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

Second 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' Second 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 October 1, 2026, unless otherwise indicated.

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

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

AVOPEF - HCP260401PYRDB

Topic/Issue

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

Applicant's suggested language: JXXXX, “Injection, etoposide (avyxa), 10 mg”

Summary of Applicant's Submission

AVYXA Pharma, LLC submitted a request to establish a new HCPCS Level II code to identify AVOPEF (etoposide). AVOPEF was approved by the Food and Drug Administration (FDA) under a 505(b)(2) New Drug Application (NDA) on February 13, 2026. AVOPEF is a topoisomerase inhibitor indicated in combination with other chemotherapy and/or immunotherapy, for the treatment of adults with refractory testicular cancer and small cell lung cancer. The recommended dosage of AVOPEF for refractory testicular cancer is 50 mg/m² to 100 mg/m² daily on days 1 to 5, or 100 mg/m² daily on days 1, 3 and 5. The recommended dosage of AVOPEF for small cell lung cancer is 35 mg/m² daily on days 1 to 4, or 50 mg/m² daily on days 1 to 5. AVOPEF is for intravenous administration and treatment cycles should be repeated every 3 to 4 weeks. AVOPEF is a sterile, clear, colorless to light yellow liquid available in 100 mg/5 mL (20 mg/mL) multiple-dose glass vials.

CMS Final HCPCS Coding Determination

Establish a new HCPCS Level II code J9186, “Injection, etoposide (avyxa), 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 J9186 designation of 1 mg.

FAVLYXA - HCP260401CTU34

Topic/Issue

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

Applicant's suggested language: JXXXX, “Injection, fluorouracil (avyxa), 500 mg”

Summary of Applicant's Submission

AVYXA Pharma, LLC submitted a request to establish a new HCPCS Level II code to identify FAVLYXA (fluorouracil). FAVLYXA was approved by the Food and Drug Administration (FDA) under a 505(b)(2) New Drug Application (NDA) on February 20, 2026. FAVLYXA is a nucleoside metabolic inhibitor. FAVLYXA is indicated for treatment of individuals with adenocarcinoma of the colon and rectum, adenocarcinoma of the breast, gastric adenocarcinoma, and pancreatic adenocarcinoma. In combination with leucovorin or as a component of a multidrug chemotherapy regimen that includes leucovorin, FAVLYXA is used for the treatment of adenocarcinoma of the colon and rectum. FAVLYXA is recommended for administration either as an intravenous bolus or as an intravenous infusion. The recommended infusion dose is 400 mg/m² for one dose, followed by 2,400 mg/m² to 3,000 mg/m² over 46 hours on day 1 of each 2-week cycle or in combination with leucovorin, the recommended bolus dose is 500 mg/m² on days 1, 8, 15, 22, 29 and 36 of each 8-week cycle. In combination with a cyclophosphamide based multidrug regimen, FAVLYXA is used for the treatment of adenocarcinoma of the breast. The recommended bolus dose is 500 mg/m² or 600 mg/m² on days 1 and 8 of each 28-day cycle. In combination with a platinum-containing multidrug regimen for the treatment of gastric adenocarcinoma, the recommended dose is 200 mg/m² to 1,000 mg/m² over 24 hours. In combination with leucovorin or as a component of a multidrug chemotherapy regimen that includes leucovorin, FAVLYXA is used for the treatment of pancreatic adenocarcinoma. The recommended infusion dose is 400 mg/m² on day 1, followed by 2,400 mg/m² over 46 hours every 2 weeks. FAVLYXA is a sterile colorless to light yellow clear solution available in 250 mg/10 mL in a single-dose vial.

CMS Final HCPCS Coding Determination

Establish a new HCPCS Level II code J9191, “Injection, fluorouracil (avyxa), 10 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 J9191 designation of 10 mg.

Bendamustine Hydrochloride Injection - HCP260401NFDX1

Topic/Issue

Request to establish a new HCPCS Level II code to identify bendamustine hydrochloride injection.

Applicant's suggested language: JXXXX, “Injection, bendamustine hydrochloride (avyxa), 1 mg”

Summary of Applicant's Submission

AVYXA Pharma, LLC submitted a request to establish a new HCPCS Level II code to identify bendamustine hydrochloride injection. AVYXA's bendamustine hydrochloride injection was approved by the Food and Drug Administration (FDA) under a 505(b)(2) New Drug Application (NDA) on July 3, 2025. On March 30, 2026, the product licensing was transferred from Dr. Reddy’s Laboratories, Inc. to AVYXA Pharma, LLC. Bendamustine hydrochloride is indicated for the treatment of adult individuals with chronic lymphocytic leukemia (CLL) and indolent B-cell non-Hodgkin’s lymphoma (NHL) that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen. The dosage regimen varies by indication. Bendamustine is a bifunctional mechlorethamine derivative containing a purine-like benzimidazole ring. The recommended dosage is 100 mg/m² administered intravenously over 30 minutes on days 1 and 2 of a 28-day cycle, up to 6 cycles for CLL, and 120 mg/m² administered intravenously over 60 minutes on days 1 and 2 of a 21-day cycle, up to 8 cycles for NHL. Bendamustine hydrochloride injection is supplied in individual cartons of clear multiple-dose vials containing 100 mg of bendamustine hydrochloride in 4 mL as a clear, pale yellow to yellow solution.

CMS Final HCPCS Coding Determination

Establish new HCPCS Level II code J9066, “Injection, bendamustine hydrochloride (avyxa), 1 mg”

LUTATHERA® - HCP2603318D78E

Topic/Issue

Request to revise existing HCPCS Level II code A9513, "Lutetium lu 177, dotatate, therapeutic, 1 millicurie", to change the unit descriptor to reflect dosing per therapeutic dose rather than per millicurie.

Applicant's suggested language: A9513, "Lutetium Lu 177, dotatate, therapeutic, per therapeutic dose"

Summary of Applicant's Submission

Novartis Pharmaceuticals Corporation submitted a request to revise existing HCPCS Level II code A9513 to change the unit descriptor to reflect dosing per therapeutic dose rather than per millicurie. LUTATHERA® was approved by the Food and Drug Administration (FDA) under a New Drug Application (NDA) on January 26, 2018. LUTATHERA® is a radio-labeled somatostatin analog indicated for the treatment of individuals 12 years and older with somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors, including foregut, midgut, and hindgut neuroendocrine tumors. CMS assigned HCPCS Level II code A9513 to LUTATHERA®, effective on January 1, 2019. Since the code became effective, providers have experienced operational challenges because of the unique radioactive elements of LUTATHERA®. These difficulties have the potential to impact individual access to care. Again, Novartis requests that CMS revise the LUTATHERA® code descriptor from "1 millicurie" to a "per therapeutic dose" to align with how the product is packaged, delivered, and administered in accordance with its FDA label. Such a HCPCS Level II code descriptor aligns with other HCPCS Level II codes for radiopharmaceuticals which are "per study dose", (such as HCPCS Level II code A9586), or gene therapies which are "per therapeutic dose", (such as HCPCS Level II code J1411).

CMS Final HCPCS Coding Determination

CMS is denying the request to revise existing HCPCS Level II code A9513, "Lutetium lu 177, dotatate, therapeutic, 1 millicurie."

In considering that LUTATHERA® has a long half-life and it is supplied in a single-dose vial, CMS maintains the "1 millicurie" unit descriptor is most appropriate to maximize efficiency and accuracy.

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.

PLUVICTO® - HCP2603310DB64

Topic/Issue

Request to revise existing HCPCS Level II code A9607, "Lutetium lu 177 vipivotide tetraxetan, therapeutic, 1 millicurie", to change the unit descriptor to reflect dosing per therapeutic dose rather than per millicurie.

Applicant's suggested language: A9607, "Lutetium Lu 177 vipivotide tetraxetan, therapeutic, per therapeutic dose"

Summary of Applicant's Submission

Novartis Pharmaceuticals Corporation submitted a request to revise existing HCPCS Level II code A9607 to change the unit descriptor to reflect dosing per therapeutic dose rather than per millicurie. PLUVICTO® was approved by the Food and Drug Administration (FDA) under a New Drug Application (NDA) on March 23, 2022. PLUVICTO® is a radioligand therapeutic agent indicated for the treatment of individuals with prostate-specific membrane antigen-positive metastatic castration-resistant prostate cancer (mCRPC), who have been treated with androgen-receptor pathway inhibitor therapy, and are considered appropriate to delay taxane-based chemotherapy or have received prior taxane-based chemotherapy. PLUVICTO® is a targeted radioligand therapy for eligible individuals with mCRPC that combines a targeting compound (ligand) with a therapeutic radioisotope (a radioactive particle). CMS assigned HCPCS Level II code A9607 to PLUVICTO®, effective on October 1, 2022. Since the code became effective, providers have experienced operational challenges because of the unique radioactive elements of PLUVICTO®. These difficulties have the potential to impact individual access to care. Again, Novartis requests that CMS revise the PLUVICTO® code descriptor from "1 millicurie" to "per therapeutic dose", to align with how the product is packaged, delivered, and administered in accordance with its FDA label. Such a HCPCS Level II code descriptor aligns with other HCPCS Level II codes for radiopharmaceuticals which are "per study dose", (such as HCPCS Level II code A9586), or gene therapies which are "per therapeutic dose", (such as HCPCS Level II code J1411).

CMS Final HCPCS Coding Determination

CMS is denying the request to revise existing HCPCS Level II code A9607, "Lutetium lu 177 vipivotide tetraxetan, therapeutic, 1 millicurie."

In considering that PLUVICTO® has a long half-life and it is supplied in a single-dose vial, CMS maintains the "1 millicurie" unit descriptor is most appropriate to maximize efficiency and accuracy.

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.

GOPRELTO - HCP260331J9NJM

Topic/Issue

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

Applicant's suggested language: XXXXX, “Solution, cocaine hydrochloride, 1 mg”

Summary of Applicant's Submission

LXO US submitted a request to establish a new HCPCS Level II code to identify GOPRELTO (cocaine hydrochloride nasal solution, 4%). GOPRELTO was approved by the Food and Drug Administration (FDA) under a 505(b)(2) New Drug Application (NDA) on December 14, 2017. GOPRELTO is a cocaine hydrochloride nasal solution, 4%, single source drug ester local anesthetic indicated for adults for the induction of local anesthesia of the mucous membranes when performing diagnostic procedures and surgeries on or through the nasal cavities. The method of action involves preventing conduction in nerve fibers by reversibly blocking sodium channels and thereby preventing the transient rise in sodium conductance. The recommended dose of GOPRELTO is two soaked cotton pledgets placed in each nasal cavity, equivalent to 40 mg cocaine hydrochloride per pledget, for a total dose of 160 mg for four pledgets. The route of administration is intranasal. GOPRELTO is a clear, green-colored liquid available in a dosage strength of 160 mg/4 mL (40 mg/mL or 4%) in a single-use bottle, equivalent to 142.4 mg/4 mL (35.6 mg/mL) cocaine free-base.

CMS Final HCPCS Coding Determination

1. Establish a new HCPCS Level II code J0014, “Cocaine hydrochloride nasal solution (goprelto), 1 mg”

2. Discontinue HCPCS Level II code C9046, “Cocaine hydrochloride nasal solution (goprelto), 1 mg”

Baxdela - HCP260330YKCNY

Topic/Issue

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

Applicant's suggested language: XXXXX, “Injection, delafloxacin, per 1 mg”

Summary of Applicant's Submission

CorMedix Therapeutics submitted a request to establish a new HCPCS Level II code to identify Baxdela (delafloxacin meglumine). Baxdela was approved by the Food and Drug Administration (FDA) under a 505(b) supplemental New Drug Application (sNDA) on October 24, 2019. Baxdela is a fluoroquinolone antibacterial single source drug indicated for adults for the treatment of acute bacterial skin and skin structure infections (ABSSSI), and to treat community-acquired bacterial pneumonia. Baxdela reduces the development of drug-resistant bacteria and should be used only to treat infections that are proven or strongly suspected to be caused by bacteria. Baxdela for injection, 300 mg, is a sterile lyophilized powder that contains 300 mg delafloxacin (equivalent to 433 mg delafloxacin meglumine) and the inactive ingredients Edetate disodium (3.4 mg); meglumine (59 mg); sulfobutylether-β-cyclodextrin (2400 mg). The recommended dosage regimen of Baxdela for adults with ABSSSI is 300 mg of Baxdela injection every 12 hours over 60 minutes by intravenous infusion for 5 to 14 days, or administer 300 mg of Baxdela injection every 12 hours over 60 minutes by intravenous infusion and then switch to a 450 mg Baxdela tablet orally every 12 hours for a total duration of 5 to 14 days. Based on the physician’s discretion, a 450 mg Baxdela tablet can be administered orally every 12 hours without the Baxdela injection for a total duration of 5 to 14 days. Baxdela is supplied as a sterile, lyophilized powder in light yellow to tan cake color in single-dose clear glass vials containing 300 mg delafloxacin (equivalent to 433 mg delafloxacin meglumine).

CMS Final HCPCS Coding Determination

3. Establish a new HCPCS Level II code J3268, “Injection, delafloxacin, 1 mg”

4. Discontinue HCPCS Level II code C9462, “Injection, delafloxacin, 1 mg”

PONLIMSI™ - HCP2603317J7CX

Topic/Issue

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

Applicant's suggested language: QXXXX, "Injection, denosumab-adet (Ponlimsi), biosimilar, 1 mg"

Summary of Applicant's Submission

Teva Pharmaceuticals submitted a request to establish a new HCPCS Level II code to identify PONLIMSI™ (denosumab-adet). PONLIMSI™ (denosumab-adet) was approved by the Food and Drug Administration (FDA) under a 351(k) Biologics License Application (BLA) on March 27, 2026, as a biosimilar to the biological reference product, PROLIA® (denosumab). PONLIMSI™ is a human monoclonal antibody receptor activator that targets and binds to the receptor activator of nuclear factor-kappa-B ligand inhibitor. PONLIMSI™ 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; of 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 non-metastatic prostate cancer; and to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer. The recommended dosage of PONLIMSI™ is 60 mg once every 6 months as a subcutaneous injection in the upper arm, upper thigh, or abdomen. PONLIMSI™ should be administered by a healthcare provider. PONLIMSI™ is distributed as a single-dose prefilled syringe containing 60 mg per 1 mL solution.

CMS Final HCPCS Coding Determination

Establish a new HCPCS Level II code Q5173, "Injection, denosumab-adet (ponlimsi), biosimilar, 1 mg"

AVLAYAH™ - HCP260330P2GQJ

Topic/Issue

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

Applicant's suggested language: JXXXX, "Injection, tividenofusp alfa-eknm, 1 mg"

Summary of Applicant's Submission

Denali Therapeutics Inc. submitted a request to establish a new HCPCS Level II code to identify AVLAYAH™ (tividenofusp alfa-eknm). AVLAYAH™ was approved by the Food and Drug Administration (FDA) under a 351(a) Biologics License Application (BLA) on March 24, 2026. AVLAYAH™ is indicated for the treatment of neurologic symptoms in children with Hunter syndrome weighing at least 5 kg, prior to advanced neurologic disease. The recommended starting dosage of AVLAYAH™ is 3 mg/kg administered weekly via intravenous infusion. The recommended maintenance dosage of AVLAYAH™ is 15 mg/kg administered weekly via intravenous infusion. AVLAYAH™ is available as a lyophilized powder in a single-dose 150 mg vial.

CMS Final HCPCS Coding Determination

Establish a new HCPCS Level II code J1757, "Injection, tividenofusp alfa-eknm, 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. The 1 mg assigned dose descriptor for HCPCS Level II code J1757 will allow for accurate payment for the minimum dosage, which equates to 15 mg (based on the recommended starting dose of 3 mg/kg for the lowest eligible individual weight of 5 kg). Billing in 1 mg increments enables providers to report the precise dose administered across the full range of clinically indicated doses, supporting both accurate reimbursement and appropriate utilization reporting.

AVLAYAH™ is indicated for the treatment of neurologic symptoms in pediatric individuals with Hunter syndrome weighing at least 5 kg, prior to advanced neurologic disease. CMS recognizes that individuals with Hunter syndrome follow a distinctive biphasic growth pattern and typically present with significantly lower body weights than the general adult population. Relying on an average adult weight of 70 kg to determine maximum dosage is not appropriate in this clinical context, as most will require doses well below a calculated maximum based on standard adult weight assumptions.

In light of the considerable variability in individual body weight within this population, a 1 mg dose descriptor is appropriate to support accurate and flexible reporting of the dose administered across the full range of individuals who may receive AVLAYAH™.

OMISIRGE® - HCP2603273LNPT

Topic/Issue

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

Applicant's suggested language: JXXXX, "Omidubicel-onlv, per treatment"

Summary of Applicant's Submission

Gamida Cell submitted a request to establish a new HCPCS Level II code to identify OMISIRGE® (omidubicel-onlv). OMISIRGE® was first approved by the Food and Drug Administration (FDA) under a 351(a) Biologics License Application (BLA) on April 17, 2023; and was most recently approved by the FDA under a supplemental BLA on December 5, 2025. OMISIRGE® is indicated to reduce the time to neutrophil recovery and the incidence of infection in individuals 12 years of age and older with hematologic malignancies planned for umbilical cord blood transplantation following myeloablative conditioning. OMISIRGE® is also indicated for the treatment of individuals 6 years of age and older with severe aplastic anemia following reduced intensity conditioning. OMISIRGE® is a nicotinamide modified allogeneic hematopoietic progenitor cell therapy derived from cord blood that is used as an allogeneic stem cell donor source. OMISIRGE® is for intravenous use only. A single dose of OMISIRGE® is composed of two cryopreserved cell fractions derived from the same cord blood unit that must both be infused as a cultured fraction (CF) minimum 8.0×10^8 total viable cells and non-cultured fraction (NF) minimum 4.0×10^8 total viable cells. Each fraction requires dilution with separate infusion solution bags. Infusion of NF should begin within 1 hour after completion of CF infusion. OMISIRGE® is packaged as two separate cryopreserved bags (one for each fraction) and is shipped in two shipping containers, a liquid nitrogen dry vapor shipper at ≤ -150 ℃, containing the two cryopreserved cell fractions, chimerism testing sample(s), and a refrigerated shipping container at 2-8 ℃, containing two infusion solutions. OMISIRGE® is a personalized donor source biologic.

CMS Final HCPCS Coding Determination

Establish new HCPCS Level II code J3406, "Injection, omidubicel-onlv, per therapeutic dose"

PYLARIFY TRUVU™ - HCP260327CK5TK

Topic/Issue

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

Applicant's suggested language: AXXXX, “Piflufolastat F-18 (PYLARIFY TRUVU) 1 millicurie (mCi)”

Summary of Applicant's Submission

Lantheus Medical Imaging, Inc. submitted a request to establish a new HCPCS Level II code to identify PYLARIFY TRUVU™ (piflufolastat F 18) injection, for intravenous use. PYLARIFY TRUVU™ was approved by the Food and Drug Administration (FDA) under a 505(b)(2) New Drug Application (NDA) on March 6, 2026. PYLARIFY TRUVU™ is a radioactive diagnostic agent indicated for positron emission tomography (PET) of prostate-specific membrane antigen (PSMA) positive lesions in individuals with prostate cancer with suspected metastasis who are candidates for initial definitive therapy or with suspected recurrence based on elevated serum prostate-specific antigen (PSA) level. PYLARIFY TRUVU™ contains fluorine 18 (F 18), radiolabeled prostate-specific membrane antigen inhibitor imaging agent. Piflufolastat F 18 binds to cells that express PSMA, including malignant prostate cancer cells, which usually overexpress PSMA. F 18 is a β+ emitting radionuclide that enables positron emission tomography. The recommended dose is 9 mCi with an acceptable range 8 mCi to 10 mCi, administered as a bolus intravenous injection, and imaging should be initiated approximately 60 minutes after PYLARIFY TRUVU™ administration. PYLARIFY TRUVU™ is supplied in a 50 mL multiple-dose glass vial containing a clear, colorless to pale yellow solution at a strength of 1 mCi/mL to 120 mCi/mL piflufolastat F 18 at calibration time and date.

CMS Final HCPCS Coding Determination

1. Establish new HCPCS Level II code A9613, “Piflufolastat f 18 (pylarify truvu), diagnostic, 1 millicurie”

2. Revise existing HCPCS Level II code A9595, “Piflufolastat f-18, diagnostic, 1 millicurie” to instead read “Piflufolastat f 18 (pylarify), diagnostic, 1 millicurie”

Loargys® - HCP260321K358J

Topic/Issue

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

Applicant's suggested language: XXXXX, "Injection, pegzilarginase-nbln (Loargys), for infusion, 0.1 mg"

Summary of Applicant's Submission

Immedica USA Inc. submitted a request to establish a new HCPCS Level II code to identify Loargys® (pegzilarginase-nbln). Loargys® was approved by the Food and Drug Administration (FDA) under a 351(a) Biologics License Application (BLA) on February 23, 2026. Loargys® is indicated for the treatment of hyperargininemia in individuals 2 years of age and older with Arginase 1 Deficiency, in conjunction with dietary protein restriction. The recommended starting dosage of Loargys® is 0.2 mg/kg administered via intravenous infusion weekly. Loargys® is available in 2 mg/0.4 mL and 5 mg/mL single-dose vial.

CMS Final HCPCS Coding Determination

Establish a new HCPCS Level II code J1818, "Injection, pegzilarginase-nbln, 0.05 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 J1818 designation of 0.05 mg.

FILKRI - HCP2603165YMVY

Topic/Issue

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

Applicant's suggested language: XXXXX, "Injection, filgrastim-laha (filkri), 1 mcg"

Summary of Applicant's Submission

Accord Biopharma submitted a request to establish a new HCPCS Level II code to identify FILKRI (filgrastim-laha). FILKRI was approved by the Food and Drug Administration (FDA) under a 351(k) Biologics License Application (BLA) on January 15, 2025. FILKRI is a biosimilar to Neupogen (filgrastim). FILKRI is indicated for the following: to decrease the incidence of infection, as manifested by febrile neutropenia, in individuals with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever; to reduce the time to neutrophil recovery and the duration of fever, following induction or consolidation chemotherapy treatment of individuals with acute myeloid leukemia; to reduce the duration of neutropenia and neutropenia-related clinical sequelae, e.g., febrile neutropenia, in individuals with nonmyeloid malignancies undergoing myeloablative chemotherapy followed by bone marrow transplantation; to reduce the incidence and duration of sequelae of neutropenia in symptomatic individuals with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia; and to increase survival in individuals acutely exposed to myelosuppressive doses of radiation. FILKRI is administered subcutaneously, via a short intravenous infusion, or via a continuous intravenous infusion. The recommended starting dose of FILKRI depends on the indication and ranges between 5 mcg/kg/day to 6 mcg/kg twice daily. Filgrastim stimulates bone marrow to produce more white blood cells, specifically neutrophils, into the bloodstream to prevent infections in individuals with low white blood cell counts due to chemotherapy, bone marrow transplants, or radiation. FILKRI injection is a clear, colorless, preservative-free solution supplied as single-dose prefilled syringes each containing 300 mcg/0.5 mL of filgrastim-laha, or 480 mcg/0.8 mL of filgrastim-laha.

CMS Final HCPCS Coding Determination

Establish new HCPCS Level II code Q5172, "Injection, filgrastim-laha (filkri), biosimilar, 1 microgram"

VYKOURA™ - HCP260313C0LEV

Topic/Issue

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

Applicant's suggested language: JXXXX, “Injection, leucovorin calcium (vykoura), 50 mg”

Summary of Applicant's Submission

Avyxa Pharma LLC submitted a request to establish a new HCPCS Level II code to identify VYKOURA™ (leucovorin calcium). VYKOURA™ was approved by the Food and Drug Administration (FDA) under a 505(b)(2) New Drug Application (NDA) on February 3, 2026. VYKOURA™ is a folate analog indicated for rescue following high-dose methotrexate therapy in individuals with osteosarcoma. VYKOURA™ reduces toxicity and counteracts the effects of impaired methotrexate elimination and inadvertent overdosage of folic acid antagonists. VYKOURA™ is also indicated for the treatment of megaloblastic anemias due to folic acid deficiency when oral therapy is not feasible, and to prolong survival in individuals with advanced colorectal cancer. In high-dose methotrexate therapy, leucovorin administration counteracts both the therapeutic and toxic effects of folic acid antagonists such as methotrexate, which act by inhibiting dihydrofolate reductase. When used in combination with fluorouracil for colorectal cancer, leucovorin enhances both the therapeutic and toxic effects of fluoropyrimidines, including 5-fluorouracil. Leucovorin is readily converted to 5,10-methylenetetrahydrofolate, a reduced folate that stabilizes the binding of fluorodeoxyuridylic acid to thymidylate synthase, thereby enhancing inhibition of this enzyme. VYKOURA™ is indicated for intravenous or intramuscular administration with dosing varying by indication.

CMS Final HCPCS Coding Determination

1. Establish new HCPCS Level II code J0644, “Injection, leucovorin calcium (avyxa), 1 mg”

2. Discontinue HCPCS Level II code C9310, “Injection, leucovorin calcium (avyxa), 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. The 1 mg assigned dose descriptor for HCPCS Level II code J0644 will allow for accurate payment for the minimum daily dosage, which equates to 1 mg/day. Billing in 1 mg increments enables providers to report the precise dose administered across the full range of clinically indicated doses, supporting both accurate reimbursement and appropriate utilization reporting. Some individuals may have low body weight before starting treatment due to disease-related weight loss, and additional weight loss during systemic therapy is also common. As a result, an adult’s actual body surface area (BSA) may be lower than 1.81 m^2 in many cases. Given this variability, and consistent with CMS' historical approach of using an average BSA of 1.81 m^2 when estimating minimum and maximum dosing, a 1 mg dose descriptor remains appropriate to support accurate reporting of

the dose administered. This framework explains the distinction between the applicant's proposed dosage of 50 mg and the HCPCS Level II code J0644 designation of 1 mg.

Lasix® ONYU - HCP2603057N5KD

Topic/Issue

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

Applicant's suggested language: JXXXX, "Injection, furosemide (Lasix ONYU), 80 mg”

Summary of Applicant's Submission

SQ Innovation Inc. submitted a request to establish a new HCPCS Level II code to identify Lasix® ONYU (furosemide). Lasix® ONYU was approved by the Food and Drug Administration (FDA) under a New Drug Application (NDA) on October 7, 2025. Lasix® ONYU is a subcutaneous delivery system indicated for the treatment of edema in adult individuals with chronic heart failure. Lasix® ONYU is a loop diuretic administered via subcutaneous injection with 112% bioavailability compared to intravenous bolus furosemide, offering comparable diuretic efficiency. The product is dosed at 80 mg (30 mg/mL). Lasix® ONYU is packaged in two boxes: box 1 contains the reusable unit, charger, and instructions for use, while box 2 contains the prefilled cartridge, disposable drug delivery unit, and two alcohol pads. While primarily intended for home use, the drug delivery system may also be prepared and placed in an emergency room, a physician’s office, or a hospital outpatient setting.

CMS Final HCPCS Coding Determination

Establish a new HCPCS Level II code J1946, "Injection, furosemide (lasix onyu), 1 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 80 mg and the HCPCS Level II code J1946 designation of 1 mg.

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

Discontinue ten, revise one, and establish thirteen 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
J0640	Delete	Leucovorin calcium, 50 mg
J0643	Add	Injection, leucovorin calcium, not otherwise specified, 1 mg
J0871	Add	Injection, daptomycin (endo), not therapeutically equivalent to j0878, 1 mg
J1941	Delete	Injection, furosemide (furoscix), 20 mg
J1947	Add	Injection, furosemide (furoscix), 1 mg
J1953	Delete	Injection, levetiracetam, 10 mg
J1957	Add	Injection, levetiracetam, 5 mg
J1958	Add	Injection, levetiracetam in sodium chloride, 5 mg
J7514	Delete	Mycophenolate mofetil (myhibbin), oral suspension, 100 mg
J7517	Delete	Mycophenolate mofetil, oral, 250 mg
J7519	Delete	Injection, mycophenolate mofetil, 10 mg
J7524	Add	Mycophenolate mofetil, oral, 5 mg
J7526	Add	Injection, mycophenolate mofetil, 5 mg
J7528	Delete	Mycophenolate mofetil, for suspension, oral, 100 mg
J7529	Add	Mycophenolate mofetil, for suspension, oral, 5 mg
J7530	Add	Mycophenolate mofetil (myhibbin), oral suspension, 5 mg
J7531	Add	Prednisolone sodium phosphate, orally disintegrating tablet, 1 mg
J9033	Revise	Injection, bendamustine hydrochloride, not otherwise specified, 1 mg
J9181	Delete	Injection, etoposide, 10 mg
J9187	Add	injection, etoposide, 1 mg
J9190	Delete	Injection, fluorouracil, 500 mg
J9192	Add	Injection, fluorouracil, 10 mg
J9352	Delete	Injection, trabectedin, 0.1 mg
J9362	Add	Injection, trabectedin, 0.01 mg