DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

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

First 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' First 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 July 1, 2026, unless otherwise indicated.

The HCPCS Level II coding determinations below will also be included in the July 2026 HCPCS Quarterly Update, pending publication by CMS in the coming weeks at: https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update.

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

CMS has a long-standing convention to assign dose descriptors in the smallest amount that could be billed in multiple units to accommodate a variety of doses and support streamlined billing. This long-standing policy makes coding more robust and facilitates accurate payment and reporting of the exact dose administered, as only 999 units can appear on a claim line for 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 dose descriptors assigned to codes established in this quarterly coding cycle are in alignment with these policies.

Table of Contents

Final determinations for the First Quarter 2026 Drug and Biological HCPCS Level II coding applications.

1. FORZINITY™ - HCP251229AQ8J8 3
2. QIVIGY® - HCP25123009DH3 4
3. YIMMUGO® - HCP251222CX6LM 5
4. GAMMAGARD
5. LIQUID ERC® - HCP2512036P1LV 6
6. ITVISMA® - HCP251201K4J6E 7
7. WASKYRA™ - HCP251218L81R8 8
8. IOPIDINE 1% - HCP251226TDTBH 9
9. Epioxa HD and Epioxa - HCP251229CYB4Y 10
10. TYZAVAN™ - HCP2510149DMNL 11
11. YARTEMLEA® - HCP260102R7784 12
12. FERABRIGHT - HCP2512261N39W 13
13. CONTEPO - HCP251215BMWH8 14
14. Exdensur - HCP251223WWAED 15
15. Blenrep - HCP251219HQ16E 16
16. RYBREVANT FASPRO™ - HCP251218LKHH3 17
17. FESILTY™ - HCP251219CE6CB 18
18. NUFYMCO® - HCP2512312ALP1 19
19. Boncresa® - HCP251229MWG1A 20
20. Oziltus® - HCP25122928637 21
21. EYDENZELT® - HCP251224W2WNQ 23
22. OSVYRTI® and JUBEREQ® – HCP251223P6F0U 24
23. Enoby™ and Xtrenbo™ - HCP2512237JP7Y 25
24. Armlupeg® - HCP251218NLMEL 26
25. STARJEMZA® - HCP2512081N27P 27
26. Tofidence™ - HCP260309UMNMK 28
27. 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 30
28. 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” 31

FORZINITY™ - HCP251229AQ8J8

Topic/Issue

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

Applicant's suggested language: JXXXX, “FORZINITY (elamipretide) injection, for subcutaneous use, 40 mg”

Summary of Applicant's Submission

Stealth BioTherapeutics submitted a request to establish a new HCPCS Level II code to identify FORZINITY™ (elamipretide). FORZINITY™ was approved by the Food and Drug Administration (FDA) under an accelerated New Drug Application (NDA) with Orphan Drug Designation on September 19, 2025. FORZINITY™ is indicated to improve muscle strength in individuals with Barth syndrome weighing at least 30 kg. FORZINITY™ is a water-soluble, aromatic-cationic, mitochondria-targeting tetrapeptide that readily penetrates and localizes to the inner mitochondrial membrane, where it associates with cardiolipin, improving mitochondrial morphology and function. Cardiolipin plays an integral role in mitochondrial function by facilitating cristae formation, mitochondrial fusion, and mitochondrial DNA stability, ultimately leading to appropriate segregation and organization of the mitochondrial respiratory complexes into super complexes that are used for cellular energy production through oxidative phosphorylation. FORZINITY™ improves inner mitochondrial membrane stability, protein-to-protein interactions, and reduces pathogenic formation of reactive oxygen species. By improving cardiolipin biosynthesis and remodeling, FORZINITY™ targets the key deficits in Barth syndrome. The recommended dosage of FORZINITY™ in individuals weighing at least 30 kg is 40 mg administered as a subcutaneous injection in the abdomen (at least 2 inches from the navel) or outer thigh once daily. Administration should be at the same time each day, rotating the injection site. Dosing for individuals with an estimated glomerular filtration rate < 30 mL/min, not on dialysis, indicative of kidney impairment, is 20 mg daily. FORZINITY™ injection is a sterile, clear, colorless to yellow aqueous solution supplied as a carton containing four 280 mg/3.5 mL (80 mg/mL) single-use vials.

CMS Final HCPCS Coding Determination

FORZINITY™ 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 physicians’ service, provided the drugs are not usually self-administered or they are administered via a covered item of durable medical equipment (DME). FORZINITY™ meets CMS’ criteria for classification as a SAD. CMS is denying the request to establish a new HCPCS Level II code to identify FORZINITY™ as the medication is self-administered.

QIVIGY® - HCP25123009DH3

Topic/Issue

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

Applicant's suggested language: JXXXX, “Injection, immune globulin (QIVIGY), intravenous, non-lyophilized (e.g. liquid), 500mg”

Summary of Applicant's Submission

Kedrion Biopharma, Inc. submitted a request to establish a new HCPCS Level II code to identify QIVIGY® (immune globulin intravenous, human-kthm) 10% solution. QIVIGY® was approved by the Food and Drug Administration (FDA) under a 351(a) Biologics License Application (BLA) on September 26, 2025. QIVIGY® is an immunoglobulin G (IgG) replacement therapy indicated for the treatment of individuals with primary humoral immunodeficiency (PI). QIVIGY® supplies a broad spectrum of opsonizing and neutralizing IgG antibodies against bacterial and viral agents. The mechanism of action of IgG in PI has not been fully elucidated. The first infusion of QIVIGY® has a dose of 300 to 800 mg/kg, with an initial infusion rate of 1 mg/kg/min, and maintenance infusion rate (as tolerated) increase every 30 minutes to a maximum of 8 mg/kg/min. The second and subsequent infusions use the same dose, but have an initial infusion rate of 2 mg/kg/min and a maintenance infusion rate (as tolerated) increase every 15 minutes to a maximum of 8 mg/kg/min. The route of administration is intravenous. QIVIGY® is supplied in a carton of single dose 50 mL vials containing 5 grams of protein, or single dose 100 mL vials containing 10 grams of protein.

CMS Final HCPCS Coding Determination[1]

Establish new HCPCS Level II code J1577, “Injection, immune globulin (qivigy), 100 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 500 mg and the HCPCS Level II code J1577 designation of 100 mg.

We will be accepting feedback on the code descriptor in an upcoming biannual public meeting.

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

YIMMUGO® - HCP251222CX6LM

Topic/Issue

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

Applicant's suggested language: JXXXX: "Injection, immune globulin (YIMMUGO), intravenous, non-lyophilized (e.g., liquid), 500mg"

Summary of Applicant's Submission

Kedrion Biopharma, Inc submitted a request to establish a new HCPCS Level II code to identify YIMMUGO® (immune globulin intravenous, human-dira), 10% liquid. YIMMUGO® was approved by the Food and Drug Administration (FDA) under a 351(a) Biologics License Application (BLA) on June 13, 2024. YIMMUGO® is indicated for the treatment of individuals with primary humoral immunodeficiency. YIMMUGO® provides a broad spectrum of opsonizing and neutralizing immune globulin G antibodies against a wide variety of pathogens and their toxins, which helps to avoid recurrent serious opportunistic infections. The mechanism of action has not been fully elucidated by may include immunomodulatory effects. The first infusion of YIMMUGO® is dosed at 300 to 800 mg/kg (3 to 8 mL/kg) every 3 to 4 weeks, given 0.5 mg/kg/min for 30 minutes, and gradually increased every 30 minutes up to 3 mg/kg/min. From the second infusion, the dose and initial infusion rate remain the same, however the maintenance rate is gradually increased up to 13 mg/kg/min. YIMMUGO® is administered intravenously. YIMMUGO® is supplied in cartons of 50 mL (5 g), 100 mL (10 g) and 200 mL (20 g) single dose vials.

CMS Final HCPCS Coding Determination[2]

CMS established HCPCS Level II code J1553, "Injection, immune globulin (yimmugo), 100 mg" to identify YIMMUGO® via Appendix A of the Fourth Quarter 2025 Drug and Biological HCPCS Level II code application review cycle, effective April 1, 2026.[3]

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 500 mg and the HCPCS Level II code J1553 designation of 100 mg.

We will be accepting feedback on the code descriptor in an upcoming biannual public meeting.

[2] Please refer to Appendix A for additional HCPCS Level II coding actions regarding intravenous immunoglobulin products.
[3] CMS HCPCS Application Summaries and Coding Determinations, Fourth Quarter 2025 Coding Cycle at https://www.cms.gov/medicare/coding-billing/healthcare-common-procedure-system/current-prior-years-level-ii-coding-decisions

GAMMAGARD LIQUID ERC® - HCP2512036P1LV

Topic/Issue

Request to revise existing HCPCS Level II code J1569, "Injection, immune globulin, (Gammagard liquid), non-lyophilized, (e.g., liquid), 500 mg" to add GAMMAGARD LIQUID ERC® to the code descriptor.

Applicant's suggested language: J1569, "Injection, immune globulin, (Gammagard liquid/Gammagard liquid ERC), non-lyophilized, (e.g., liquid), 500 mg"

Summary of Applicant's Submission

Takeda Pharmaceuticals submitted a request to revise existing HCPCS Level II code J1569 to add GAMMAGARD LIQUID ERC®. GAMMAGARD LIQUID ERC® was approved by the Food and Drug Administration (FDA) under a 351(a) Supplemental Biologics License Application (sBLA) on June 27, 2025. GAMMAGARD LIQUID ERC® is a ready-to-use liquid, with the lowest immunoglobulin A (IgA) content of any ready-to-use liquid immunoglobulin therapy. GAMMAGARD LIQUID ERC® is indicated as replacement therapy for individuals two years of age and older with primary humoral immunodeficiency. The route of administration is intravenous infusion or subcutaneous infusion. The recommended dosage for the intravenous infusion is 300 to 600 mg/kg every 3 to 4 weeks based on clinical response. The initial dose for the subcutaneous infusion is 1.37 × previous intravenous dose divided by number of weeks between intravenous doses. The maintenance dose for the subcutaneous infusion is based on clinical response and target immunoglobulin G (IgG) trough level. GAMMAGARD LIQUID ERC® is available as a 10% IgG (100 mg/mL) solution with less than or equal to 2 µg/mL IgA. GAMMAGARD LIQUID ERC® is available in a 50 mL and 100 mL single-dose vial.

CMS Final HCPCS Coding Determination

Revise existing HCPCS Level II code J1569, "Injection, immune globulin, (gammagard liquid), non-lyophilized, (e.g., liquid), 500 mg" to instead read "Injection, immune globulin, (gammagard liquid/gammagard liquid erc), 500 mg" to describe GAMMAGARD LIQUID ERC®.

Effective January 1, 2027, CMS will discontinue HCPCS Level II code J1569 and establish HCPCS Level II code J1586, "Injection, immune globulin (gammagard liquid/gammagard liquid erc), 200 mg." Please refer to Appendix A for additional HCPCS Level II coding actions regarding intravenous immunoglobulin products, including GAMMAGARD LIQUID ERC®. We will be accepting feedback on the code descriptor in an upcoming biannual public meeting.

ITVISMA® - HCP251201K4J6E

Topic/Issue

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

Applicant's suggested language: JXXXX, “injection, onasemnogene abeparvovec-brve (intrathecal use), per treatment, 1.2 × 10^14 vector genomes”

Summary of Applicant's Submission

Novartis Pharmaceuticals Corporation submitted a request to establish a new HCPCS Level II code to identify ITVISMA® (onasemnogene abeparvovec-brve). ITVISMA® was approved by the Food and Drug Administration (FDA) under a 351(a) Biologics License Application (BLA) on November 24, 2025. ITVISMA® is a suspension of an adeno-associated virus (AAV) vector-based gene therapy designed to introduce a functional copy of the survival motor neuron gene (SMN1) in the transduced cells to address the monogenic root cause of spinal muscular atrophy (SMA). As an alternative source of SMN protein expression in motor neurons, it is expected to promote the survival and function of transduced motor neurons. ITVISMA® is an intrathecal injection of the AAV vector-based gene therapy indicated for the treatment of SMA in individuals 2 years of age and older with a confirmed mutation in SMN1. Intrathecal administration enables fixed-dose administration directly into the intrathecal space of the central nervous system. ITVISMA® is supplied as a single-dose vial containing 1.2 x 10^14 vg of onasemnogene abeparvovec-brve in 3 mL of suspension with a nominal concentration of 4 x 10^13 vg/mL, and the vial contains an extractable volume of not less than 3 mL.

CMS Final HCPCS Coding Determination

1. Establish a new HCPCS Level II code J3405, “Injection, onasemnogene abeparvovec-brve, per treatment”

2. Discontinue HCPCS Level II code C9309, “Injection, onasemnogene abeparvovec-brve, per treatment”

WASKYRA™ - HCP251218L81R8

Topic/Issue

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

Applicant's suggested language: XXXXX, “Injection, etuvetidigene autotemcel, per treatment”

Summary of Applicant's Submission

Fondazione Telethon submitted a request to establish a new HCPCS Level II code to identify WASKYRA™ (etuvetidigene autotemcel). WASKYRA™ was approved by the Food and Drug Administration (FDA) under a 351(a) Biologics License Application (BLA) on December 9, 2025. WASKYRA™ is a single-dose cell suspension administered by intravenous infusion. It is indicated for individuals 6 months and older with Wiskott-Aldrich Syndrome (WAS) who have a mutation in the WAS gene, for whom hematopoietic stem cell transplantation is appropriate, and no suitable human leukocyte antigens matched related stem cell donor is available. The therapy involves the collection of hematopoietic stem and progenitor cells, enrichment for cluster of differentiation 34+ cells, and genetic modification using a replication-incompetent, self-inactivating lentiviral vector (LVV) that carries the WAS gene. Mechanistically, WASKYRA™ introduces full-length copies of the WAS complementary deoxyribonucleic acid into the individual's hematopoietic stem cells via LVV. After infusion, these genetically modified cells engraft in the bone marrow, repopulate the hematopoietic compartment, and restore immune function by enabling expression of WAS protein, which regulates actin structure in blood cells.

CMS Final HCPCS Coding Determination

Establish a new HCPCS Level II code J3386, “Injection, etuvetidigene autotemcel, per treatment”

IOPIDINE 1% - HCP251226TDTBH

Topic/Issue

Request to establish a new HCPCS Level II code to identify IOPIDINE 1%.

Applicant's suggested language: JXXXX, “apraclonidine hydrochloride ophthalmic, 1% solution, 0.1 mL”

Summary of Applicant's Submission

Harrow Inc. submitted a request to establish a new HCPCS Level II code to identify IOPIDINE 1% (apraclonidine hydrochloride ophthalmic solution). IOPIDINE 1% was approved by the Food and Drug Administration (FDA) under a New Drug Application (NDA) on December 31, 1987. IOPIDINE 1% is an alpha-adrenergic agonist indicated to control or prevent post-surgical elevations in intraocular pressure after argon laser trabeculoplasty, argon laser iridotomy, or Neodymium-doped Yttrium Aluminum Garnet posterior capsulotomy. IOPIDINE 1% is a sterile, topical application that is administered by instillation. Dosing is one drop in the eye one hour before initiating anterior segment laser surgery and a second drop in the same eye immediately after surgery. IOPIDINE 1% is packaged in plastic ophthalmic dispensers, 0.1 mL, two per pouch.

CMS Final HCPCS Coding Determination

Establish a new HCPCS Level II code J2374, “Apraclonidine hydrochloride ophthalmic, 1% solution, 0.1 ml”

Epioxa HD and Epioxa - HCP251229CYB4Y

Topic/Issue

Request to establish a new HCPCS Level II code to identify Epioxa HD and Epioxa.

Applicant's suggested language: JXXXX, “Riboflavin 5'-phosphate, ophthalmic solution (Epioxa), per treatment”

Summary of Applicant's Submission

Glaukos submitted a request to establish a new HCPCS Level II code to identify Epioxa HD (riboflavin 5’-phosphate ophthalmic solution) 0.239%, and Epioxa (riboflavin 5’-phosphate ophthalmic solution), 0.177%. Epioxa HD and Epioxa were approved by the Food and Drug Administration (FDA) under a 505(b)(2) New Drug Application (NDA) on October 17, 2025. Epioxa HD and Epioxa are photo-enhancing drugs indicated for individuals 13 years and older with epithelium-on corneal cross-linking, known as Keratoconus. Keratoconus is an ocular condition in which a thin cornea bulges, causing distorted vision. Epioxa HD and Epioxa are for topical ophthalmic use in conjunction with the O_2n™ System and the Boost Goggles. Epioxa HD (0.239%) and Epioxa (0.177%) are packaged in a kit containing one single-dose 2 mL glass syringe each.

CMS Final HCPCS Coding Determination[4]

Establish a new HCPCS Level II code J2789, “Riboflavin 5’-phosphate, ophthalmic solution (epioxa hd/epioxa), up to 2 ml”

[4] Please refer to Appendix A for an additional HCPCS Level II coding action regarding riboflavin 5’-phosphate ophthalmic solution.

TYZAVAN™ - HCP2510149DMNL

Topic/Issue

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

Applicant's suggested language: JXXXX, “Inj vancomycin (TYZAVAN) 5mg”

Summary of Applicant's Submission

Hikma Pharmaceuticals USA Inc. submitted a request to establish a new HCPCS Level II code to identify TYZAVAN™ (vancomycin injection). TYZAVAN™ was approved by the Food and Drug Administration (FDA) under a supplemental 505(b)(2) New Drug Application (sNDA) on June 27, 2025. TYZAVAN™ is a glycopeptide antibacterial indicated for the treatment of individuals with septicemia, infective endocarditis, skin and skin structure infections, bone infections, or lower respiratory tract infections. TYZAVAN™ is available at room temperature and requires no compounding, thawing, activation or dilution.

CMS Final HCPCS Coding Determination

TYZAVAN™ was approved by the FDA under supplemental 505(b)(2) NDA (211962), which was previously associated with certain vancomycin injection products packaged by Xellia Pharmaceuticals. As such, CMS will:

Revise existing HCPCS Level II code J3375, "Injection, vancomycin hydrochloride (xellia), not therapeutically equivalent to j3373, 10 mg” to instead read “Injection, vancomycin hydrochloride (tyzavan), not therapeutically equivalent to j3373, 10 mg” to describe TYZAVAN™.

YARTEMLEA® - HCP260102R7784

Topic/Issue

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

Applicant's suggested language: JXXXX, “Injection, narsoplimab-wuug, 1 mg”

Summary of Applicant's Submission

Omeros Corporation submitted a request to establish a new HCPCS Level II code to identify YARTEMLEA® (narsoplimab-wuug). YARTEMLEA® was approved by the Food and Drug Administration (FDA) under a 351(a) Biologics License Application (BLA) on December 23, 2025. YARTEMLEA® is a mannan-binding lectin-associated serine protease 2 (MASP-2) inhibitor for the treatment of individuals with hematopoietic stem cell transplant-associated thrombotic microangiopathy (TA-TMA). YARTEMLEA® inhibits MASP-2, the effector enzyme of the lectin pathway of the complement system, blocking lectin-dependent activation of complement components 3 and 4 without affecting the classical and alternative pathways of complement. In hematopoietic stem cell TA-TMA, MASP-2 inhibition is thought to prevent lectin pathway-mediated cellular injury, including endothelial cell injury in small blood vessels. YARTEMLEA® is supplied in a 370 mg/2 mL single-dose vial as a sterile, preservative-free, clear to slightly opalescent, slightly yellow to yellow-brown solution for intravenous infusion.

CMS Final HCPCS Coding Determination

Establish new HCPCS Level II code J1289, “Injection, narsoplimab-wuug, 1 mg”

FERABRIGHT - HCP2512261N39W

Topic/Issue

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

Applicant's suggested language: AXXXX, “Intravenous Injection, FERABRIGHT (Ferumoxytol), 1 mL (contains 30 mg of elemental iron (30 mg/mL)) for use with magnetic resonance imaging of the brain”

Summary of Applicant's Submission

Azurity Pharmaceuticals Inc. submitted a request to establish a new HCPCS Level II code to identify FERABRIGHT (Ferumoxytol). FERABRIGHT was approved by the Food and Drug Administration (FDA) under a New Drug Application (NDA) on October 16, 2025. FERABRIGHT is an iron-based contrast agent indicated for use with magnetic resonance imaging of the brain for individuals with known or suspected malignant neoplasms in the brain to visualize lesions with a disrupted blood-brain barrier. The recommended dose of FERABRIGHT is 300 mg for individuals weighing 50 kg or less and 510 mg for individuals weighing 51 kg or more. FERABRIGHT is available in single-dose vials containing 300 mg/10 mL or 510 mg/17 mL (30 mg/mL) of elemental iron. FERABRIGHT must be diluted before administration in either 0.9% sodium chloride or 5% dextrose injection to achieve a concentration of 2 mg/mL to 8 mg/mL of elemental iron as an intravenous infusion over at least 15 minutes.

CMS Final HCPCS Coding Determination

Establish a new HCPCS Level II code A9574, “Injection, ferumoxytol, 1 mg”

Given that drug volume fluctuates based on the amount of diluent used during reconstitution, milligrams (mg) rather than milliliters (mL) serve as the appropriate unit of measurement for HCPCS Level II drug code descriptors. This ensures consistent and accurate dosing based on the active drug quantity administered, independent of preparation variables. 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 30 mg/mL and the HCPCS Level II code A9574 designation of 1 mg.

CONTEPO - HCP251215BMWH8

Topic/Issue

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

Applicant's suggested language: JXXXX, “Injection, fosfomycin, 1g”

Summary of Applicant's Submission

Meitheal Pharmaceuticals, Inc. submitted a request to establish a new HCPCS Level II code to identify CONTEPO (fosfomycin). CONTEPO was approved by the Food and Drug Administration (FDA) under a 505(b)(2) New Drug Application (NDA) on October 22, 2025. CONTEPO is an epoxide antibacterial indicated for the treatment of individuals 18 years of age and older with complicated urinary tract infections, including acute pyelonephritis caused by susceptible isolates of Escherichia coli and Klebsiella pneumoniae. To reduce the development of drug-resistant bacteria and maintain the effectiveness of CONTEPO and other antibacterial drugs, CONTEPO should be used only to treat infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy. The recommended dosage of CONTEPO is 6 grams administered every 8 hours by intravenous infusion over 1 hour in individuals 18 years of age or older with an estimated creatinine clearance greater than 50 mL/min; additional dosing recommendations may be required due to changes in the estimated creatinine clearance. The duration of therapy is up to 14 days and should be guided by the severity of infection and the individual’s clinical status. CONTEPO is supplied in a clear Type I glass single-dose vial for reconstitution and further dilution, with a rubber closure and a twist-off cap. The vial contains 6 grams of fosfomycin, which is a white to almost white sterile powder. Each gram of fosfomycin disodium contains 330 mg of sodium (i.e., each vial contains 1,980 mg of sodium). A total of 12 vials are supplied in each carton.

CMS Final HCPCS Coding Determination

Establish a new HCPCS Level II code J0528, “Injection, fosfomycin disodium, 20 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 1 g and the HCPCS Level II code J0528 designation of 20 mg.

Exdensur - HCP251223WWAED

Topic/Issue

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

Applicant's suggested language: JXXXX, "Injection, depemokimab-ulaa (Exdensur), 1 mg"

Summary of Applicant's Submission

GSK submitted a request to establish a new HCPCS Level II code to identify Exdensur (depemokimab-ulaa.) Exdensur was approved by the Food and Drug Administration (FDA) under a 351(a) Biologics License Application (BLA) on December 16, 2025. Exdensur is indicated as an add-on maintenance treatment for adults and children 12 years and older with severe asthma characterized by an eosinophilic phenotype. Exdensur is not indicated for the relief of acute bronchospasm or status asthmaticus. The recommended dosage is 100 mg administered by a healthcare professional every 6 months as a subcutaneous injection. Exdensur is supplied as a 100 mg/mL single dose prefilled syringe.

CMS Final HCPCS Coding Determination

Establish a new HCPCS Level II code J2361, **"**Injection, depemokimab-ulaa, 1 mg"

Blenrep - HCP251219HQ16E

Topic/Issue

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

Applicant's suggested language: JXXXX, "Injection, belantamab mafodotin-blmf (Blenrep), 0.1 mg"

Summary of Applicant's Submission

GSK submitted a request to establish a new HCPCS Level II code to identify Blenrep. Blenrep was approved by the Food and Drug Administration (FDA) under a 351(a) Biologics License Application (BLA) on October 23, 2025. Previously, Blenrep was approved by the FDA and marketed on August 5, 2020; that BLA was subsequently revoked by the FDA on February 6, 2023. Blenrep is indicated in combination with bortezomib and dexamethasone for the treatment of adults with relapsed or refractory multiple myeloma who have received at least two prior lines of therapy, including a proteasome inhibitor and an immunomodulatory agent. The recommended dosage for Blenrep is 2.5 mg/kg of body weight every 3 weeks in combination with bortezomib and dexamethasone for the first 8 cycles, followed by Blenrep 2.5 mg/kg of body weight every 3 weeks as a single agent until disease progression or unacceptable toxicity occur. It is administered intravenously by a healthcare professional. Blenrep is supplied in a carton containing one 70 mg single-dose vial.

CMS Final HCPCS Coding Determination

Reinstate HCPCS Level II code J9037, "Injection, belantamab mafodontin-blmf, 0.5 mg" effective July 1, 2026.

Previously, HCPCS Level II code J9037 was established effective April 1, 2021. After the FDA revoked the biologic license for Blenrep on February 6, 2023, the code was discontinued effective April 1, 2025.

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 J9037 designation of 0.5 mg.

RYBREVANT FASPRO™ - HCP251218LKHH3

Topic/Issue

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

Applicant's suggested language: JXXXX, "Injection, amivantamab 160 mg and hyaluronidase-lpuj, for subcutaneous injection"

Summary of Applicant's Submission

Johnson & Johnson Heath Care Systems Inc submitted a request to establish a new HCPCS Level II code to identify RYBREVANT FASPRO™ (amivantamab and hyaluronidaselpuj). RYBREVANT FASPRO™ was approved by the Food and Drug Administration (FDA) under a 351(a) Biologics License Application (BLA) on December 17, 2025. RYBREVANT FASPRO™ is indicated for treatment of adults with epidermal growth factor receptor (EGFR)-mutated non-small cell lung cancer (NSCLC). In combination with lazertinib, RYBREVANT FASPRO™ is used for the first-line treatment of locally advanced or metastatic NSCLC; in combination with carboplatin and pemetrexed, for the treatment of locally advanced or metastatic NSCLC, whose disease has progressed on or after treatment with an EGFR tyrosine kinase inhibitor; in combination with carboplatin and pemetrexed, for the first-line treatment of locally advanced or metastatic NSCLC; and as a single agent for the treatment of locally advanced or metastatic NSCLC, whose disease has progressed on or after platinum-based chemotherapy. The recommended dosage of RYBREVANT FASPRO™ is based on baseline body weight. RYBREVANT FASPRO™ must be administered subcutaneously in the abdomen by a healthcare professional. RYBREVANT FASPRO™ is provided in two vial sizes: 1,600 mg of amivantamab and 20,000 units of hyaluronidase per 10 mL (160 mg and 2,000 units/mL) solution in a single-dose vial, and 2,240 mg of amivantamab and 28,000 units of hyaluronidase per 14 mL (160 mg and 2,000 units/mL) solution in a single dose vial.

CMS Final HCPCS Coding Determination

Establish a new HCPCS Level II code J9062, "Injection, amivantamab 5 mg and hyaluronidase-lpuj"

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 160 mg and the HCPCS Level II code J9062 designation of 5 mg.

FESILTY™ - HCP251219CE6CB

Topic/Issue

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

Applicant's suggested language: JXXXX, “Injection, human fibrinogen concentrate (fesilty), 1 mg”

Summary of Applicant's Submission

Grifols Therapeutics, LLC submitted a request to establish a new HCPCS Level II code to identify FESILTY™ (fibrinogen, human - chmt). FESILTY™ was approved by the Food and Drug Administration (FDA) under a 351(k) Biologics License Application (BLA) on December 16, 2025. FESILTY™ is indicated for the treatment of individuals with acute bleeding episodes due to congenital fibrinogen deficiency, including hypo- or afibrinogenemia. FESILTY™ is not indicated for individuals with dysfibrinogenemia. FESILTY™ is for intravenous use after reconstitution only. Fibrinogen (Factor I) is a soluble plasma protein that, during the coagulation process, is converted to fibrin, one of the key components of the blood clot. The end product of the coagulation cascade, cross-linked fibrin, stabilizes and reinforces the primary platelet plug to achieve secondary hemostasis and stop bleeding. The target plasma fibrinogen level is 100 mg/dL for minor bleeding and 150 mg/dL for major bleeding. When plasma fibrinogen level is known, the dose for each individual must be calculated taking into consideration age, the location and extent of bleeding, the plasma level of fibrinogen, and the clinical condition of the individual. When plasma fibrinogen level is not known, the recommended dose is 70 mg/kg for individuals of all ages. FESILTY™ is a sterile, lyophilized, white in color powder for solution for intravenous injection. FESILTY™ is provided as one single-dose glass vial containing nominally 1 gram of human fibrinogen. The actual amount of fibrinogen in milligrams fibrinogen per vial is printed on the vial label and carton.

CMS Final HCPCS Coding Determination

Establish new HCPCS Level II code J7176, “Injection, human fibrinogen - chmt (fesilty), 1 mg”

NUFYMCO® - HCP2512312ALP1

Topic/Issue

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

Applicant's suggested language: XXXXX, “Injection, ranibizumab-leyk, biosimilar (Nufymco), 0.1 mg”

Summary of Applicant's Submission

Bioeq AG submitted a request to establish a new HCPCS Level II code to identify NUFYMCO® (ranibizumab-leyk). NUFYMCO® was approved by the Food and Drug Administration (FDA) under a 351(k) Biologics License Application (BLA) on December 18, 2025. NUFYMCO® is a vascular endothelial growth factor (VEGF) inhibitor and a biosimilar to LUCENTIS™ (ranibizumab). NUFYMCO® is indicated for the treatment of individuals with neovascular (wet) age-related macular degeneration (AMD), macular edema following retinal vein occlusion (RVO), diabetic macular edema (DME), diabetic retinopathy (DR), or myopic choroidal neovascularization (mCNV). The product acts by inhibiting VEGF, thereby reducing pathologic neovascularization and vascular permeability within ocular tissues. The recommended dose for AMD, RVO, and mCNV is 0.5 mg administered once monthly, approximately every 28 days. For DME and DR, the recommended dose is 0.3 mg administered once monthly, approximately every 28 days. For mCNV, the recommended dose is 0.5 mg administered once monthly. NUFYMCO® is for ophthalmic intravitreal injection only. Each NUFYMCO® 0.5 mg carton contains a single-dose glass vial with a blue cap designed to deliver 0.05 mL of 10 mg/mL ranibizumab-leyk solution. Each NUFYMCO® 0.3 mg carton contains a single-dose glass vial with a white cap designed to deliver 0.05 mL of 6 mg/mL ranibizumab-leyk solution. Each carton is for single-eye use only.

CMS Final HCPCS Coding Determination

Establish new HCPCS Level II code Q5168, “Injection, ranibizumab-leyk (nufymco), biosimilar, 0.1 mg”

Boncresa® - HCP251229MWG1A

Topic/,Issue

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

Applicant's suggested language: QXXXX, “Boncresa (denosumab-mobz) injection, for subcutaneous use, 1 mg”

Summary of Applicant's Submission

Amneal Pharmaceuticals submitted a request to establish a new HCPCS Level II code to identify Boncresa® (denosumab-mobz). Boncresa® (denosumab-mobz) was approved by the Food and Drug Administration (FDA) under a 351(k) Biologics License Application (BLA) on December 19, 2025, as a biosimilar to its respective biological reference product, Prolia® (denosumab). Boncresa® is a receptor activator of nuclear factor kappa-B ligand (RANKL) inhibitor, a transmembrane or soluble protein that promotes bone breakdown (resorption) by preventing RANKL from binding and activating its receptor activator of nuclear factor kappa-B (RANK) receptor on the surface of osteoclasts and their precursors. This protein is essential for the formation, function, and survival of osteoclasts, the cells responsible for bone resorption. Prevention of the RANKL/RANK interaction inhibits osteoclast formation, function, and survival, thereby decreasing bone resorption and increasing bone mass and strength in both cortical and trabecular bone. Boncresa® is indicated for the treatment of postmenopausal women with osteoporosis at high risk for fracture, to increase bone mass in men with osteoporosis at high risk for fracture, to treat glucocorticoid-induced osteoporosis in individuals at high risk for fracture, to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer, and to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer. Boncresa® should be administered by a healthcare provider. The recommended dose of Boncresa® is 60 mg administered as a single subcutaneous injection once every 6 months. Boncresa® injection is a clear, colorless to pale yellow solution supplied in a single-dose prefilled syringe, 1 per carton with a needle safety guard.

CMS Final HCPCS Coding Determination

Establish a new HCPCS Level II code Q5171, “Injection, denosumab-mobz (boncresa), biosimilar, 1 mg”

Oziltus® - HCP25122928637

Topic/Issue

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

Applicant's suggested language: QXXXX, “Oziltus (denosumab-mobz) injection, for subcutaneous use, 1 mg”

Summary of Applicant's Submission

Amneal Pharmaceuticals submitted a request to establish a new HCPCS Level II code to identify Oziltus® (denosumab-mobz). Oziltus® (denosumab-mobz) was approved by the Food and Drug Administration (FDA) under a 351(k) Biologics License Application (BLA) on December 19, 2025, as a biosimilar to its respective biological reference product, Xgeva® (denosumab). Oziltus® is a receptor activator of nuclear factor kappa-B ligand (RANKL) inhibitor, a transmembrane or soluble protein that promotes bone breakdown (resorption) by preventing RANKL from binding and activating its receptor activator of nuclear factor kappa-B (RANK) receptor on the surface of osteoclasts and their precursors, and osteoclast-like giant cells in both cortical and trabecular bone. This protein is essential for the formation, function, and survival of osteoclasts, the cells responsible for bone resorption, thereby modulating calcium release from bone. Prevention of the RANKL/RANK interaction inhibits osteoclast formation, function, and survival, thereby decreasing bone resorption and increasing bone mass and strength. Increased osteoclast activity, stimulated by RANKL, is a mediator of bone pathology in solid tumors with osseous metastases. Similarly, giant cell tumors of bone consist of stromal cells expressing RANKL, and osteoclast-like giant cells expressing RANK receptor, and signaling through the RANK receptor contributes to osteolysis and tumor growth.Oziltus® is indicated for the treatment of postmenopausal women with osteoporosis at high risk for fracture, to increase bone mass in men with osteoporosis at high risk for fracture, to treat glucocorticoid-induced osteoporosis in individuals at high risk for fracture, to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer, and to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer. It is also for the prevention of skeletal-related events in individuals with multiple myeloma, in individuals with bone metastases from solid tumors, for the treatment of adults and skeletally mature adolescents with giant cell tumor of bone that is unresectable, or where surgical resection is likely to result in severe morbidity, and for the treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy. Oziltus® should be administered by a healthcare provider, and is administered via a subcutaneous route only, and should not be administered intravenously, intramuscularly, or intradermally. For multiple myeloma and bone metastasis from solid tumors, the recommended dose of Oziltus® is 120 mg administered as a subcutaneous injection every 4 weeks in the upper arm, upper thigh, or abdomen. For giant cell tumor of bone, the recommended dose of Oziltus® is 120 mg administered every 4 weeks, with additional 120 mg doses on days 8 and 15 of the first month of therapy. For hypercalcemia of malignancy, the recommended dose of Oziltus® is again 120 mg administered every 4 weeks, with additional 120 mg doses on days 8 and 15 of the first month of therapy. Oziltus® injection is a clear, colorless to pale yellow solution supplied in a single-dose vial of 120 mg/1.7 mL (70 mg/mL), with 1 vial per carton.

CMS Final HCPCS Coding Determination

Establish a new HCPCS Level II code Q5165, “Injection, denosumab-mobz (oziltus), biosimilar, 1 mg”

EYDENZELT® - HCP251224W2WNQ

Topic/Issue

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

Applicant's suggested language: QXXXX, “Injection, aflibercept-boav (eydenzelt), 1 mg”

Summary of Applicant’s Submission

Celltrion USA, Inc. submitted a request to establish a new HCPCS Level II code to identify EYDENZELT® (aflibercept-boav) injection, for intravitreal use. EYDENZELT® was approved by the Food and Drug Administration (FDA) under a 351(k) Biologics License Application (BLA) on October 2, 2025. EYDENZELT® is a biosimilar to EYELEA® (aflibercept). EYDENZELT® is a vascular endothelial growth factor (VEGF) inhibitor indicated for the treatment of individuals with neovascular (wet) age-related macular degeneration, macular edema following retinal vein occlusion, diabetic macular edema, and diabetic retinopathy. EYDENZELT® is a recombinant fusion protein consisting of portions of human VEGF receptors 1 and 2 extracellular domains fused to the Fragment crystallizable portion of human Immunoglobulin G1, formulated as an iso-osmotic solution for intravitreal administration. Vascular endothelial growth factor-A (VEGF-A) and placental growth factor (PlGF) are members of the VEGF family of angiogenic factors that can act as mitogenic, chemotactic, and vascular permeability factors for endothelial cells. VEGF acts via two receptor tyrosine kinases, VEGFR-1 and VEGFR-2, present on the surface of endothelial cells. PlGF binds only to VEGFR-1, which is also present on the surface of leucocytes. Activation of these receptors by VEGF-A can result in neovascularization and vascular permeability. EYDENZELT® acts as a soluble decoy receptor that binds VEGF-A and PlGF and thereby can inhibit the binding and activation of these cognate VEGF receptors. Dosing varies based on diagnosis. For neovascular (wet) age-related macular degeneration, the recommended dose for EYDENZELT® is 2 mg (0.05 mL of 40 mg/mL solution) administered by intravitreal injection every 4 weeks (approximately every 28 days, monthly) for the first 3 months, followed by 2 mg (0.05 mL of 40 mg/mL solution) via intravitreal injection once every 8 weeks (2 months). For macular edema following retinal vein occlusion, the recommended dose for EYDENZELT® is 2 mg (0.05 mL of 40 mg/mL solution) administered by intravitreal injection once every 4 weeks (approximately every 25 days, monthly). For diabetic macular edema and diabetic retinopathy, the recommended dose for EYDENZELT® is 2 mg (0.05 mL of 40 mg/mL solution) administered by intravitreal injection every 4 weeks (approximately every 28 days, monthly) for the first 5 injections followed by 2 mg (0.05 mL of 40 mg/mL solution) via intravitreal injection once every 8 weeks (2 months). EYDENZELT® injection is a clear to slightly opalescent, colorless to very pale brownish-yellow solution, and is supplied in two presentations including a 2 mg (0.05 mL of 40 mg/mL) solution in a single-dose pre-filled syringe, and a 2 mg (0.05 mL of 40 mg/mL) solution in a single-dose vial.

CMS Final HCPCS Coding Determination

Establish a new HCPCS Level II code Q5170, “Injection, aflibercept-boav (eydenzelt), biosimilar, 1 mg”

OSVYRTI® and JUBEREQ® – HCP251223P6F0U

Topic/Issue

Request to establish a new HCPCS Level II code to identify OSVYRTI® and JUBEREQ®.

Applicant's suggested language: QXXXX, "Injection, denosumab-desu (Osvyrti/Jubereq), biosimilar, 1 mg"

Summary of Applicant's Submission

Accord Biopharma submitted a request to establish a new HCPCS Level II code to identify OSVYRTI® (denosumab-desu) and JUBEREQ® (denosumab-desu). OSVYRTI® and JUBEREQ® were approved by the Food and Drug Administration (FDA) under a 351(k) Biologics License Application (BLA) on October 29, 2025, as biosimilars to their respective biological reference products, PROLIA® and XGEVA®. OSVYRTI® and JUBEREQ® are human monoclonal antibodies that target and block the receptor activator of nuclear factor kappa-B ligand (RANKL), and are thus inhibitors of RANKL, a protein that promotes bone breakdown (resorption) and by preventing RANKL from binding to its RANK receptor, it slows bone turnover, increasing bone density and strength. OSVYRTI® is indicated for the treatment of postmenopausal women with osteoporosis at high risk for fracture, for treatment to increase bone mass in men with osteoporosis at high risk for fracture, for the treatment of glucocorticoid-induced osteoporosis in men and women at high risk of fracture, as a treatment to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for non-metastatic prostate cancer, and as a treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer. Pregnancy must be ruled out prior to administration of OSVYRTI®. The recommended dose of OSVYRTI® is 60 mg administered as a single subcutaneous injection once every 6 months. OSVYRTI® is administered via subcutaneous injection in the upper arm, the upper thigh or the abdomen. JUBEREQ® is indicated for the prevention of skeletal-related events in individuals with multiple myeloma and in individuals with bone metastases from solid tumors, for the treatment of adults and skeletally mature adolescents with giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity, and for the treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy. JUBEREQ® is intended for subcutaneous route only and should not be administered intravenously, intramuscularly, or intradermally. It should be administered in the upper arm, upper thigh, or abdomen. The recommended dose of JUBEREQ® is a 120 mg injection every 4 weeks, with additional 120 mg doses on days 8 and 15 of the first months of therapy, depending on the indication. Calcium and Vitamin D should be administered as necessary to treat or prevent hypocalcemia. OSVYRTI® and JUBEREQ® should be administered by a healthcare provider. OSVYRTI® injection is a clear and colorless to pale yellow solution supplied in a 60 mg/mL single-dose prefilled syringe with an UltraSafe Plus Passive safety guard. JUBEREQ® injection is a clear and colorless to pale yellow solution supplied in a 120 mg/1.7 mL single-dose vial.

CMS Final HCPCS Coding Determination

Establish a new HCPCS Level II code Q5166, "Injection, denosumab-desu (osvyrti/jubereq), biosimilar, 1 mg"

Enoby™ and Xtrenbo™ - HCP2512237JP7Y

Topic/Issue

Request to establish a new HCPCS Level II code to identify Enoby™ and Xtrenbo™.

Applicant's suggested language: QXXXX, "Injection, denosumab-qbde (Xtrenbo and Enoby), 1 mg"

Summary of Applicant's Submission

Hikma Pharmaceuticals USA Inc. submitted a request to establish a new HCPCS Level II code to identify Enoby™ (denosumab-qbde) and Xtrenbo™ (denosumab-qbde). Enoby™ and Xtrenbo™ were approved by the Food and Drug Administration (FDA) under a 351(k) Biologics License Application (BLA) on September 26, 2025, as biosimilars to their respective biological reference products, Prolia® and Xgeva®. Denosumab products are indicated for the treatment of postmenopausal women with osteoporosis, preventing skeletal-related complications in cancer that has spread to the bone, and for the treatment of unresectable giant cell tumors of the bone.

CMS Final HCPCS Coding Determination

Establish a new HCPCS Level II code Q5167, "Injection, denosumab-qbde (enoby/xtrenbo), biosimilar, 1 mg"

Armlupeg® - HCP251218NLMEL

Topic/Issue

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

Applicant's suggested language: QXXXX, “Armlupeg® (pegfilgrastim-unne) injection”

Summary of Applicant’s Submission

Valorum Biologics LLC submitted a request to establish a new HCPCS Level II code to identify Armlupeg® (pegfilgrastim-unne). Armlupeg® was approved by the Food and Drug Administration (FDA) under a 351(k) Biologics License Application (BLA) on November 27, 2025. Armlupeg® injection, a leukocyte growth factor, is indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in individuals with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia. Armlupeg® is also indicated to increase survival in individuals acutely exposed to myelosuppressive doses of radiation. Pegfilgrastim products are colony-stimulating factors that act on hematopoietic cells by binding to specific cell surface receptors, thereby stimulating proliferation, differentiation, commitment, and end cell functional activation. The recommended dosage of Armlupeg® for adults of any weight, and pediatric 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 Armlupeg® between 14 days before and 24 hours after administration of chemotherapy. For individuals with hematopoietic subsyndrome of acute radiation syndrome, the recommended dosage of Armlupeg® for adults of any weight and pediatric individuals weighing at least 45 kg 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. Armlupeg® is supplied as a single-dose prefilled syringe for subcutaneous administration. Armlupeg® is packaged in a carton containing one 0.6 mL single-dose prefilled syringe containing 6 mg pegfilgrastim-unne (based on protein weight), glacial acetic acid (0.77 mg), polysorbate 20 (0.02 mg), sodium acetate (0.066 mg), and sorbitol (30 mg) in water for injection.

CMS Final HCPCS Coding Determination

Establish a new HCPCS Level II code Q5169, “Injection, pegfilgrastim-unne (armlupeg), biosimilar, 0.5 mg”

STARJEMZA® - HCP2512081N27P

Topic/Issue

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

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

Summary of Applicant's Submission

Hikma Pharmaceuticals submitted a request to establish a new HCPCS Level II code to identify STARJEMZA® (ustekinumab-hmny). STARJEMZA® was approved by the Food and Drug Administration (FDA) under a 351(k) Biologics License Application (BLA) on May 22, 2025. STARJEMZA® is a biosimilar to Stelara®, a human monoclonal antibody that inhibits the bioactivity of human interleukin 12 (IL-12) and interleukin 23 (IL-23) by preventing the shared p40 subunit from binding to the interleukin-12 receptor β1 (IL-12Rβ1) subunit within the IL-12Rβ1/β2 and IL-12Rβ1/23R receptor complexes on the surface of immune cells. IL-12 and IL-23 are involved in inflammatory and immune responses, including natural killer cell activation and CD4+ T-cell differentiation as well as downstream cytokine production. Dysregulated IL-12 and IL-23 signaling has been implicated in chronic inflammatory diseases, including psoriasis, psoriatic arthritis, Crohn’s disease, and ulcerative colitis. By neutralizing human IL-12 and IL-23 and inhibiting downstream T helper 1 and 17 signaling pathways, STARJEMZA® blocks the pathologic inflammatory processes underlying these immune mediated disorders.

CMS Final HCPCS Coding Determination

Establish a new HCPCS Level II code Q5164, “Injection, ustekinumab-hmny (starjemza), biosimilar, 1 mg”

Tofidence™ - HCP260309UMNMK

Topic/Issue

Request to establish a new HCPCS Level II code to identify Tofidence™ for the treatment of COVID-19.

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

Summary of Applicant's Submission

Tofidence™ (tocilizumab-bavi) was approved by the Food and Drug Administration (FDA) under a 351(k) Biologics License Application (BLA) on September 29, 2023, with a supplemental approval for the treatment of COVID-19 on July 22, 2024. Tofidence™ is a biosimilar to ACTEMRA® (tocilizumab). Tofidence™ is indicated for intravenous administration in hospitalized adults with COVID-19 who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation.

CMS Final HCPCS Coding Determination

1. Establish a new HCPCS Level II code Q0234, “Injection, tocilizumab-bavi, 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 only, 1 mg”

2. Establish a new HCPCS Level II code M0231, “Intravenous infusion, tocilizumab-bavi, 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 only, includes infusion and post administration monitoring, first dose”

3. Establish a new HCPCS Level II code M0232, “Intravenous infusion, tocilizumab-bavi, 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 only, includes infusion and post administration monitoring, second dose”

Tofidence™ (tocilizumab-bavi), a biosimilar to ACTEMRA® (tocilizumab), is approved for the treatment of rheumatoid arthritis, giant cell arteritis, polyarticular juvenile idiopathic arthritis, systemic juvenile idiopathic arthritis, and coronavirus disease 2019 (COVID-19). Effective April 1, 2024, CMS established HCPCS Level II code Q5133, “Injection, tocilizumab-bavi (tofidence), biosimilar, 1 mg,” to describe Tofidence™, which is payable under Medicare Part B at a rate of average sales price (ASP) plus 6%. In 2020, CMS established payment policies for monoclonal antibody (mAb) products with an indication for post-exposure prophylaxis or treatment of COVID-19 to be paid under the Medicare Part B preventive vaccine benefit at 95% of the average wholesale price (AWP) through the end of

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

Typically, CMS does not establish new HCPCS Level II codes for drug and biological products to distinguish an indication; however, the HCPCS Level II code Q5133 for Tofidence™ would not be suitable for the treatment of COVID-19 based on CMS' current payment policies, similar to what has been done for prior mAb products with this indication (such as HCPCS Level II code Q0249 for ACTEMRA®) for appropriate Medicare Part B payment. As such, CMS is establishing HCPCS Level II code Q0234 to describe Tofidence™ for post-exposure prophylaxis or treatment of COVID-19 to align with the appropriate Medicare payment policies. These codes would be effective through the end of the calendar year in which the EUA declaration under section 564 of the FD&C Act ends. At that time, COVID-19 mAb products used for the treatment or for post-exposure prophylaxis of COVID19 as biological products will be paid under section 1847A of the Act and the appropriate HCPCS Level II code Q5133 should be billed for these indications.

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

CMS has been reviewing its approach for establishing HCPCS Level II codes to identify products approved under a 505(b)(2) New Drug Application (NDA) or a BLA after October 2003. These products are not rated as therapeutically equivalent to their reference listed drug in the Food and Drug Administration's (FDA) Orange Book[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. 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 Determination

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

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

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[i]	Action	Long Descriptor
J0850	Delete	Injection, cytomegalovirus immune globulin intravenous (human), per vial
J0851	Add	Injection, cytomegalovirus immune globulin (human), 50 mg
J1459	Delete	Injection, immune globulin (privigen), intravenous, non-lyophilized (e.g., liquid), 500 mg
J1461	Add	Injection, immune globulin (privigen), 200 mg
J1552	Delete	Injection, immune globulin (alyglo), 500 mg
J1554	Delete	Injection, immune globulin (asceniv), 500 mg
J1556	Delete	Injection, immune globulin (bivigam), 500 mg
J1557	Delete	Injection, immune globulin, (gammaplex), intravenous, non-lyophilized (e.g., liquid), 500 mg
J1561	Delete	Injection, immune globulin, (gamunex-c/gammaked), non-lyophilized (e.g., liquid), 500 mg
J1566	Delete	Injection, immune globulin, intravenous, lyophilized (e.g., powder), not otherwise specified, 500 mg
J1568	Delete	Injection, immune globulin, (octagam), intravenous, non-lyophilized (e.g., liquid), 500 mg
J1569	Delete	Injection, immune globulin, (gammagard liquid/gammagard liquid erc), 500 mg
J1572	Delete	Injection, immune globulin, (flebogamma/flebogamma dif), intravenous, non-lyophilized (e.g., liquid), 500 mg
J1576	Delete	Injection, immune globulin, (panzyga), intravenous, non-lyophilized (e.g., liquid), 500 mg
J1578	Add	Injection, immune globulin (alyglo), 100 mg
J1579	Add	Injection, immune globulin (asceniv), 100 mg
J1581	Add	Injection, immune globulin (bivigam), 100 mg
J1582	Add	Injection, immune globulin (gammaplex), 100 mg
J1583	Add	Injection, immune globulin (gamunex-c/gammaked), 200 mg
J1584	Add	Injection, immune globulin, lyophilized (e.g., powder), not otherwise specified, 100 mg
J1585	Add	Injection, immune globulin (octagam), 200 mg
J1586	Add	Injection, immune globulin (gammagard liquid/gammagard liquid erc), 200 mg
J1587	Add	Injection, immune globulin (flebogamma/flebogamma dif), 100 mg
J1588	Add	Injection, immune globulin (panzyga), 200 mg
J1589	Add	Injection, immune globulin, non-lyophylized (e.g., liquid), 200 mg
J1599	Delete	Injection, immune globulin, intravenous, non-lyophilized (e.g., liquid), not otherwise specified, 500 mg
J2787	Revise	Riboflavin 5'-phosphate, ophthalmic solution (photrexa viscous/photrexa), up to 3 ml

J7504	Delete	Lymphocyte immune globulin, antithymocyte globulin, equine, parenteral, 250 mg
J7511	Delete	Lymphocyte immune globulin, antithymocyte globulin, rabbit, parenteral, 25 mg
J7522	Add	Injection, lymphocyte immune globulin, antithymocyte globulin, equine, 2 mg
J7523	Add	Injection, lymphocyte immune globulin, antithymocyte globulin, rabbit, 1 mg
J9232	Add	Injection, docetaxel (hospira), not therapeutically equivalent to j9171, 1 mg

[i] The effective date for these HCPCS Level II coding actions is January 1, 2027, with the exception of HCPCS Level II codes J2787 and J9232, which will have an effective date of July 1, 2026.