose instead of the next scheduled IV dose. SC administration is not approved for cytokine release syndrome or for the treatment of Coronavirus Disease 2019. AVTOZMA® SC injection is a preservative-free, sterile, clear to slightly opalescent, colorless to yellow solution. For SC administration, each single-dose prefilled syringe delivers 162 mg/0.9 mL, and each single-dose prefilled autoinjector delivers 162 mg/0.9 mL.

CMS Final HCPCS Coding Determination

AVTOZMA® SC injection is a self-administered drug (SAD) that can be administered by the individual or a caregiver. Generally, Medicare Part B covers drugs that are furnished "incident to" a physician's service, provided the drugs are not usually self-administered or they are administered via a covered item of durable medical equipment. AVTOZMA® SC injection meets CMS' criteria for classification as a SAD. CMS is denying the request to establish a HCPCS Level II code to identify AVTOZMA® SC injection, as the medication is self-administered.

Avzivi® - HCP260701APV32

Topic/Issue

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

Applicant's suggested language: XXXXX, "Injection, bevacizumab-tjnj, biosimilar, (Avzivi), 10mg"

Summary of Applicant's Submission

Sandoz submitted a request to establish a new HCPCS Level II code to identify Avzivi® (bevacizumab-tjnj). Avzivi® was approved by the Food and Drug Administration (FDA) under a 351(k) Biologics License Application (BLA) on December 6, 2023. Avzivi® is a biosimilar to AVASTIN® (bevacizumab). Avzivi® is indicated for the treatment of individuals with: (1) metastatic colorectal cancer (mCRC), in combination with intravenous fluorouracil-based chemotherapy for first- or second-line treatment, and in combination with fluoropyrimidine-irinotecan- or fluoropyrimidine-oxaliplatin-based chemotherapy for second-line treatment in individuals who have progressed on a first-line bevacizumab product-containing regimen (Avzivi® is not indicated for adjuvant treatment of colon cancer); (2) unresectable, locally advanced, recurrent, or metastatic non-squamous non-small cell lung cancer (NSCLC), in combination with carboplatin and paclitaxel for first-line treatment; (3) recurrent glioblastoma (GBM); (4) metastatic renal cell carcinoma (mRCC), in combination with interferon alfa; (5) persistent, recurrent, or metastatic cervical cancer, in combination with paclitaxel and cisplatin or paclitaxel and topotecan; and (6) platinum-resistant recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer, in combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan, in individuals who received no more than two prior chemotherapy regimens. Avzivi® is administered by intravenous infusion after dilution. The first infusion is administered over 90 minutes; the second infusion may be administered over 60 minutes if the first is tolerated; and all subsequent infusions may be administered over 30 minutes if the second infusion over 60 minutes is tolerated. Recommended dosing varies by indication: 5 mg/kg every 2 weeks or 10 mg/kg every 2 weeks for mCRC (regimen-dependent); 15 mg/kg every 3 weeks for first-line NSCLC; 10 mg/kg every 2 weeks for recurrent GBM; 10 mg/kg every 2 weeks for mRCC; 15 mg/kg every 3 weeks for cervical cancer; and 10 mg/kg every 2 weeks or 15 mg/kg every 3 weeks for platinum-resistant recurrent ovarian/fallopian tube/primary peritoneal cancer (chemotherapy partner-dependent). Avzivi® is supplied as a sterile, preservative-free, clear to slightly opalescent, colorless to pale brown solution for intravenous use in single-dose vials in two strengths: 100 mg/4 mL (25 mg/mL) and 400 mg/16 mL (25 mg/mL).

CMS Final HCPCS Coding Determination

Establish new HCPCS Level II code Q5174, "Injection, bevacizumab-tjnj, biosimilar, 10 mg"

Aprepitant Injectable Emulsion - HCP260701CK4MW

Topic/Issue

Request to establish a new HCPCS Level II code to identify Aprepitant Injectable Emulsion.

Applicant's suggested language: XXXXX, "Injection, aprepitant (Sandoz), 1mg"

Summary of Applicant's Submission

Sandoz submitted a request to establish a new HCPCS Level II code to identify Aprepitant Injectable Emulsion (aprepitant). Aprepitant was approved by the Food and Drug Administration (FDA) under a 505(b)(2) New Drug Application (NDA) on June 16, 2026. The recommended dosage varies based on the regimen. A single-dose regimen for highly emetogenic cancer chemotherapy and moderate emetogenic cancer chemotherapy is 130 mg intravenously. For a 3-day regimen, 100 mg is administered intravenously on day 1, followed by oral aprepitant 80 mg on days 2 and 3. Aprepitant is a sterile, opaque, off-white to amber liquid in a single-dose vial for intravenous use. Each vial contains 130 mg aprepitant in 18 mL of emulsion.

CMS Final HCPCS Coding Determination

Establish a new HCPCS Level II code J8503, "Injection, aprepitant (sandoz), 1 mg"

IMMGOLIS™ and IMMGOLIS™ INTRI - HCP260630PA9MC

Topic/Issue

Request to establish a new HCPCS Level II code to identify IMMGOLIS™ and IMMGOLIS™ INTRI.

Applicant's suggested language: XXXXX, "Injection, Golimumab-sldi, biosimilar, 1 mg"

Summary of Applicant's Submission

Accord Biopharma Inc. submitted a request to establish a new HCPCS Level II code to identify IMMGOLIS™ (golimumab-sldi) and IMMGOLIS™ INTRI (golimumab-sldi). IMMGOLIS™ and IMMGOLIS™ INTRI were approved by the Food and Drug Administration (FDA) under a 351(k) Biologics License Application (BLA) on May 15, 2026. IMMGOLIS™ is a biosimilar to SIMPONI® (golimumab) and IMMGOLIS™ INTRI is a biosimilar to SIMPONI ARIA® (golimumab). IMMGOLIS™ is indicated for the treatment of adults with moderately to severely active rheumatoid arthritis (RA) and adults with moderately to severely active ulcerative colitis. The recommended IMMGOLIS™ dosage in adults with RA is 50 mg, administered by subcutaneous injection monthly in combination with methotrexate. The recommended IMMGOLIS™ dosage in adults with moderately to severely active ulcerative colitis is 200 mg at week 0, 100 mg at week 2, 100 mg at week 6, and every 4 weeks thereafter, administered by subcutaneous injection. IMMGOLIS™ is available in 50 mg/0.5 mL and 100 mg/mL single-dose prefilled syringes. IMMGOLIS™ INTRI is indicated for the treatment of adults with moderately to severely active RA. IMMGOLIS™ INTRI dosage is 2 mg/kg, administered as an intravenous infusion over 30 minutes at weeks 0 and 4, and every 8 weeks thereafter in combination with methotrexate. IMMGOLIS™ INTRI injection is a clear, colorless to light yellow solution available in packs of one vial. Each single-dose vial contains 50 mg of IMMGOLIS™ INTRI per 4 mL.

CMS Final HCPCS Coding Determination

Establish a new HCPCS Level II code Q5175, "Injection, golimumab-sldi, biosimilar, 1 mg (code may be used for medicare when drug administered under the direct supervision of a physician, not for use when drug is self administered)"

NAVITRUX - HCP26063062JQR

Topic/Issue

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

Applicant's suggested language: JXXXX, "Injection, fosaprepitant (Avyxa), 1 mg"

Summary of Applicant's Submission

AVYXA Pharma, LLC submitted a request to establish a new HCPCS Level II code to identify NAVITRUX (fosaprepitant). NAVITRUX was approved by the Food and Drug Administration (FDA) under a 505(b)(2) New Drug Application (NDA) on June 24, 2026. NAVITRUX is an antiemetic agent and a substance P/neurokinin-1 (NK₁) receptor antagonist that functions by selectively antagonizing human NK₁ receptors. NAVITRUX is indicated, in combination with other antiemetic agents, for individuals 6 months of age and older for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy, including high-dose cisplatin, and for the prevention of delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy. In adults, NAVITRUX is administered as a single dose 150 mg intravenous infusion on day 1 over 20 to 30 minutes, completed approximately 30 minutes prior to chemotherapy. Pediatric dosing is weight- and age-based, ranging from 3 mg/kg to 150 mg, administered intravenously through a central venous catheter over 30 to 60 minutes. NAVITRUX is packaged as 150 mg of sterile, white to off-white lyophilized powder in a single-dose glass vial, 1 vial per carton.

CMS Final HCPCS Coding Determination

Establish a new HCPCS Level II code J1433, "Injection, fosaprepitant (avyxa), 1 mg"

ENNUMO™ - HCP26063022KFD

Topic/Issue

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

Applicant's suggested language: QXXXX, “Injection, Ennumo, 0.5mg”

Summary of Applicant's Submission

Accord Biopharma Inc. submitted a request to establish a new HCPCS Level II code to identify ENNUMO™ (pegfilgrastim-pccg). ENNUMO™ was approved by the Food and Drug Administration (FDA) under a 351(k) Biologics License Application (BLA) on May 7, 2026. ENNUMO™ is a biosimilar to Neulasta® (pegfilgrastim). ENNUMO™ is a colony-stimulating factor that acts on hematopoietic cells by binding to specific cell surface receptors, thereby stimulating proliferation, differentiation, commitment, and end cell functional activation. It boosts the body's production of infection-fighting white blood cells (neutrophils). It binds to granulocyte-colony stimulating factor receptors on bone marrow cells, stimulating their proliferation and maturation into neutrophils to prevent febrile neutropenia during chemotherapy. ENNUMO™ is indicated for individuals aged newborn and older to decrease the incidence of infection, as manifested by febrile neutropenia, and in individuals with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia. ENNUMO™ is also indicated to increase survival in individuals aged newborn and older acutely exposed to myelosuppressive doses of radiation. ENNUMO™ dosing is determined by indication in individuals with cancer receiving myelosuppressive chemotherapy. The recommended dosage of ENNUMO™ for individuals weighing at least 45 kg with cancer receiving myelosuppressive chemotherapy, is a single subcutaneous injection of 6 mg administered once per chemotherapy cycle. Do not administer ENNUMO™ between 14 days before and 24 hours after administration of chemotherapy. The recommended dosage of ENNUMO™ for individuals weighing at least 45 kg with hematopoietic subsyndrome of acute radiation syndrome, is two doses, 6 mg each, administered subcutaneously one week apart. The first dose is administered as soon as possible after suspected or confirmed exposure to radiation levels greater than 2 gray. The second dose is administered one week after the first dose. ENNUMO™ injection is a clear, colorless solution supplied in a prefilled single-dose syringe for manual use containing 6 mg of pegfilgrastim-pccg, supplied with a 27-gauge, 1/2-inch needle with an UltraSafe Passive™ Needle Guard. ENNUMO™ is provided in a carton containing one sterile 6 mg/0.6 mL prefilled syringe.

CMS Final HCPCS Coding Determination

Establish a new HCPCS Level II code Q5176, “Injection, pegfilgrastim-pccg, biosimilar, 0.5 mg”.

DECNUPAZ™ - HCP260630X7AMH

Topic/Issue

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

Applicant's suggested language: JXXXX, “DECNUPAZ™ (pivekimab sunirine-pvzy), for injection, for intravenous use, per 0.1 mg”

Summary of Applicant's Submission

AbbVie submitted a request to establish a new HCPCS Level II code to identify DECNUPAZ™ (pivekimab sunirine-pvzy). DECNUPAZ™ was approved by the Food and Drug Administration (FDA) under a 351(a) Biologics License Application (BLA) on May 27, 2026. DECNUPAZ™ is a CD123-directed antibody and alkylating agent antibody-drug conjugate indicated for the treatment of adults with blastic plasmacytoid dendritic cell neoplasm. DECNUPAZ™ is prescribed by a healthcare provider and may be administered in hospital outpatient or healthcare provider office settings. The recommended dosage of DECNUPAZ™ is 0.045 mg/kg administered intravenously over approximately 15–30 minutes once every 3 weeks (21-day cycle) until disease progression or unacceptable toxicity. Dosage modifications may be required because of adverse reactions. DECNUPAZ™ for injection, for intravenous infusion, is supplied as a sterile, preservative-free, white to off-white lyophilized cake in a single-dose, 2 mg glass vial for reconstitution and dilution.

CMS Final HCPCS Coding Determination

1. Establish a new HCPCS Level II code J9279, “Injection, pivekimab sunirine-pvzy, 0.01 mg”
2. Discontinue existing HCPCS Level II code C9313, “Injection, pivekimab sunirine-pvzy, 0.01 mg”

CMS has a long-standing convention to assign dose descriptors in the smallest amount that could be billed in multiple units to accommodate a variety of doses and support streamlined billing. This long-standing policy makes coding more robust and facilitates accurate payment and reporting of the exact dose administered, as only 999 units can appear on a claim line for Original Medicare using the CMS-1500 form. This framework explains the distinction between the applicant’s proposed dosage of 0.1 mg and the HCPCS Level II code J9279 designation of 0.01 mg.

EVDI - HCP2606305X5KL

Topic/Issue

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

Applicant's suggested language: XXXXX, "Intravenous injection, trabectedin, per 0.1 mg"

Summary of Applicant's Submission

Apotex, Corp. submitted a request to establish a new HCPCS Level II code to identify EVDI (trabectedin). EVDI was approved by the Food and Drug Administration (FDA) under a 505(b)(2) New Drug Application (NDA) on May 1, 2026. EVDI injection is a single source drug indicated for the treatment of adults with unresectable or metastatic liposarcoma or leiomyosarcoma who have received a prior anthracycline-containing regimen. Trabectedin is an alkylating agent that binds to guanine residues in the minor groove of deoxyribonucleic acid (DNA), forming adducts and causing the DNA helix to bend towards the major groove. Adduct formation triggers a cascade of events that can affect the subsequent activity of DNA-binding proteins, including certain transcription factors, as well as DNA repair pathways, resulting in cell cycle disruption and eventual cell death. EVDI is supplied as a solution in a single-dose glass vial containing 1 mg/20 mL (0.05 mg/mL).

CMS Final HCPCS Coding Determination

1. Establish new HCPCS Level II code J9363, "Injection, trabectedin (apotex), not therapeutically equivalent to J9362, 0.01 mg"
2. Discontinue existing HCPCS Level II code C9312, "Injection, trabectedin (apotex), not therapeutically equivalent to J9362, 0.01 mg"

CMS has a long-standing convention to assign dose descriptors in the smallest amount that could be billed in multiple units to accommodate a variety of doses and support streamlined billing. This long-standing policy makes coding more robust and facilitates accurate payment and reporting of the exact dose administered, as only 999 units can appear on a claim line for Original Medicare using the CMS-1500 form. This framework explains the distinction between the applicant's proposed dosage of 0.1 mg and the HCPCS Level II code J9363 designation of 0.01 mg.

TYENNE® - HCP260629PECNB

Topic/Issue

Request to revise existing HCPCS Level II codes 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”, 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” and 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” to include the expanded treatment indication that now includes pediatric individuals aged 2 years and older.

Applicant's suggested language:

1. Q0238, “Injection, tocilizumab-aazg, for hospitalized adult and pediatric patients aged 2 years and older with covid-19 who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ecmo) 1mg”
2. M0233, “Intravenous infusion, tocilizumab-aazg, for hospitalized adult and pediatric patients aged 2 years and older 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. M0234, “Intravenous infusion, tocilizumab-aazg, for hospitalized adult and pediatric patients aged 2 years and older 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”

Summary of Applicant's Submission

Fresenius-Kabi submitted a request to revise existing HCPCS Level II codes Q0238, M0233, and M0234 to include the expanded treatment indication to include pediatric individuals aged 2 years and older. TYENNE® was approved by the Food and Drug Administration (FDA) under a 351(k) Biologics License Application (BLA) on March 5, 2024. TYENNE® is an intravenous monoclonal antibody supplied in single-dose vials and administered as a weight-based infusion for the treatment of COVID-19 and other approved indications. The function of this therapy is to act as an interleukin-6 receptor antagonist, thereby reducing inflammatory response and improving clinical outcomes in the indicated individual populations.

CMS Final HCPCS Coding Determination

1. Revise existing 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” to instead read “Injection, tocilizumab-aazg, for hospitalized adults and pediatric patients (2 years of age and older) 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. Revise existing 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” to instead read “Intravenous infusion, tocilizumab-aazg, for hospitalized adults and pediatric patients (2 years of age and older) 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. Revise existing 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” to instead read “Intravenous infusion, tocilizumab-aazg, for hospitalized adults and pediatric patients (2 years of age and older) 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”.

Lumvoa - HCP2606294F2RP

Topic/Issue

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

Applicant's suggested language: JXXXX, "Injection, veligrotug-vvze, 10 mg"

Summary of Applicant's Submission

Viridian Therapeutics submitted a request to establish a new HCPCS Level II code to identify Lumvoa (veligrotug-vvze). Lumvoa was approved by the Food and Drug Administration (FDA) under a 351(a) Biologics License Application (BLA) on June 26, 2026. Lumvoa is indicated for the treatment of thyroid eye disease regardless of thyroid eye disease activity or duration. Lumvoa, an insulin-like growth factor-1 receptor inhibitor (IGF-1R), is a humanized IgG1κ monoclonal antibody produced in Chinese hamster ovary cells. Lumvoa binds to IGF-1R and inhibits IGF-1R signaling by blocking ligand- induced receptor autophosphorylation. Lumvoa is a full antagonist of IGF-1R. The recommended dose of Lumvoa is 10 mg/kg administered by intravenous infusion every three weeks for a total of five infusions. Lumvoa is administered as an intravenous infusion over 45 minutes for the first infusion and a minimum of 30- to 45-minute infusion for subsequent infusions. Lumvoa should only be prepared and administered by a healthcare provider. Lumvoa is supplied as a sterile, preservative-free, yellowish to brown, slightly opalescent solution in a carton containing a single-dose glass vial of Lumvoa 500 mg/10 mL (50 mg/mL).

CMS Final HCPCS Coding Determination

Establish a new HCPCS Level II code J3242, "Injection, veligrotug-vvze, 1 mg"

CMS has a long-standing convention to assign dose descriptors to 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. This framework explains the distinction between the applicant's proposed dosage of 10 mg and the HCPCS Level II code J3242 designation of 1 mg.

CLIGAVYX – HCP260629G71J3

Topic/Issue

Request to revise existing HCPCS Level II code J9393, “Injection, fulvestrant (teva), not therapeutically equivalent to j9395, 25 mg” to remove the manufacturer’s name and add the brand name CLIGAVYX to the descriptor.

Applicant's suggested language: J9393, “Injection, fulvestrant (cligavyx), 25 mg”

Summary of Applicant's Submission

Avyxa Pharma, LLC submitted a request to revise existing HCPCS Level II code J9393 to remove the manufacturer’s name and add the brand name CLIGAVYX (fulvestrant) to the descriptor. CLIGAVYX was approved by the Food and Drug Administration (FDA) under a 505(b)(2) supplemental New Drug Application (sNDA) on June 10, 2026. CLIGAVYX is an estrogen receptor antagonist that binds to the estrogen receptor in a competitive manner. CLIGAVYX is indicated for the treatment of the following conditions in postmenopausal individuals: hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced breast cancer not previously treated with endocrine therapy; HR-positive advanced breast cancer with disease progression following endocrine therapy; HR-positive, HER2-negative advanced or metastatic breast cancer in combination with ribociclib, as initial endocrine based therapy or following disease progression on endocrine therapy; and HR-positive, HER2-negative advanced or metastatic breast cancer in combination with palbociclib or abemaciclib with disease progression after endocrine therapy. The recommended adult clinical regimen is 500 mg administered intramuscularly on days 1, 15, and 29, then once monthly thereafter. For individuals with moderate hepatic impairment, the dosage is 250 mg intramuscularly on days 1, 15, and 29, and once monthly thereafter. CLIGAVYX is supplied as single-dose prefilled syringes containing 250 mg/5 mL of fulvestrant.

CMS Final HCPCS Coding Determination

1. Establish a new HCPCS Level II code J9396, “Injection, fulvestrant (avyxa), 1 mg”
2. Discontinue existing HCPCS Level II code J9393, “Injection, fulvestrant (teva), not therapeutically equivalent to j9395, 25 mg”

CMS has a long-standing convention to assign dose descriptors to 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. This framework explains the distinction between the applicant’s proposed dosage of 25 mg and the HCPCS Level II code J9396 designation of 1 mg.

Meropenem - HCP26062934GYL

Topic/Issue

Request to revise existing HCPCS Level II code J2183, “Injection, meropenem (wg critical care), not therapeutically equivalent to J2185, 100 mg” by removing the reference to a specific manufacturer of meropenem.

Applicant's suggested language: J2183, “Injection, meropenem, not therapeutically equivalent to J2185, 100 mg”

Summary of Applicant's Submission

Mylan Institutional LLC, a Viatris company, submitted a request to revise the existing HCPCS Level II code J2183 by removing the manufacturer-specific reference “wg critical care.” Meropenem, marketed by Mylan Institutional LLC, was approved by the Food and Drug Administration (FDA) under an Abbreviated New Drug Application (ANDA) on June 23, 2025. Meropenem is indicated for the treatment of individuals three months of age and older with bacterial meningitis caused by *Haemophilus influenzae*, *Neisseria meningitidis*, and penicillin-susceptible isolates of *Streptococcus pneumoniae*. Meropenem is a bactericidal carbapenem antibiotic that acts by inhibiting bacterial cell wall synthesis through binding to penicillin-binding protein targets. The recommended dosage for pediatric individuals three months of age and older with bacterial meningitis is 40 mg/kg administered every 8 hours, with a maximum dose of 2 grams every 8 hours. The product is administered by intravenous infusion over approximately 15 to 30 minutes and is supplied as a white to slightly yellow crystalline powder in 2 gram single-dose vials, packaged 6 vials per carton and requires reconstitution and dilution prior to intravenous infusion. In cases where products meet the statutory definition of “multiple source drug” under section 1847A(c)(6) of the Social Security Act (the Act), the brand name of the drug should be removed from any existing HCPCS Level II code to accommodate any associated generic product, if approved and marketed, that is rated as therapeutically equivalent in the FDA Orange Book. Mylan’s meropenem product is rated as a therapeutically equivalent generic of the meropenem reference product approved by the FDA under a 505(b)(2) New Drug Application (NDA) and marketed by WG Critical Care LLC, and the Average Sales Price HCPCS-National Drug Code crosswalk assigns the product to existing HCPCS Level II code J2183. However, the code descriptor for HCPCS Level II code J2183 specifically identifies “wg critical care” as the manufacturer, creating provider confusion about whether HCPCS Level II code J2183 applies to the therapeutically equivalent Mylan product.

CMS Final HCPCS Coding Determination

Revise existing HCPCS Level II code, J2183, “Injection, meropenem (wg critical care), not therapeutically equivalent to j2185, 100 mg” to instead read “Injection, meropenem, not therapeutically equivalent to j2185, 100 mg.”

Rocuronium Bromide - HCP260626HFE4J

Topic/Issue

Request to establish a new HCPCS Level II code to identify rocuronium bromide.

Applicant's suggested language: XXXXX, "Injection, rocuronium bromide 0.1 mg"

Summary of Applicant's Submission

Fresenius Kabi USA submitted a request to establish a new HCPCS Level II code to identify rocuronium bromide. Rocuronium bromide was approved by the Food and Drug Administration (FDA) under a 505(b)(2) New Drug Application (NDA) on June 9, 2025. Rocuronium bromide is a nondepolarizing neuromuscular blocking agent indicated as an adjunct to general anesthesia to facilitate both rapid sequence and routine tracheal intubation, and to provide skeletal muscle relaxation during surgery or mechanical ventilation. Rocuronium bromide is a fast-acting, intermediate-duration, non-depolarizing neuromuscular blocking agent used to produce temporary skeletal muscle relaxation. The dosage is individualized based on the individual's weight, the clinical objective (routine verses emergency) and concurrent anesthetic agents. Rocuronium bromide is administered intravenously only by experienced clinicians familiar with the use, actions, characteristics, and complications of neuromuscular blocking agents. Peripheral nerve stimulator recommended for determination of drug response and need for additional doses, and to evaluate recovery. Rocuronium bromide is provided in a ready-to-use formulation that does not require further preparation prior to administration and is stored at controlled room temperature (20° C to 25° C); refrigeration is not required.

CMS Final HCPCS Coding Determination

Establish a new HCPCS Level II code J0332, "Injection, rocuronium bromide, 0.1 mg"

OTARMENI™ - HCP260626NVDLG

Topic/Issue

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

Applicant's suggested language: JXXXX, "Injection, lunsotogene parvec-cwha, per treated ear, 7.2×10^{12} vector genomes"

Summary of Applicant's Submission

Regeneron Pharmaceuticals, Inc. submitted a request to establish a new HCPCS Level II code to identify OTARMENI™ (lunsotogene parvec-cwha) suspension for intracochlear infusion. OTARMENI™ was approved by the Food and Drug Administration (FDA) under a 351(a) Biologics License Application (BLA) on April 23, 2026. This indication is approved under accelerated approval based on the improvement of hearing sensitivity assessed by average pure tone audiometry at week 24 of treatment. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory clinical trial. OTARMENI™ is an adeno-associated virus vector-based gene therapy indicated for the treatment of children and adults with severe-to-profound and profound sensorineural hearing loss (any frequency >90 dB hearing level) associated with molecularly confirmed biallelic variants in the OTOF gene, preserved outer hair cell function, and no prior cochlear implant in the same ear. The recommended dose of OTARMENI™ for each ear is 7.2×10^{12} vector genomes in a total volume of 0.24 mL, administered by a single dose intracochlear infusion. OTARMENI™ is administered in the surgical suite under general anesthesia by a surgeon experienced in intracochlear surgery. OTARMENI™ is supplied as a 2 mL single-dose vial enclosed in a sealed barrier bag as package 1 of 2. Each vial contains a nominal titer of 3.0×10^{13} vg/mL of OTARMENI™ and has an extractable volume of 0.63 mL. The administration kit for use with OTARMENI™ is supplied separately as package 2 of 2.

CMS Final HCPCS Coding Determination

Establish a new HCPCS Level II code J3407, "Injection, lunsotogene parvec-cwha, per treatment"

KRESLADI – HCP260623NW2JH

Topic/Issue

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

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

Summary of Applicant's Submission

Rocket Pharmaceuticals, Inc. submitted a request to establish a new HCPCS Level II code to identify KRESLADI (marnetegrane autotemcel). KRESLADI was approved by the Food and Drug Administration (FDA) under a 351(a) Biologics License Application (BLA) on March 26, 2026. KRESLADI is an autologous hematopoietic stem cell-based gene therapy indicated for the treatment of pediatric individuals with severe leukocyte adhesion deficiency type-I due to biallelic variants in integrin subunit beta 2 without an available human leukocyte antigen-matched sibling donor for allogeneic hematopoietic stem cell transplant. KRESLADI is administered as a one-time, single dose intravenous infusion at a recommended minimum dose of 2.8×10^6 CD34+ cells/kg, calculated based on the individual's weight prior to the first apheresis. KRESLADI is supplied in one or two infusion bags, each containing approximately 30 mL of a frozen suspension of genetically modified autologous cells enriched for CD34+ cells in a cryopreservative medium containing 5% dimethyl sulfoxide and dextran 40. Each infusion bag is individually packed within an overwrap in a metal cassette for protection and shipped from the manufacturing facility to the infusion center for the treatment of one individual.

CMS Final HCPCS Coding Determination

Establish a new HCPCS Level II code J3388, “Injection, marnetegrane autotemcel, per treatment”

Ranluspec™ - HCP260623P3W7X

Topic/Issue

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

Applicant's suggested language: QXXXX, “Injection, ranibizumab-hkdz (Ranluspec), 0.1 mg”

Summary of Applicant's Submission

Lupin Pharmaceuticals, Inc. submitted a request to establish a new HCPCS Level II code to identify Ranluspec™ (ranibizumab-hkdz). Ranluspec™ was approved by the Food and Drug Administration (FDA) under a 351(k) Biologics License Application (BLA) on June 7, 2026. Ranluspec™ is biosimilar to and interchangeable with Lucentis® (ranibizumab injection) for the treatment of neovascular (wet) age-related macular degeneration, diabetic macular edema, diabetic retinopathy, macular edema following retinal vein occlusion or myopic choroidal neovascularization. By inhibiting vascular endothelial growth factor (VEGF), the growth of abnormal new blood vessels in the back of the eye can be stopped and fluid leakage will be reduced. Ranluspec™ works by blocking VEGF to prevent vision loss with the above noted diseases. Ranluspec™ is to be administered once a month (approximately every 28 days) and must be administered by a licensed ophthalmologist as an intravitreal injection (directly into the vitreous gel inside the eye), in an outpatient procedure. Ranluspec™ is packaged two ways: single-dose prefilled syringe, and single-dose glass vial.

CMS Final HCPCS Coding Determination

Establish new HCPCS Level II code Q5177, “Injection, ranibizumab-hkdz, biosimilar, 0.1 mg”

AMBELVIST® - HCP2606222T4G9

Topic/Issue

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

Applicant's suggested language: AXXXX, “Injection, gadoquatane, 1 mL”

Summary of Applicant's Submission

Bayer HealthCare LLC submitted a request to establish a new HCPCS Level II code to identify AMBELVIST® (gadoquatane). AMBELVIST® was approved by the Food and Drug Administration (FDA) under a 505(b) New Drug Application (NDA) on June 12, 2026. AMBELVIST® is indicated for use in individuals, including term neonates, in conjunction with Magnetic Resonance Imaging (MRI) to detect and visualize lesions with abnormal vascularity in the central nervous system (brain, spine, and associated tissues), the body (head and neck, thorax, abdomen, pelvis, and musculoskeletal system). AMBELVIST® is a macrocyclic gadolinium-based contrast agent (mGBCA) with a novel tetrameric structure and high relaxivity. AMBELVIST®, as a paramagnetic tetrameric macrocyclic non-ionic complex of gadolinium (Gd), develops a magnetic moment when placed in a magnetic field. The magnetic moment alters the relaxation rates of water protons in its vicinity in the body, leading to an increase in the signal intensity (brightness) of tissues. AMBELVIST® is the lowest dose mGBCA with a recommended dose of 0.01 mmol/kg actual body weight, delivering 0.04 mmol Gd/kg of body weight, resulting in 60% less Gd compared to mGBCAs with a Gd content of 0.1 mmol Gd/kg body weight and 20% less Gd compared to gadopichlenol with a Gd content of 0.05 mmol Gd/kg body weight. AMBELVIST®, when used with contrast-enhanced MRI, results yield increased lesion visualization scores (contrast enhancement, border delineation, internal morphology) for the combined pre-contrast and post-contrast MRI sets versus pre-contrast imaging alone. AMBELVIST® is administered via intravenous injection. It is supplied in various sized single-dose vials, pre-filled syringes, and imaging and pharmacy bulk packages as a sterile, clear, colorless to pale yellow solution. Each mL contains 257.9 mg gadoquatane. AMBELVIST® visualization scores and the number of lesions identified per individual were similar to those of other tested GBCAs in descriptive analyses.

CMS Final HCPCS Coding Determination

Establish a new HCPCS Level II code A9696, “Injection, gadoquatane, 0.1 ml”

Daptomycin - HCP2606086E7N9

Topic/Issue

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

Applicant's suggested language: JXXXX, "Injection, daptomycin (Par Health), room temperature, not therapeutically equivalent to J0878 or J0872, 1 mg"

Summary of Applicant's Submission

MAIA Pharmaceuticals, Inc. submitted a request to establish a new HCPCS Level II code to identify daptomycin. Daptomycin approved by the Food and Drug Administration (FDA) under a 505(b)(2) New Drug Application (NDA) on November 21, 2024. This HCPCS Level II code application request is submitted in order to separately identify daptomycin 500 mg/vial, marketed under NDA 217630, and Par Health. Daptomycin is a sterile lyophilized powder in single-dose vials for reconstitution and intravenous (IV) use. This drug functions as a cyclic lipopeptide antibacterial for infections caused by susceptible gram-positive bacteria. The existing HCPCS Level II codes J0878, "Injection, daptomycin, 1 mg" and J0872, "Injection, daptomycin (xellia), unrefrigerated, not therapeutically equivalent to j0878 or j0873, 1 mg", do not adequately describe the item because they identify other daptomycin products and do not identify the distinct FDA-approved Par Health-labeled product under NDA 217630. This product is not rated as therapeutically equivalent to products described by HCPCS Level II codes J0878 or J0872, and has labeled characteristics, including room-temperature storage, rapid reconstitution, flexible dilution, and longer in-use stability, that affect preparation, compounding, storage, handling, dispensing, inventory, nursing administration, outpatient infusion, home infusion, waste mitigation, and outpatient parenteral antimicrobial therapy delivery. Daptomycin 500 mg/vial is indicated for individuals with complicated skin and skin structure infections (cSSSI); *Staphylococcus aureus* (*S. aureus*) bloodstream infections, including right-sided infective endocarditis in adults; and *S. aureus* bloodstream infections in individuals aged one to seventeen years old. This drug is not indicated for pneumonia or left-sided infective endocarditis due to *S. aureus*, and is not recommended for individuals under the age of 1 year. It binds to the bacterial cell membrane in a calcium-dependent manner, causing depolarization, ion leakage, inhibition of deoxyribonucleic acid, ribonucleic acid, protein synthesis, and bacterial cell death. Adult dosing is 4 mg/kg IV every 24 hours for 7 to 14 days for cSSSI, and 6 mg/kg IV every 24 hours for 2 to 6 weeks for *S. aureus* bacteremia/right-sided infective endocarditis in adults with creatinine clearance at least 30 mL/min. Adults with creatinine clearance below 30 mL/min., require every 48-hour dosing. Pediatric dosing is 5 to 10 mg/kg IV every 24 hours for cSSSI for up to 14 days, and 7 to 12 mg/kg IV every 24 hours for *S. aureus* bacteremia for up to 42 days. Pediatric renal-impairment dosing has not been established. Adults may receive IV injection over 2 minutes, or IV infusion over 30 minutes; pediatric individuals receive IV infusion only, over 30 minutes for ages 7 to 17, and over 60 minutes for ages 1 to 6.

CMS Final HCPCS Coding Determination

Revise existing HCPCS Level II code J0871, "Injection, daptomycin (endo), not therapeutically equivalent to j0878, 1 mg", to instead read, "Injection, daptomycin (par health), not therapeutically equivalent to j0878, 1 mg".

WAINUA® - HCP260511E76LP

Topic/Issue

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

Applicant's suggested language: JXXXX, "Injection, eplontersen, 1 mg (code may be used for medicare when drug administered under the direct supervision of a physician, not for use when drug is self-administered)"

Summary of Applicant's Submission

AstraZeneca Pharmaceuticals LP. submitted a request to establish a new HCPCS Level II code to identify WAINUA® (eplontersen). WAINUA® was approved by the Food and Drug Administration (FDA) under a New Drug Application (NDA) on April 15, 2026. WAINUA® is indicated for the treatment of polyneuropathy in adults with hereditary transthyretin-mediated amyloidosis. WAINUA® is a transthyretin-directed antisense oligonucleotide (ASO) covalently linked to a ligand containing three N-acetylgalactosamine (GalNAc) residues to facilitate delivery of the ASO to hepatocytes. WAINUA® contains eplontersen sodium as the active ingredient. It is a GalNAc-conjugated antisense oligonucleotide that binds to transthyretin (TTR) messenger ribonucleic acid (mRNA), resulting in degradation of mutant and wild-type TTR mRNA and subsequent reduction of serum TTR protein levels and TTR protein deposits in tissues. The recommended dosage of WAINUA® is 45 mg administered by subcutaneous injection once monthly using an autoinjector or a prefilled syringe. Each autoinjector and prefilled syringe contains a single dose of WAINUA®. The autoinjector is intended for self-administration or administration by caregivers, while the prefilled syringe must be administered by a healthcare provider. WAINUA® injection is supplied as a sterile, preservative-free, clear, colorless to yellow solution.

CMS Final HCPCS Coding Determination

1. Establish a new HCPCS Level II code J0226, "Injection, eplontersen, 1 mg (code may be used for medicare when drug administered under the direct supervision of a physician, not for use when drug is self administered)"
2. Discontinue existing HCPCS Level II code C9311, "Injection, eplontersen, 1 mg (code may be used for medicare when drug administered under the direct supervision of a physician, not for use when drug is self administered)"

Mepivacaine Hydrochloride - IHC260528FXMAG

Topic/Issue

Request to discontinue existing HCPCS Level II code J0670, “Injection, mepivacaine hydrochloride, per 10 ml” and establish a new HCPCS Level II code to reflect a weight-based dose descriptor to identify mepivacaine hydrochloride.

Applicant's suggested language: JXXXX, “Injection, mepivacaine hydrochloride, 1 mg”

Summary of Applicant's Submission

An internal request was received to discontinue existing HCPCS Level II code J0670 and establish a new HCPCS Level II code to reflect a weight-based dose descriptor to identify mepivacaine hydrochloride. The existing HCPCS Level II code J0670 dose descriptor is currently based on the volume (10 mL) but the total drug amount administered can vary and claims may not accurately reflect utilization. Mepivacaine hydrochloride is approved by the Food and Drug Administration (FDA) under several Abbreviated New Drug Applications (ANDAs). Mepivacaine hydrochloride is indicated for production of local or regional analgesia and anesthesia by local infiltration, peripheral nerve block techniques, and central neural techniques. Mepivacaine hydrochloride is available in different strengths (e.g., 1%, 1.5%, 2% and 3%, corresponding to 10 mg/mL, 15 mg/mL, 20 mg/mL, and 30 mg/mL). The recommended adult dose of mepivacaine hydrochloride (or the total of a series of doses given in one procedure) for non-sedated, healthy, normal-sized individuals should not usually exceed 400 mg.

CMS Final HCPCS Coding Determination

Effective April 1, 2027, CMS will:

1. Establish a new HCPCS Level II code J0671, “Injection, mepivacaine hydrochloride, 1 mg”
2. Discontinue existing HCPCS Level II code J0670, “Injection, mepivacaine hydrochloride, per 10 ml”

Acetylcysteine Inhalation Solution - IHC260528KXHFX

Topic/Issue

Request to discontinue existing HCPCS Level II codes J7604, “Acetylcysteine, inhalation solution, compounded product, administered through dme, unit dose form, per gram” and J7608, “Acetylcysteine, inhalation solution, fda-approved final product, non-compounded, administered through dme, unit dose form, per gram” and establish two new HCPCS Level II codes to reflect smaller dose descriptors for acetylcysteine inhalation solution.

Applicant's suggested language:

1. JXXXX, “Acetylcysteine, inhalation solution, compounded product, administered through dme, unit dose form, 5 mg”
2. JXXXX, “Acetylcysteine, inhalation solution, fda-approved final product, non-compounded, administered through dme, unit dose form, 5 mg”

Summary of Applicant's Submission

An internal request was received to discontinue existing HCPCS Level II codes, J7604 and J7608, and establish two new HCPCS Level II codes for acetylcysteine inhalation solution to reflect smaller dose descriptors and prevent potential overpayment, particularly when smaller administered doses are rounded up to the 1-gram unit. Acetylcysteine oral inhalation solution is approved by the Food and Drug Administration (FDA) under several Abbreviated New Drug Applications (ANDAs). Acetylcysteine inhalation solution is indicated as adjuvant therapy for individuals with abnormal, viscid, or inspissated mucous secretions in such conditions as chronic or acute bronchopulmonary disease, pulmonary complications of cystic fibrosis, tracheostomy care, pulmonary complications associated with surgery, use during anesthesia, post-traumatic chest conditions, atelectasis due to mucous obstruction, or diagnostic bronchial studies. Depending upon the indication and when used in a nebulizer, the recommended dosage of acetylcysteine inhalation solution ranges from 3 to 5 mL of the 20% (200 mg/mL) solution or 6 to 10 mL of the 10% (100 mg/mL) solution 3 to 4 times a day.

CMS Final HCPCS Coding Determination

Effective April 1, 2027, CMS will:

1. Establish a new HCPCS Level II code J7623, “Acetylcysteine, inhalation solution, compounded product, administered through dme, unit dose form, 5 mg”
2. Establish a new HCPCS Level II code J7646, “Acetylcysteine, inhalation solution, fda-approved final product, non-compounded, administered through dme, unit dose form, 5 mg”
3. Discontinue existing HCPCS Level II code J7604, “Acetylcysteine, inhalation solution, compounded product, administered through dme, unit dose form, per gram”

4. Discontinue existing HCPCS Level II code J7608, “Acetylcysteine, inhalation solution, fda-approved final product, non-compounded, administered through dme, unit dose form, per gram”

ZYCUBO® – IHC260819RY8FT

Topic/Issue

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

Applicant's suggested language: XXXXX, “Injection, copper histidinate, 1 mg”

Summary of Applicant’s Submission

An internal request was received to establish a new HCPCS Level II code to identify ZYCUBO® (copper histidinate). ZYCUBO® was approved by the Food and Drug Administration (FDA) under a New Drug Application (NDA) on January 12, 2026. ZYCUBO® is a copper replacement product indicated for pediatric individuals with Menkes disease. The recommended dosage of ZYCUBO® is a subcutaneous injection of 1.45 mg twice daily in individuals less than 1 year of age and 1.45 mg once daily in individuals 1 year of age to less than 17 years of age. ZYCUBO® is supplied in a single-dose vial containing 2.9 mg as a lyophilized powder for reconstitution. ZYCUBO® can administered by the individual or a caregiver after proper training in subcutaneous injection technique if a healthcare provider determines that it is appropriate.

CMS Final HCPCS Coding Determination

Establish a new HCPCS Level II code J7293, “Injection, copper histidinate, 0.01 mg (code may be used for medicare when drug administered under the direct supervision of a physician, not for use when drug is self administered)”

Dextrose 5% Injection – IHC260820AYYG8

Topic/Issue

Request to discontinue existing HCPCS Level II codes J7070, “Infusion, d5w, 1000 cc” and J7060, “5% dextrose/water (500 ml = 1 unit)” and establish a new HCPCS Level II code with a smaller dose descriptor to identify dextrose 5% injection.

Applicant’s suggested language: JXXXX, “Infusion, dextrose 5% in water solution, 250 ml”

Summary of Applicant's Submission

An internal request was received to discontinue existing HCPCS Level II codes J7070 and J7060 and establish a new HCPCS Level II code with a smaller dose descriptor to identify dextrose 5% injection. Dextrose 5% injection was approved by the Food and Drug Administration (FDA) under several New Drug Applications (NDAs) prior to October 1, 2003, and several Abbreviated New Drug Applications. Dextrose 5% is indicated for intravenous infusion as a source of water and calories in adult and pediatric individuals and may also be used as a diluent for reconstitution of a powder or liquid drug product. Dextrose 5% (50 mg/mL) injection is supplied in single-dose flexible containers of various volumes ranging from 25 mL to 1000 mL. Discontinuing HCPCS Level II codes J7060 and J7070 can streamline the coding system and enhance clarity for all related products. A new HCPCS Level II code with a smaller dose descriptor will help prevent potential overpayment, particularly when smaller administered doses are rounded up to 1000 mL or 500 mL units.

CMS Final HCPCS Coding Determination

Effective April 1, 2027, CMS will:

1. Establish a new HCPCS Level II code J7065, “Infusion, dextrose 5% in water solution, 250 ml”
2. Discontinue existing HCPCS Level II code J7060, “5% dextrose/water (500 ml = 1 unit)”
3. Discontinue existing HCPCS Level II code J7070, “Infusion, d5w, 1000 cc”

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 Book¹, 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) crosswalk² to identify the correct billing and payment code for each applicable product.

CMS Final HCPCS Coding Determination

Discontinue six, revise two, and establish four new 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 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.

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/payment/fee-for-service-providers/part-b-drugs/average-drug-sales-price>.

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
J0491	Revise	Injection, anifrolumab-fnia, intravenous, 1 mg
J2544	Add	Injection, piperacillin sodium/tazobactam sodium (b. braun), 1 gram/0.125 grams (1.125 grams)
J7030	Delete	Infusion, normal saline solution, 1000 cc
J7040	Delete	Infusion, normal saline solution, sterile (500 ml = 1 unit)
J7050	Revise	Infusion, normal saline solution, 250 ml
J7518	Delete	Mycophenolic acid, oral, 180 mg
J7532	Add	Mycophenolate sodium, oral, 5 mg
J9245	Delete	Injection, melphalan hydrochloride, not otherwise specified, 50 mg
J9251	Add	Injection, melphalan hydrochloride, not otherwise specified, 1 mg
J9394	Delete	Injection, fulvestrant (fresenius kabi) not therapeutically equivalent to j9395, 25 mg
J9395	Delete	Injection, fulvestrant, 25 mg
J9397	Add	Injection, fulvestrant, 1 mg