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 Recommendations

Third Quarter, 2024 HCPCS Coding Cycle

This document presents a summary of each HCPCS Level II code application and CMS' coding decision for each application processed in CMS' Third Quarter 2024 Drug and Biological HCPCS Level II code application review cycle. Each individual summary includes the request number; topic/issue; summary of the applicant's submission as written by the applicant with occasional non-substantive editorial changes made by CMS; and CMS' final HCPCS Level II coding decision. All new coding actions will be effective January 1, 2025, unless otherwise indicated.

The HCPCS Level II coding decisions below will also be included in the January 2025 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 to the insurer(s) in whose jurisdiction(s) claim(s) would be filed. Specifically, contact the Medicaid agency in the state in which a Medicaid claim is filed, the individual private insurance entity, the Department of Veterans Affairs, or, for local Medicare coverage determinations, contact the Medicare contractor in the jurisdiction the claim would be filed. For detailed information describing CMS' national coverage determination process, refer to information published at https://www.cms.gov/Medicare/Coverage/DeterminationProcess and https://www.cms.gov/Center/Special-Topic/Medicare-Coverage-Center.

CMS has a long-standing convention to assign dose descriptors in the smallest amount that could be billed in multiple units to accommodate a variety of doses and support streamlined billing. This long-standing policy makes coding more robust and facilitates accurate payment and reporting of the exact dose administered, as only 999 units can appear on a claim line for Medicare fee-for-service using the CMS-1500 form. In addition, CMS will use the generic or chemical name if there are no other similar chemical products on the market. If there are multiple products on the market with the same generic or chemical name, CMS will further distinguish a new code by using the 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 Third Quarter 2024 Drug and Biological HCPCS Level II Applications.

BKEMV™ - HCP240628RTHJN

Topic/Issue

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

Applicant's suggested language: QXXXX, "Injection, eculizumab-aeeb (bkemv), biosimilar 10 mg"

Summary of Applicant's Submission

Amgen Inc. submitted a request to establish a new HCPCS Level II code to identify BKEMV™ (eculizumab-aeeb). BKEMV™ was approved by the Food and Drug Administration (FDA) under the 351(k) Biologics License Application (BLA) pathway on February 28, 2024. BKEMV™ is a recombinant humanized monoclonal IgG2/4 kappa antibody indicated for treatment of patients with paroxysmal nocturnal hemoglobinuria (PNH) to reduce hemolysis and patients with atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy. BKEMV™ is a monoclonal antibody that specifically binds to the complement protein C5 with high affinity, thereby inhibiting its cleavage to C5a and C5b and preventing the generation of the terminal complement complex C5b-9. BKEMV™ inhibits terminal complement-mediated intravascular hemolysis in individuals with PNH and complement-mediated thrombotic microangiopathy in individuals with aHUS. BKEMV™ must be administered by intravenous infusion. For individuals with PNH who are 18 years of age and older, the recommended dosage regimen is: 600 mg weekly for the first 4 weeks, followed by 900 mg for the fifth dose 1 week later, then 900 mg every 2 weeks thereafter. For individuals with aHUS who are 18 years of age and older, the recommended dosage regimen is: 900 mg weekly for the first 4 weeks, followed by 1200 mg for the fifth dose 1 week later, then 1200 mg every 2 weeks thereafter. For individuals with aHUS who are less than 18 years of age, the recommended dosage regimen varies based on body weight. BKEMV™ is packaged in a 300 mg/30 mL (10 mg/mL) single-dose vial per carton.

CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code Q5139, "Injection, eculizumab-aeeb (bkemv), biosimilar, 10 mg"

MYHIBBIN™ - HCP2406248EV0G

Topic/Issue

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

Applicant's suggested language: JXXXX, “Oral Suspension, MYHIBBIN (Mycophenolate Mofetil) 200 mg/mL”

Summary of Applicant's Submission

Azurity Pharmaceuticals, Inc. submitted a request to establish a new HCPCS Level II code to identify MYHIBBIN™ (mycophenolate mofetil). MYHIBBIN™ was approved by the Food and Drug Administration (FDA) under a 505(b)(2) New Drug Application (NDA) on May 1, 2024. MYHIBBIN™ is an antimetabolite immunosuppressant indicated in adult and pediatric recipients 3 months of age and older for the prophylaxis of organ rejection of allogeneic kidney, heart or liver transplants, in combination with other immunosuppressants. MYHIBBIN™ is an inosine monophosphate dehydrogenase inhibitor and a 2-morpholinoethyl ester of mycophenolic acid. For adults with a kidney transplant, the recommended dosage regimen is 1 gram twice daily. For adults with a heart transplant or liver transplant, the recommended dosage is 1.5 grams twice daily. For pediatric recipients, the recommended dosage regimen varies based on body surface area, up to a maximum dosage of 2 grams for kidney transplant, and 3 grams for heart transplant or liver transplant. MYHIBBIN™ is a white to off-white suspension of mycophenolate mofetil 200 mg/mL for oral use. MYHIBBIN™ is supplied as 175 mL of suspension in 225 mL bottle with a child-resistant closure.

CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code J7514, “Mycophenolate mofetil (myhibbin), oral suspension, 100 mg”

PIASKY® - HCP240701CE2K5

Topic/Issue

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

Applicant's suggested language: XXXXX, "Injection, crovalimab-akkz, 10 mg"

Summary of Applicant's Submission

Genentech submitted a request to establish a new HCPCS Level II code to identify PIASKY® (crovalimab-akkz). PIASKY® was approved by the Food and Drug Administration (FDA) under the 351(a) Biologics License Application (BLA) pathway on June 20, 2024. PIASKY® is a complement C5 inhibitor indicated for the treatment of adults and pediatric individuals 13 years and older with paroxysmal nocturnal hemoglobinuria (PNH) and body weight of at least 40 kg. It is a monoclonal antibody that specifically binds with high affinity to the complement protein C5, inhibiting its cleavage into subunits C5a and C5b. This prevents the formation of the membrane attack complex that causes membrane disruption and consequent cell lysis or intravascular hemolysis, which is the hallmark of PNH. If not prevented, intravascular hemolysis can lead to anemia, hemoglobinuria, and potentially life-threatening thromboembolic events. PIASKY® was designed with a recycling technology to prolong the activity of the antibody, and allow it to bind multiple C5 proteins, thereby inhibiting terminal complement-mediated intravascular hemolysis in patients with PNH. PIASKY® will be administered by a healthcare professional via intravenous (IV) infusion or subcutaneous (SC) injection. The recommended dosage regimen consists of one IV loading dose on day 1, followed by four additional weekly SC loading doses on days 2, 8, 15, and 22. The maintenance dose starts on day 29 and is then administered every 4 weeks by SC injection. Doses will be administered based on the individual's actual body weight. Each PIASKY® carton contains one 340 mg/2 mL (170 mg/mL) single-dose vial for IV or SC use. Intravenous use requires dilution prior to administration.

CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code J1307, "Injection, crovalimab-akkz, 10 mg"

CASGEVY® - HCP2406258W9YX

Topic/Issue

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

Applicant's suggested language: XXXXX, "Infusion, exagamglogene autotemcel, per treatment"

Summary of Applicant's Submission

Vertex Pharmaceuticals Incorporated submitted a request to establish a new HCPCS Level II code to identify CASGEVY® (exagamglogene autotemcel). CASGEVY® was approved by the Food and Drug Administration (FDA) under the 351(a) Biologics License Application (BLA) pathway on December 8, 2023. CASGEVY® is a CRISPR-based gene editing therapy for individuals aged 12 years and older for the treatment of sickle cell disease with recurrent vaso-occlusive crises and transfusion-dependent beta-thalassemia. CASGEVY® is an autologous, hematopoietic stem-cell non-viral therapy modified ex vivo by CRISPR/Cas9 that is administered via a stem cell transplant procedure. CASGEVY® is a cell suspension for intravenous infusion. A single dose of CASGEVY® is composed of one or more vials, all vials should be administered. Each vial contains 4 to 13 × 10^6 CD34+ cells/mL suspended in 1.5 to 20 mL of cryopreservative medium. The minimum recommended dose of CASGEVY® is 3 × 10^6 CD34+ cells per kg of body weight. CASGEVY® is stored in the vapor phase of liquid nitrogen and is shipped from the manufacturing facility to the treatment center storage facility in a cryoshipper. One carton of CASGEVY® contains a single lot of consisting of 1 to 9 vials. A single dose of CASGEVY® may consist of multiple CASGEVY® lots, and therefore may consist of multiple cartons.

CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code J3392, "Injection, exagamglogene autotemcel, per treatment"

Hercessi™ - HCP2405310UJUY

Topic/Issue

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

Applicant's suggested language: QXXXX, "Inj., Hercessi, 10mg"

Summary of Applicant's Submission

Accord Biopharma Incorporated submitted a request to establish a new HCPCS Level II code to identify Hercessi™ (trastuzumab-strf). Hercessi™ was approved by the Food and Drug Administration (FDA) under the 351(a) Biologics License Application (BLA) pathway on April 25, 2024, as biosimilar to Herceptin® (trastuzumab). Hercessi™ is a monoclonal antibody against human epidermal growth factor receptor 2 (HER2). Hercessi™ is indicated for adjuvant treatment of individuals with HER2-overexpressing node-positive or node-negative or with high-risk feature breast cancer; in combination with paclitaxel for first-line treatment of HER2-overexpressing metastatic breast cancer, and as a single agent for the treatment of HER2-overexpressing breast cancer in individuals who received one or more chemotherapy agents; or in combination with cisplatin and capecitabine or 5-fluorouracil, for the treatment of individuals with HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma who have not received prior treatment. Hercessi™ dosing for adjuvant treatment of breast cancer is an initial dose of 4 mg/kg as an intravenous (IV) infusion over 90 minutes, then 2 mg/kg over 30 minutes IV infusion weekly for 12 weeks (with paclitaxel or docetaxel) or 18 weeks (with docetaxel and carboplatin). One week after the last weekly dose, the next doses of Hercessi™ is 6 mg/kg as an IV infusion over 30−90 minutes every three weeks. As a single agent, within 3 weeks following completion of multi-modality, anthracycline-based chemotherapy regimens, the initial dose of Hercessi™ is 8 mg/kg as an IV infusion over 90 minutes with subsequent doses at 6 mg/kg as an IV infusion over 30-90 minutes every 3 weeks. For metastatic breast cancer, Hercessi™ may be administered alone or in combination with paclitaxel, at an initial dose of 4 mg/kg as a 90-minute IV infusion, followed by subsequent weekly doses of 2 mg/kg as 30-minute IV infusions until disease progression. For metastatic gastric cancer, an initial dose of Hercessi™ is 8 mg/kg over 90 minutes IV infusion, followed by subsequent doses of 6 mg/kg over 30 to 90 minutes IV infusion every 3 weeks until disease progression. Hercessi™ is supplied in a 150 mg/mL single-dose vial as a white to pale yellow lyophilized sterile powder with a cake-like appearance under vacuum.

CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code Q5146, "Injection, trastuzumab-strf (hercessi), biosimilar, 10 mg"

Avyxa's Pemetrexed for Injection - HCP240701E9D94

Topic/Issue

Request to establish a new HCPCS Level II code to identify Avyxa's Pemetrexed for Injection.

Applicant's suggested language: JXXXX, "Injection, pemetrexed (AVYXA), 10 mg"

Summary of Applicant's Submission

Avyxa Holdings, LLC submitted a request to establish a new HCPCS Level II code to identify Pemetrexed for Injection. Avyxa's Pemetrexed for Injection was approved by the Food and Drug Administration (FDA) under a 505(b)(2) New Drug Application (NDA) on June 28, 2024. Avyxa's Pemetrexed for Injection is a folate analog metabolic inhibitor indicated for initial treatment of individuals with locally advanced or metastatic, non-squamous non-small cell lung cancer (NSCLC) in combination with cisplatin, as a single agent for the maintenance treatment of individuals with locally advanced or metastatic, non-squamous NSCLC whose disease has not progressed after four cycles of platinum-based first-line chemotherapy, or as a single agent for the treatment of individuals with recurrent, metastatic non-squamous NSCLC after prior chemotherapy. The recommended dosing of Avyxa's Pemetrexed for Injection is 500 mg/m² as an intravenous infusion over 10 minutes on day 1 of each 21-day cycle administered in individuals with a creatinine clearance of 45 mL/minute or greater. Avyxa's Pemetrexed for Injection is a sterile, preservative free, white-to-light yellow or green-yellow lyophilized powder supplied in 100 mg and 500 mg single-dose vials for reconstitution.

CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code J9292, "Injection, pemetrexed (avyxa), not therapeutically equivalent to j9305, 10 mg"

POSFREA - HCP2407016KG8H

Topic/Issue

Request to revise existing HCPCS Level II code J2468, “Injection, palonosetron hydrochloride (avyxa), not therapeutically equivalent to j2469, 25 micrograms” to include the brand name POSFREA.

Applicant’s suggested language: J2468, “Injection, palonosetron HCL (POSFREA), 25 mcg”

Summary of Applicant's Submission

Avyxa Holdings, LLC submitted a request to revise the existing HCPCS Level II code J2468, “Injection, palonosetron hydrochloride (avyxa), not therapeutically equivalent to j2469, 25 micrograms” to include the brand name POSFREA (palonosetron hydrochloride). Palonosetron hydrochloride injection was approved by the Food and Drug Administration (FDA) under a 505(b)(2) New Drug Application (NDA) on March 1, 2016. HCPCS Level II code J2468, “Injection, palonosetron hydrochloride (avyxa), not therapeutically equivalent to J2469, 25 micrograms” was established April 1, 2024. The brand name, POSFREA, was approved by the FDA under a supplemental NDA on July 17, 2024. Therefore, Avyxa is requesting a J code descriptor change to include the brand name, POSFREA. POSFREA is indicated for use in adults as prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of moderately or emetogenic cancer chemotherapy, as well as for prevention of postoperative nausea and vomiting (PONV) for up to 24 hours following surgery. For chemotherapy-induced nausea and vomiting, the recommended adult dosage is 0.25 mg as a single intravenous dose administered over 30 seconds, which should occur approximately 30 minutes before the start of chemotherapy. For PONV, the recommended adult dosage is 0.075 mg as a single intravenous dose administered over 10 seconds immediately before the induction of anesthesia. POSFREA is supplied as a sterile, clear, and colorless solution in single dose vials containing 0.25 mg palonosetron in 5 mL or 0.075 mg palonosetron in 1.5 mL.

CMS Final HCPCS Coding Decision

Revise existing HCPCS Level II code J2468, “Injection, palonosetron hydrochloride (avyxa), not therapeutically equivalent to j2469, 25 micrograms” to instead read “Injection, palonosetron hydrochloride (posfrea), 25 micrograms”

Baxter's Cyclophosphamide Injection - HCP240701DCJB6

Topic/Issue

Request to establish a new HCPCS Level II code to identify Baxter's Cyclophosphamide Injection.

Applicant's suggested language: JXXXX, "Injection, Cyclophosphamide (Baxter), 200mg"

Summary of Applicant's Submission

Baxter Healthcare Corporation submitted a request to establish a new HCPCS Level II code to identify Baxter's Cyclophosphamide Injection. Baxter's Cyclophosphamide Injection was approved by the Food and Drug Administration (FDA) under a 505(b)(2) New Drug Application (NDA) on June 28, 2023. Baxter's Cyclophosphamide Injection is indicated for the treatment of adults and pediatric individuals with malignant diseases, including malignant lymphomas (Hodgkin's disease, lymphocytic lymphoma, mixed-cell type lymphoma, histiocytic lymphoma, Burkitt's lymphoma), multiple myeloma, leukemias, mycosis fungoides, neuroblastoma, adenocarcinoma of the ovary, retinoblastoma, and breast carcinoma. Baxter's Cyclophosphamide Injection is an antineoplastic drug that interferes with the growth of susceptible, rapidly proliferating malignant cells. For adults and pediatric individuals, the initial course of Baxter's Cyclophosphamide Injection for individuals who do not have hematologic deficiencies usually consists of 40 mg/kg to 50 mg/kg given intravenously in divided doses throughout 2 to 5 days when used as the only oncolytic drug therapy. Other intravenous regimens include 10 mg/kg to 15 mg/kg given every 7 to 10 days or 3 mg/kg to 5 mg/kg twice weekly. Dosages may also be adjusted based on antitumor activity and/or leukopenia. The total leukocyte count may be used to manage dosage. When it is included in combined cytotoxic regimens, the dose of Baxter's Cyclophosphamide Injection may need to be reduced, as well as that of the other drugs. Baxter's Cyclophosphamide Injection is supplied as a sterile ready-to-dilute, clear, colorless solution in multiple-dose vials of 500 mg/2.5 mL and 1,000 mg/5 mL.

CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code J9076, "Injection, cyclophosphamide (baxter), 5 mg"

VAFSEO® - HCP240624AB3QD

Topic/Issue

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

Applicant's suggested language: JXXXX, "Vadadustat, oral, 1 mg (for esrd on dialysis)"

Summary of Applicant's Submission

Akebia Therapeutics, Inc. (Akebia) submitted a request to establish a new HCPCS Level II code to identify VAFSEO® (vadadustat). VAFSEO® was approved by the Food and Drug Administration (FDA) under a New Drug Application (NDA) on March 27, 2024. VAFSEO® is indicated for use in adults for the treatment of anemia due to chronic kidney disease who have been receiving dialysis for at least three months. VAFSEO® is an oral drug known as a hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI). It is a reversible inhibitor of HIF-prolyl-4-hydroxylases (PH)1, PH2, and PH3 (IC50 in the nM range), which results in the stabilization and nuclear accumulation of HIF-1a and HIF-2a transcription factors, and increased production of erythropoietin (EPO). Anemia is a prevalent and serious condition that develops in individuals with chronic kidney disease which leads to inadequate production of red blood cells that deliver oxygen to the body. The recommended starting dose for VAFSEO® is 300 mg taken orally once daily. Dose adjustments should be made in increments of 150 mg to achieve or maintain hemoglobin levels of 10 g/dL to 11 g/dL. Doses may range from 150 mg to 600 mg. VAFSEO® is formulated as film-coated tablets that are available in 150 mg, 300 mg and 450 mg strengths, and packaged in 60-count bottles.

CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code J0901, "Vadadustat, oral, 1 mg (for esrd on dialysis)"

Breyanzi® - HCP240701229TJ

Topic/Issue

Request to revise existing HCPCS Level II code Q2054, “Lisocabtagene maraleucel, up to 110 million autologous anti-cd19 car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose” to remove the preparation portion of the language.

Applicant’s suggested language: Q2054, “Lisocabtagene maraleucel, up to 110 million autologous anti-cd19 car-positive viable t cells, per therapeutic dose”

Summary of Applicant's Submission

The American Society for Transplantation and Cellular Therapy (ASTCT) submitted a request to revise the existing HCPCS Level II code Q2054, “Lisocabtagene maraleucel, up to 110 million autologous anti-cd19 car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose” to remove the preparation portion of the code language for the Breyanzi® (lisocabtagene maraleucel) CAR-T product. The ASTCT is not requesting a revision of any portion of the code description pertaining to the actual description of the product lisocabtagene maraleucel or the cell dose information. These clinical services should not be in the Q code as they are appropriately represented using HCPCS Level I Current Procedural Terminology (CPT®) codes for CAR-T cell collection (0537T, to be replaced by Level I code 3X018 as of January 1, 2025), and CAR-T cell preparation and cell processing services (0538T and 0539T, to be replaced by Level I codes 3X019 and 3X020 as of January 1, 2025). Breyanzi® is a CD19-directed genetically modified autologous T-cell immunotherapy indicated for the treatment of adults with relapsed or refractory mantle cell lymphoma, and adults with relapsed or refractory B-cell precursor acute lymphoblastic leukemia.

CMS Final HCPCS Coding Decision

CMS has not identified a program operating need for Medicare or other payers to revise the existing HCPCS Level II code Q2054. The current HCPCS Level II coding for the CAR-T cell therapies include “leukapheresis and dose preparation procedures”, as these services are included in the manufacturing of these products. Medicare does not generally pay separately for each step used to manufacture a drug or biological product; therefore, payment for these services is incorporated into the code. This payment policy necessitates maintaining the current descriptor language for the HCPCS Level II code. This topic was most recently discussed in the Calendar Year 2022 Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System final rule with comment period (86 FR 63550 through 63551).

ABECMA® – HCP24070191K98

Topic/Issue

Request to revise existing HCPCS Level II code Q2055, “Idecabtagene vicleucel, up to 510 million autologous b-cell maturation antigen (bcma) directed car-positive t cells, including leukapheresis and dose preparation procedures, per therapeutic dose” to remove the preparation portion of the language.

Applicant’s suggested language: Q2055, “Idecabtagene vicleucel, up to 510 million autologous b-cell maturation antigen (bcma) directed car-positive t cells, per therapeutic dose”

Summary of Applicant's Submission

The American Society for Transplantation and Cellular Therapy (ASTCT) submitted a request to revise the existing HCPCS Level II code Q2055, “Idecabtagene vicleucel, up to 510 million autologous b-cell maturation antigen (bcma) directed car-positive t cells, including leukapheresis and dose preparation procedures, per therapeutic dose” to remove the preparation portion of the language for the ABECMA® (idecabtagene vicleucel) CAR-T product. The ASTCT is not requesting a revision of any portion of the code description pertaining to the actual description of the product idecabtagene vicleucel or the cell dose information. These clinical services should not be in the Q code as they are appropriately represented using HCPCS Level I Current Procedural Terminology (CPT®) codes for CAR-T cell collection (0537T, to be replaced by Level I code 3X018 as of January 1, 2025), and CAR-T cell preparation and cell processing services (0538T and 0539T, to be replaced by Level I codes 3X019 and 3X020 as of January 1, 2025). ABECMA® is a B-cell maturation antigen (BCMA)-directed genetically modified autologous T-cell immunotherapy indicated for the treatment of adults with relapsed or refractory multiple myeloma after two or more prior lines of therapy including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody.

CMS Final HCPCS Coding Decision

CMS has not identified a program operating need for Medicare or other payers to revise the existing HCPCS Level II code Q2055. The current HCPCS Level II coding for the CAR-T cell therapies include “leukapheresis and dose preparation procedures”, as these services are included in the manufacturing of these products. Medicare does not generally pay separately for each step used to manufacture a drug or biological product; therefore, payment for these services is incorporated into the code. This payment policy necessitates maintaining the current descriptor language for the HCPCS Level II code. This topic was most recently discussed in the Calendar Year 2022 Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System final rule with comment period (86 FR 63550 through 63551).

CARVYKTI® - HCP24070161H23

Topic/Issue

Request to revise existing HCPCS Level II code Q2056, “Ciltacabtagene autoleucel, up to 100 million autologous b-cell maturation antigen (bcma) directed car-positive t cells, including leukapheresis and dose preparation procedures, per therapeutic dose” to remove the preparation portion of the language.

Applicant’s suggested language: Q2056, “Ciltacabtagene autoleucel, up to 100 million autologous b-cell maturation antigen (bcma) directed car-positive t cells, per therapeutic dose”

Summary of Applicant's Submission

The American Society for Transplantation and Cellular Therapy (ASTCT) submitted a request to revise the existing HCPCS Level II code Q2056, “Ciltacabtagene autoleucel, up to 100 million autologous b-cell maturation antigen (bcma) directed car-positive t cells, including leukapheresis and dose preparation procedures, per therapeutic dose to remove the preparation portion of the language for the CARVYKTI® (ciltacabtagene autoleucel) CAR-T product. The ASTCT is not requesting a revision of any portion of the code description pertaining to the actual description of the product ciltacabtagene autoleucel or the cell dose information. These clinical services should not be in the Q code as they are appropriately represented using HCPCS Level I Current Procedural Terminology (CPT®) codes for CAR-T cell collection (0537T, to be replaced by Level I code 3X018 as of January 1, 2025), and CAR-T cell preparation and cell processing services (0538T and 0539T, to be replaced by Level I codes 3X019 and 3X020 as of January 1, 2025). CARVYKTI® is a B-cell maturation antigen (BCMA)-directed genetically modified autologous T-cell immunotherapy indicated for the treatment of adults with relapsed or refractory multiple myeloma who have received at least 1 prior line of therapy, including a proteasome inhibitor and an immunomodulatory agent, and are refractory to lenalidomide.

CMS Final HCPCS Coding Decision

CMS has not identified a program operating need for Medicare or other payers to revise the existing HCPCS Level II code Q2056. The current HCPCS Level II coding for the CAR-T cell therapies include “leukapheresis and dose preparation procedures”, as these services are included in the manufacturing of these products. Medicare does not generally pay separately for each step used to manufacture a drug or biological product; therefore, payment for these services is incorporated into the code. This payment policy necessitates maintaining the current descriptor language for the HCPCS Level II code. This topic was most recently discussed in the Calendar Year 2022 Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System final rule with comment period (86 FR 63550 through 63551).

YESCARTA® - HCP2407010D0QY

Topic/Issue

Request to revise existing HCPCS Level II code Q2041, “Axicabtagene ciloleucel, up to 200 million autologous anti-cd19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose” to remove the preparation portion of the language.

Applicant’s suggested language: Q2041, “Axicabtagene ciloleucel, up to 200 million autologous anti-cd19 car positive viable t cells, per therapeutic dose”

Summary of Applicant's Submission

The American Society for Transplantation and Cellular Therapy (ASTCT) submitted a request to revise the existing HCPCS Level II code Q2041, “Axicabtagene ciloleucel, up to 200 million autologous anti-cd19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose” to remove the preparation portion of the language. for the YESCARTA® (axicabtagene ciloleucel) CAR-T product. The ASTCT is not requesting a revision of any portion of the code description pertaining to the actual description of the product axicabtagene ciloleucel or the cell dose information. These clinical services should not be in the Q code as they are appropriately represented using HCPCS Level I Current Procedural Terminology (CPT®) codes for CAR-T cell collection (0537T, to be replaced by Level I code 3X018 as of January 1, 2025), and CAR-T cell preparation and cell processing services (0538T and 0539T, to be replaced by Level I codes 3X019 and 3X020 as of January 1, 2025). YESCARTA® (axicabtagene ciloleucel) is a CD19-directed genetically modified autologous T-cell immunotherapy (CAR-T therapy) indicated for the treatment of adults with large B-cell lymphoma that is refractory to first-line chemoimmunotherapy or that relapses within 12 months of first-line chemoimmunotherapy, or adults with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, primary mediastinal large B-cell lymphoma, high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma.

CMS Final HCPCS Coding Decision

CMS has not identified a program operating need for Medicare or other payers to revise the existing HCPCS Level II code Q2041. The current HCPCS Level II coding for the CAR-T cell therapies include “leukapheresis and dose preparation procedures”, as these services are included in the manufacturing of these products. Medicare does not generally pay separately for each step used to manufacture a drug or biological product; therefore, payment for these services is incorporated into the code. This payment policy necessitates maintaining the current descriptor language for the HCPCS Level II code. This topic was most recently discussed in the Calendar Year 2022 Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System final rule with comment period (86 FR 63550 through 63551).

TECARTUS® - HCP2407017N61X

Topic/Issue

Request to revise existing HCPCS Level II code Q2053, “Brexucabtagene autoleucel, up to 200 million autologous anti-cd19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose” to remove the preparation portion of the language.

Applicant’s suggested language: Q2053, “Brexucabtagene autoleucel, up to 200 million autologous anti-cd19 car positive viable t cells, per therapeutic dose”

Summary of Applicant's Submission

The American Society for Transplantation and Cellular Therapy (ASTCT) submitted a request to revise the existing HCPCS Level II code Q2053, “Brexucabtagene autoleucel, up to 200 million autologous anti-cd19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose” to remove the preparation portion of the language for the TECARTUS® (brexucabtagene autoleucel,) CAR-T product. The ASTCT is not requesting a revision of any portion of the code description pertaining to the actual description of the product brexucabtagene autoleucel or the cell dose information. These clinical services should not be in the Q code as they are appropriately represented using HCPCS Level I Current Procedural Terminology (CPT®) codes for CAR-T cell collection (0537T, to be replaced by Level I code 3X018 as of January 1, 2025), and CAR-T cell preparation and cell processing services (0538T and 0539T, to be replaced by Level I codes 3X019 and 3X020 as of January 1, 2025). TECARTUS® is a CD19-directed genetically modified autologous T-cell immunotherapy indicated for the treatment of adults with relapsed or refractory mantle cell lymphoma, and adults with relapsed or refractory B-cell precursor acute lymphoblastic leukemia.

CMS Final HCPCS Coding Decision

CMS has not identified a program operating need for Medicare or other payers to revise the existing HCPCS Level II code Q2053. The current HCPCS Level II coding for the CAR-T cell therapies include “leukapheresis and dose preparation procedures”, as these services are included in the manufacturing of these products. Medicare does not generally pay separately for each step used to manufacture a drug or biological product; therefore, payment for these services is incorporated into the code. This payment policy necessitates maintaining the current descriptor language for the HCPCS Level II code. This topic was most recently discussed in the Calendar Year 2022 Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System final rule with comment period (86 FR 63550 through 63551).

KYMRIAH® - HCP2407017H1KE

Topic/Issue

Request to revise existing HCPCS Level II code Q2042, “Tisagenlecleucel, up to 600 million car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose” to remove the preparation portion of the language.

Applicant’s suggested language: Q2042, “Tisagenlecleucel, up to 600 million car-positive viable t cells, per therapeutic dose”

Summary of Applicant's Submission

The American Society for Transplantation and Cellular Therapy (ASTCT) submitted a request to revise the existing HCPCS Level II code Q2042, “Tisagenlecleucel, up to 600 million car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose” to remove the preparation portion of the language for the KYMRIAH® (tisagenlecleucel) CAR-T product. The ASTCT is not requesting a revision of any portion of the code description pertaining to the actual description of the product tisagenlecleucel or the cell dose information. These clinical services should not be in the Q code as they are appropriately represented using HCPCS Level I Current Procedural Terminology (CPT®) codes for CAR-T cell collection (0537T, to be replaced by Level I code 3X018 as of January 1, 2025), and CAR-T cell preparation and cell processing services (0538T and 0539T, to be replaced by Level I codes 3X019 and 3X020 as of January 1, 2025). KYMRIAH® is a CD19-directed genetically modified autologous T-cell immunotherapy indicated for the treatment of individuals up to 25 years of age with B-cell precursor acute lymphoblastic leukemia that is refractory or in second or later relapse, adults with relapsed or refractory (r/r) large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, high grade B-cell lymphoma and DLBCL arising from follicular lymphoma.

CMS Final HCPCS Coding Decision

CMS has not identified a program operating need for Medicare or other payers to revise the existing HCPCS Level II code Q2042. The current HCPCS Level II coding for the CAR-T cell therapies include “leukapheresis and dose preparation procedures”, as these services are included in the manufacturing of these products. Medicare does not generally pay separately for each step used to manufacture a drug or biological product; therefore, payment for these services is incorporated into the code. This payment policy necessitates maintaining the current descriptor language for the HCPCS Level II code. This topic was most recently discussed in the Calendar Year 2022 Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System final rule with comment period (86 FR 63550 through 63551).

Cyclophosphamide - HCP2407012XH53

Topic/Issue

Request to revise existing HCPCS Level II code J9072, “Injection, cyclophosphamide (dr.reddy’s), 5 mg” to change the manufacturer from Dr. Reddy’s to Avyxa.

Applicant's suggested language: J9072, “Injection, cyclophosphamide, (AVYXA), 5 mg”

Summary of Applicant's Submission

Avyxa Holdings, LLC submitted a request to revise HCPCS Level II code J9072 that describes Cyclophosphamide injection to change the manufacturer to Avyxa. Cyclophosphamide was approved by the Food and Drug Administration (FDA) under a 505(b)(2) New Drug Application (NDA) on June 7, 2023. Cyclophosphamide was assigned the HCPCS Level II code, J9072, and descriptor, “Injection, cyclophosphamide (dr.reddy), 5 mg,” effective January 1, 2024. In June 2024, Dr. Reddy's Laboratories transferred the NDA for Cyclophosphamide to Avyxa Holdings, LLC and therefore is requesting a code descriptor change to “Injection, cyclophosphamide (avyxa), 5 mg” to account for the product transfer.

CMS Final HCPCS Coding Decision

Revise existing HCPCS Level II code J9072, “Injection, cyclophosphamide (dr.reddy’s), 5 mg” to instead read “Injection, cyclophosphamide (avyxa), 5 mg”

RYTELO - HCP240625T9MXF

Topic/Issue

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

Applicant's suggested language: JXXXX, “Injection, imetelstat, per 0.1mg”

Summary of Applicant's Submission

Geron Corporation submitted a request to establish a new HCPCS Level II code to identify RYTELO (imetelstat). RYTELO was approved by the Food and Drug Administration (FDA) under a New Drug Application (NDA) on June 6, 2024. RYTELO is indicated for the treatment of adults with low to intermediate-1 risk myelodysplastic syndromes with transfusion-dependent anemia requiring 4 or more red blood cell units over 8 weeks who have not responded to or have lost response to or are ineligible for erythropoiesis stimulating agents. RYTELO is an oligonucleotide telomerase inhibitor that binds to the template region of the Ribonucleic acid component of human telomerase, inhibits telomerase enzymatic activity, and prevents telomere binding. The recommended dosage of RYTELO is 7.1 mg/kg administered as an intravenous infusion over 2 hours every 4 weeks. RYTELO is supplied as a lyophilized powder in a single-dose vial and must be reconstituted and diluted prior to administration. RYTELO does not contain a preservative. Each single-dose vial contains either 47 mg of imetelstat (equivalent to 50 mg imetelstat sodium) or 188 mg of imetelstat (equivalent to 200 mg imetelstat sodium).

CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code J0870, “Injection, imetelstat, 1 mg”

OHTUVAYRE - HCP240627V42BB

Topic/Issue

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

Applicant's suggested language: XXXXX, “Ensifentrine, inhalation suspension, FDA approved final product, non-compounded, administered through DME, unit dose form, 3 mg”

Summary of Applicant's Submission

Verona Pharma, Inc. submitted a request to establish a new HCPCS Level II code to identify OHTUVAYRE (ensifentrine) inhalation suspension. OHTUVAYRE was approved by the Food and Drug Administration (FDA) under a New Drug Application (NDA) on June 26, 2024. OHTUVAYRE (ensifentrine) inhalation suspension combines bronchodilator and non-steroidal anti-inflammatory activities in one compound. It was approved for the maintenance treatment of adults with chronic obstructive pulmonary disease. OHTUVAYRE is administered via a standard jet nebulizer with mouthpiece. OHTUVAYRE is packaged in a 3 mg ampule (2.5 mL) in a box of 60 ampules. The recommended dosage is 3 mg twice daily.

CMS Final HCPCS Coding Decision[1]

Establish a new HCPCS Level II code J7601, “Ensifentrine, inhalation suspension, fda approved final product, non-compounded, administered through dme, unit dose form, 3 mg”

[1] Updated on October 4, 2024 to revise “solution” to instead read “suspension” within the long description for HCPCS Level II code J7601.

LUMISIGHT - HCP240701PVPA4

Topic/Issue

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

Applicant's suggested language: JXXXX, "Injection, pegulicianine, 1 mg/kg"

Summary of Applicant's Submission

Lumicell, Inc. submitted a request to establish a new HCPCS Level II code to identify LUMISIGHT (pegulicianine). LUMISIGHT was approved by the Food and Drug Administration (FDA) under a New Drug Application (NDA) on April 17, 2024. LUMISIGHT (pegulicianine) is an optical imaging agent indicated for fluorescence imaging in the treatment of adults with breast cancer as an adjunct for the interoperative detection of cancerous tissue within the resection cavity following removal of the primary specimen during lumpectomy surgery. LUMISIGHT is used with an FDA-approved fluorescence imaging device for specific use with pegulicianine in the breast, such as the Lumicell™ Direct Visualization System (DVS), that provides illumination to excite the fluorescent components of LUMISIGHT and collects images showing LUMISIGHT's fluorescence emission. Regions suspected to contain cancerous tissues are highlighted in red as positive signals on the Lumicell™ DVS display. The recommended dose is 1 mg/kg, thus, the total amount for administration depends on the individual's weight. Multiple vials of LUMISIGHT may need to be reconstituted to achieve the correct dose. For an individual weighing 70 kg, the dose will be 70 mg of LUMISIGHT when injected at the recommended dose of 1 mg/kg. LUMISIGHT is administered by intravenous injection 2 hours to 6 hours prior to intraoperative, post resection, imaging over 3 minutes. LUMISIGHT is supplied in a carton of 10, 39 mg single use vials.

CMS Final HCPCS Coding Decision

1. Establish a new HCPCS Level II code A9615, "Injection, pegulicianine, 1 mg"

   Effective January 1, 2025

2. Discontinue HCPCS Level II code C9171, "Injection, pegulicianine, 1 mg"

   Effective December 31, 2024

ANKTIVA® - HCP2405249LXVH

Topic/Issue

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

Applicant's suggested language: JXXXX, "Injection, nogapendekin alfa inbakicept-pmln, per therapeutic dose"

Summary of Applicant's Submission

Immunity Bio, Inc. submitted a request to establish a new HCPCS Level II code to identify ANKTIVA® (nogapendekin alfa inbakicept-pmln). ANKTIVA® was approved by the Food and Drug Administration (FDA) under the 351(a) Biologics License Application (BLA) pathway on April 22, 2024. ANKTIVA® (nogapendekin alfa inbakicept-pmln) is an interleukin-15 (IL-15) receptor agonist indicated in combination with Bacillus Calmette-Guérin (BCG) for the treatment of adults with BCG unresponsive non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors. During ANKTIVA®'s mechanism of action, IL-15 signals through a heterotrimeric receptor that is composed of the common gamma chain (γc) subunit, the beta chain (βc) subunit, and the IL-15-specific alpha subunit, IL-15 receptor alpha (α). IL-15 is then trans-presented by the IL-15 receptor α to the shared IL-2/IL-15 receptor (βc and γc) on the surface of CD4+ and CD8+ T-cells and natural killer (NK) cells. This results in activation and proliferation of NK, T, and memory T-cells. ANKTIVA® is for intravesical use only and must be diluted prior to instillation. The recommended induction dose is 400 mcg combined with BCG admixture, administered intravesically once a week for six weeks. ANKTIVA® and the BCG admixture are retained in the bladder for two hours and then voided. ANKTIVA® is a solution packaged in a carton containing 400 mcg/0.4 mL, single-dose vials.

CMS Final HCPCS Coding Decision

1. Establish a new HCPCS Level II code J9028, "Injection, nogapendekin alfa inbakicept-pmln, for intravesical use, 1 microgram"

   Effective January 1, 2025

2. Discontinue HCPCS Level II code C9169, "Injection, nogapendekin alfa inbakicept-pmln, for intravesical use, 1 microgram"

   Effective December 31, 2024

BEQVEZ - HCP24051699411

Topic/Issue

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

Applicant's suggested language: JXXXX "Injection, fidanacogene elaparvovec-dzkt, per therapeutic dose"

Summary of Applicant's Submission

Pfizer, Inc. submitted a request to establish a new HCPCS Level II code to identify BEQVEZ (fidanacogene elaparvovec-dzkt). BEQVEZ was approved by the Food and Drug Association (FDA) under the 351(a) Biologics License Application (BLA) pathway on April 25, 2024. BEQVEZ (fidanacogene elaparvovec-dzkt), is an adeno-associated virus (AAV) vector-based gene therapy for intravenous infusion indicated for the treatment of adults with moderate to severe hemophilia B (congenital factor IX deficiency) who currently use factor IX prophylaxis therapy, or have current or historical life-threatening hemorrhage, or have repeated, serious spontaneous bleeding episodes, and, do not have neutralizing antibodies to adeno-associated virus serotype Rh74var (AAVRh74var) capsid as detected by an FDA-approved test. BEQVEZ is based on recombinant DNA technology that consists of a recombinant viral capsid (AAVRh74var) derived from a naturally occurring AAV serotype (Rh74) vector containing the human coagulation factor IX (FIX) transgene modified to a high-specific factor IX activity variant known as FIX R338L. The AAVRh74var capsid is derived from the Rh74 AAV, which is not known to cause disease in humans. BEQVEZ is a gene therapy designed to introduce in the transduced cells a functional copy of the factor IX gene encoding a high-activity FIX variant (FIX-R338L, hFIX Padua). The AAVRh74var capsid can transduce hepatocytes, the natural site of factor IX synthesis. Single intravenous infusion of BEQVEZ results in cell transduction and an increase in circulating factor IX activity in individuals with hemophilia B. The recommended dose of BEQVEZ is a single-dose IV infusion of 5×10^{11} vector genomes per kg (vg/kg) of body weight. The dose is based on adjusted body weight for individuals with a body mass index >30 kg/m^2. BEQVEZ is administered via intravenous infusion only. BEQVEZ treatment should be initiated and administered in hospitals and other clinical centers and supervised by a physician experienced in the treatment of hemophilia. Each BEQVEZ vial contains 1×10^{13} vg per mL, and the excipients sodium chloride (10.5 mg/mL), sodium phosphate, monobasic, monohydrate (0.3 mg/mL), sodium phosphate, dibasic, heptahydrate (2.2 mg/mL), and poloxamer 188 (0.01 mg/mL) in a 1 mL extractable volume. Each 1 mL of BEQVEZ injection contains less than 5 mg each of sodium and phosphorus. BEQVEZ requires dilution prior to administration and is packaged as a sterile suspension that contains no preservative.

CMS Final HCPCS Coding Decision

1. Establish a new HCPCS Level II code J1414, "Injection, fidanacogene elaparvovec-dzkt, per therapeutic dose"

   Effective January 1, 2025

2. Discontinue HCPCS Level II code C9172, "Injection, fidanacogene elaparvovec-dzkt, per therapeutic dose"

Effective December 31, 2024

IMDELLTRA™- HCP240628W2V8D

Topic/Issue

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

Applicant's suggested language: JXXXX, "Injection, tarlatamab-dlle, 1 mg"

Summary of Applicant's Submission

Amgen submitted a request to establish a new HCPCS Level II code to identify IMDELLTRA™ (tarlatamab-dlle). IMDELLTRA™ was approved by the Food and Drug Administration (FDA) under the 351(a) Biologics License Application (BLA) pathway on May 16, 2024. IMDELLTRA™ is a bispecific delta-like ligand 3 (DLL3)-directed CD3 T-cell engager that binds to DLL3 expressed on the surface of cells, including tumor cells, and CD3 expressed on the surface of T-cells for the treatment of extensive stage small cell lung cancer (ES-SCLC). IMDELLTRA™ causes T-cell activation, release of inflammatory cytokines, and lysis of DLL3-expressing cells. IMDELLTRA™ is administered by a qualified healthcare provider as a 1-hour intravenous (IV) infusion in an appropriate healthcare setting. The recommended step-up dosing schedule of IMDELLTRA™ for cycle 1 is an initial dose of 1 mg on day 1 followed by 10 mg on days 8 and 15. For cycles 2 to 5 and subsequent infusions, the recommended dosing is 10 mg every 2 weeks until disease progression or unacceptable toxicity. IMDELLTRA™ is a sterile, preservative-free, white to slightly yellow, lyophilized powder for reconstitution and further dilution supplied in two packaging configurations: a 1 mg package containing 1 single-dose vial of 1 mg IMDELLTRA™ and 2 vials of 7 mL IV solution stabilizer, and a 10 mg package containing 1 single-dose vial of 10 mg IMDELLTRA™ and 2 vials of 7 mL IV solution stabilizer.

CMS Final HCPCS Coding Decision

1. Establish a new HCPCS Level II code J9026, "Injection, tarlatamab-dlle, 1 mg"

   Effective January 1, 2025

2. Discontinue HCPCS Level II code C9170, "Injection, tarlatamab-dlle, 1 mg"

   Effective December 31, 2024

Pantoprazole Sodium in Sodium Chloride - HCP24062072WX3

Topic/Issue

Request to establish a new HCPCS Level II code to identify Pantoprazole Sodium in Sodium Chloride.

Applicant's suggested language: JXXXX, “Injection, pantoprazole sodium in sodium chloride (baxter), 40 mg”

Summary of Applicant's Submission

Baxter Healthcare Corporation is submitting a request to establish a new HCPCS Level II code to identify Pantoprazole Sodium in Sodium Chloride Injection. Pantoprazole Sodium in Sodium Chloride Injection was approved by the Food and Drug Administration (FDA) under a 505(b)(2) New Drug Application (NDA) on February 14, 2024. Baxter's Pantoprazole Sodium in Sodium Chloride Injection is indicated for the short-term treatment (7 to 10 days) of adults with gastroesophageal reflux disease (GERD) and a history of erosive esophagitis (EE) and the treatment of pathological hypersecretory conditions, including Zollinger-Ellison (ZE) Syndrome. Pantoprazole is a proton pump inhibitor that suppresses the final step in gastric acid production by covalently binding to the (hydrogen, potassium)-ATPase enzyme system at the secretory surface of the gastric parietal cell. This effect inhibits basal and stimulated gastric acid secretion, irrespective of the stimulus. The recommended dosage for adults with GERD associated with a history of EE is 40 mg, given once daily by intravenous infusion administered over 15 minutes for 7 to 10 days. Treatment is discontinued as soon as the patient can receive treatment with pantoprazole sodium delayed-release tablets or oral suspension. The recommended dosage for adults for pathological hypersecretion, including ZE Syndrome, is 80 mg every 12 hours by intravenous infusion administered over 15 minutes. In those patients who need a higher dosage, 80 mg intravenously every 8 hours is expected to maintain acid output below ten mEq/h. Baxter's Pantoprazole Sodium is supplied as a frozen, premixed, iso-osmotic, sterile, nonpyrogenic single-dose GALAXY container.

CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code J2472, "Injection, pantoprazole sodium in sodium chloride (baxter), 40 mg"

EXPAREL® - HCP240701DP8M8

Topic/Issue

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

Applicant’s suggested language: JXXXX, "Injection, bupivacaine liposome (EXPAREL), 1 mg"

Summary of Applicant's Submission

Pacira BioSciences, Inc. submitted a request to establish a new HCPCS Level II code to identify EXPAREL® (bupivacaine liposome). EXPAREL® was approved by the Food and Drug Administration (FDA) under a 505(b)(2) New Drug Application (NDA) on October 28, 2011. EXPAREL® is indicated for individuals aged 6 and older for postsurgical local analgesia via infiltration and as an interscalene brachial plexus nerve block for postsurgical regional analgesia. EXPAREL® is also indicated for adults to produce postsurgical regional anesthesia via a sciatic nerve block in the popliteal fossa and via an adductor canal block. The recommended dose of EXPAREL® is based on the surgical site and the volume required to cover the area, with a maximum dosage not to exceed 266 mg. EXPAREL® is injected slowly with a needle into soft tissues with frequent aspiration. It is supplied in 10 mL or 20 mL single-use vials with 1.3% liposomal bupivacaine (13.3 mg/mL) packaged into cartons of 10 or 4 vials. Procedures using EXPAREL® for longer-term, non-opioid pain relief in the freestanding setting include dermatological procedures, oral and maxillofacial surgery procedures, treatment of subcutaneous lesions and infections, and other minor surgical procedures.

CMS Final HCPCS Coding Decision

1. Establish a new HCPCS Level II code J0666, "Injection, bupivacaine liposome, 1 mg"

   Effective January 1, 2025

2. Discontinue HCPCS Level II code C9290, “Injection, bupivacaine liposome, 1 mg”

   Effective December 31, 2024

PYZCHIVA® Subcutaneous (SC) - HCP24070100ET5

Topic/Issue

Request to establish a new HCPCS Level II code to identify PYZCHIVA® (SC).

Applicant's suggested language: QXXXX, "Injection, ustekinumab-ttwe (PYZCHIVA), biosimilar, subcutaneous, 1 mg"

Summary of Applicant's Submission

Sandoz Inc. submitted a request to establish a new HCPCS Level II code to identify PYZCHIVA® (ustekinumab-ttwe) (SC). PYZCHIVA® (SC) was approved by the Food and Drug Administration (FDA) under the 351(k) Biologics License Application (BLA) pathway on June 28, 2024. PYZCHIVA® (SC) is a monoclonal antibody medication to interleukin 12/23 for the treatment of autoimmune disorders including within gastroenterology, dermatology, and rheumatology. It is indicated for the treatment of adults and pediatric individuals aged 6 or older with moderate to severe plaque psoriasis, who are candidates for phototherapy or systemic therapy; treatment of adults or pediatric individuals aged 6 or older for active psoriatic arthritis; treatment of adults with moderately to severely active Crohn's disease; and treatment of adults with moderately to severely active ulcerative colitis. PYZCHIVA® (SC) is as a clear, colorless to light yellow sterile and preservative-free solution with pH of 5.7– 6.3. PYZCHIVA® (SC) is packaged as a pre-filled syringe containing 45 mg/0.5 mL or 90 mg/mL. The recommended dosage of PYZCHIVA® (SC) varies by indication and the individual's weight.

CMS Final HCPCS Coding Decision

CMS generally creates codes for products themselves, without specifying a route of administration in the code descriptor, as there might be multiple routes of administration for the same product. However, PYZCHIVA® (SC) was approved by the Food and Drug Administration (FDA) under its own unique BLA, 761373, and must be distinguished from PYZCHIVA® (IV), which also has a unique BLA, 761425.

Establish a new HCPCS Level II code Q9996, "Injection, ustekinumab-ttwe (pyzchiva), subcutaneous, 1 mg"

PYZCHIVA® Intravenous (IV) - HCP240701BULUW

Topic/Issue

Request to establish a new HCPCS Level II code to identify PYZCHIVA® (IV).

Applicant's suggested language: QXXXX, "Injection, ustekinumab-ttwe (PYZCHIVA), biosimilar, intravenous, 1 mg"

Summary of Applicant's Submission

Sandoz Inc. submitted a request to establish a new HCPCS Level II code to identify PYZCHIVA® (ustekinumab-ttwe) (IV). PYZCHIVA® (IV) was approved by the Food and Drug Administration (FDA) under the 351(k) Biologics License Application (BLA) pathway on June 28, 2024. PYZCHIVA® (IV) is a monoclonal antibody medication to interleukin - 12/23 for the treatment of autoimmune disorders including within gastroenterology, dermatology, and rheumatology. It is indicated for the treatment of adults and pediatric individuals aged 6 or older with moderate to severe plaque psoriasis, who are candidates for phototherapy or systemic therapy; treatment of adults or pediatric individuals aged 6 or older for active psoriatic arthritis; treatment of adults with moderately to severely active Crohn's disease; and treatment of adults with moderately to severely active ulcerative colitis. PYZCHIVA® (IV) is a clear, colorless to light yellow sterile and preservative-free solution with pH of 5.7– 6.3. PYZCHIVA® (IV) is packaged as a single-dose vial containing 130 mg/26 mL (5 mg/mL) of ustekinumab to be administered via intravenous infusion. The recommended dosage of PYZCHIVA® (IV) varies by indication and patient weight.

CMS Final HCPCS Coding Decision

CMS generally creates codes for products themselves, without specifying a route of administration in the code descriptor, as there might be multiple routes of administration for the same product. However, PYZCHIVA® (IV) was approved by the Food and Drug Administration (FDA) under its own unique BLA, 761425, and must be distinguished from PYZCHIVA® (SC), which also has a unique BLA, 761373.

Establish a new HCPCS Level II code Q9997, "Injection, ustekinumab-ttwe (pyzchiva), intravenous, 1 mg"

SELARSDI™ Subcutaneous (SC) - HCP240629E01NC

Topic/Issue

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

Applicant's suggested language: QXXXX, "Injection, ustekinumab-aekn (selarsdi), biosimilar, subcutaneous, 1 mg"

Summary of Applicant's Submission

Teva Pharmaceuticals, Inc. submitted a request to establish a new HCPCS Level II code to identify SELARSDI™ (ustekinumab-aekn) (SC). SELARSDI™ (SC) was approved by the Food and Drug Administration (FDA) under the 351(k) Biologics License Application (BLA) pathway on April 16, 2024. SELARSDI™ (SC) for is a human interleukin -12 and -23 antagonist. SELARSDI™ (SC) is indicated for the treatment of adults with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy, and active psoriatic arthritis. SELARSDI™ (SC) is also indicated for the treatment of pediatric individuals 6 years and older with moderate to severe plaque psoriasis, who are candidates for phototherapy or systemic therapy and active psoriatic arthritis. The recommended dosage of SELARSDI™ (SC) varies based on indication as well as the individual's weight. SELARSDI™ (SC) is packaged in a 45 mg/0.5 mL single-dose prefilled syringe and a 90 mg/mL single-dose prefilled syringe.

CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code Q9998, "Injection, ustekinumab-aekn (selarsdi), 1 mg"

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 the JA modifier for the intravenous infusion of the drug or billed with the JB modifier for subcutaneous injection of the drug.

PROBUPHINE® - IHC240918CTFFL

Topic/Issue

Request to discontinue existing HCPCS Level II code J0570 “Buprenorphine implant, 74.2 mg.”

Summary of Applicant's Submission

CMS has reviewed the discontinuation of existing HCPCS Level II code J0570, “Buprenorphine implant, 74.2 mg” that identifies PROBUPHINE® (buprenorphine hydrochloride) implant. PROBUPHINE® (buprenorphine hydrochloride) implant was approved by the Food and Drug Administration (FDA) on May 26, 2016. PROBUPHINE® is indicated for the maintenance treatment of opioid dependence in individuals who have achieved and sustained prolonged clinical stability on low-to-moderate doses of a transmucosal buprenorphine containing product. HCPCS Level II code J0570 is no longer used because PROBUPHINE® was discontinued by the FDA on October 1, 2020. The expiration date of the last lot sold of PROBUPHINE® (as reported to CMS) was April 30, 2021.

CMS Final HCPCS Coding Decision

Discontinue existing HCPCS Level II code J0570, “Buprenorphine implant, 74.2 mg”

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

Xceed™ TL Matrix - HCP240701RT2N5

Topic/Issue

Request to establish a new HCPCS Level II code to identify Xceed™ TL Matrix.

The applicant did not submit any suggested language.

Summary of Applicant's Submission

RMBB Health submitted a request to establish a new HCPCS Level II code to identify Xceed™ TL Matrix. Xceed™ TL Matrix is regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) solely under section 361 of the Public Health Service (PHS) Act and 21 CFR Part 1271 when intended for use as a "barrier or cover." Xceed™ TL Matrix is derived from processed human placental tissue and consists of three layers of placental membranes. Xceed™ TL Matrix is composed of extracellular matrix proteins and is intended for use over wounds and as a barrier or protective coverage for acute and chronic wounds. Xceed™ TL Matrix is supplied in various sizes.

CMS Final HCPCS Coding Decision

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

Establish a new HCPCS Level II code Q4353, "Xceed tl matrix, per square centimeter"

This coding decision applies to the Xceed™ TL Matrix product described in the application and accompanying FDA TRG letter dated June 20, 2024, when intended as a "barrier or cover."

Shelter™ DM Matrix - HCP240626U852D

Topic/Issue

Request to establish new HCPCS Level II code to identify Shelter™ DM Matrix.

Applicant suggests language: XXXXX, “Shelter™ DM Matrix, per cm2”

Summary of Applicant's Submission

Sequence LifeScience Inc. submitted a request to establish a new HCPCS Level II code to identify Shelter™ DM Matrix. Shelter™ DM Matrix is regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) solely under section 361 of the Public Health Service (PHS) Act and 21 CFR Part 1271 when intended for use as a “barrier or cover.” Shelter™ DM Matrix is a dual membrane, minimally manipulated, human amniotic and chorionic membrane product derived from placental tissue that retain the structural and functional characteristics of the tissue. The final product is dehydrated, packaged in different size sheets and terminally sterilized by irradiation. Shelter™ DM Matrix is composed of extracellular matrix proteins and is intended for use over wounds and as a barrier or protective coverage for acute and chronic wounds. The product is typically used for individuals with full thickness acute and chronic wounds where a biologic barrier or wound cover is required. The dosage is per centimeter square, depending on the size of the injury or site of application. Shelter™ DM Matrix is supplied in various sizes.

CMS Final HCPCS Coding Decision

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

Establish a new HCPCS Level II code Q4346, "Shelter dm matrix, per square centimeter"

This coding decision applies to the Shelter™ DM Matrix product described in the application and accompanying FDA TRG Letter dated June 20, 2024, when intended as a “barrier or cover.”

Rampart™ DL Matrix - HCP2406260383L

Topic/Issue

Request to establish new HCPCS Level II code to identify Rampart™ DL Matrix.

Applicant suggests language: XXXXX, "Rampart™ DL Matrix, per cm^2"

Summary of Applicant's Submission

Sequence LifeScience Inc. submitted a request to establish a new HCPCS Level II code to identify Rampart™ DL Matrix. Rampart™ DL Matrix is regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) solely under section 361 of the Public Health Service (PHS) Act and 21 CFR Part 1271 when intended for use as a "barrier or cover." Rampart™ DL Matrix is a dual layer, minimally manipulated, human amniotic membrane product derived from placental tissue that retains the structural and functional characteristics of the tissue. The final product is dehydrated, packaged in different size sheets and terminally sterilized by irradiation. Rampart™ DL Matrix is composed of extracellular matrix proteins and is intended for use over wounds and as a barrier or protective coverage for acute and chronic wounds. The product is typically used for individuals with full thickness acute and chronic wounds where a biologic barrier or wound cover is required. The dosage is per centimeter square, depending on the size of the injury or site of application. Rampart™ DL Matrix is supplied in various sizes.

CMS Final HCPCS Coding Decision

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

Establish a new HCPCS Level II code Q4347, "Rampart dl matrix, per square centimeter"

This coding decision applies to the Rampart™ DL Matrix product described in the application and accompanying FDA TRG Letter dated June 20, 2024, when intended as a "barrier or cover."

Sentry™ SL Matrix - HCP240626NMTL3

Topic/Issue

Request to establish a new HCPCS Level II code to identify Sentry™ SL Matrix.

Applicant suggests language: XXXXX, “Sentry™ SL Matrix, per cm2”

Summary of Applicant's Submission

Sequence LifeScience Inc. submitted a request to establish a new HCPCS Level II code to identify Sentry™ SL Matrix. Sentry™ SL Matrix is regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) solely under section 361 of the Public Health Service (PHS) Act and 21 CFR Part 1271 when intended for use as a “barrier or cover.” Sentry™ SL Matrix is a single layer, minimally manipulated, human amniotic membrane product derived from placental tissue that retain the structural and functional characteristics of the tissue. The final product is dehydrated, packaged in different size sheets and terminally sterilized by irradiation. Sentry™ SL Matrix is composed of extracellular matrix proteins and is intended for use over wounds and as a barrier or protective coverage for acute and chronic wounds. The product is typically used for individuals with full thickness acute and chronic wounds where a biologic barrier or wound cover is required. The dosage is per centimeter square, depending on the size of the injury or site of application. Sentry™ SL Matrix is supplied in various sizes.

CMS Final HCPCS Coding Decision

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

Establish a new HCPCS Level II code Q4348, “Sentry sl matrix, per square centimeter"

This coding decision applies to the Sentry™ SL Matrix product described in the application and accompanying FDA TRG Letter dated June 20, 2024, when intended as a “barrier or cover.”

Mantle™ DL Matrix - HCP2406268BUQ9

Topic/Issue

Request to establish a new HCPCS Level II code to identify Mantle™ DL Matrix.

Applicant suggests language: XXXXX, “Mantle™ DL Matrix, per cm2”

Summary of Applicant's Submission

Sequence LifeScience Inc. submitted a request to establish a new HCPCS Level II code to identify Mantle™ DL Matrix. Mantle™ DL Matrix is regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) solely under section 361 of the Public Health Service (PHS) Act and 21 CFR Part 1271 when intended for use as a “barrier or cover.” Mantle™ DL Matrix is a dual layer, minimally manipulated, human amniotic membrane product derived from placental tissue that retain the structural and functional characteristics of the tissue. The final product is dehydrated, packaged in different size sheets and terminally sterilized by irradiation. Mantle™ DL Matrix is composed of extracellular matrix proteins and is intended for use over wounds and as a barrier or protective coverage for acute and chronic wounds. The product is typically used for individuals with full thickness acute and chronic wounds where a biologic barrier or wound cover is required. The dosage is per centimeter square, depending on the size of the injury or site of application. Mantle™ DL Matrix is supplied in various sizes.

CMS Final HCPCS Coding Decision

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

Establish a new HCPCS Level II code Q4349, “Mantle dl matrix, per square centimeter"

This coding decision applies to the Mantle™ DL Matrix product described in the application and accompanying FDA TRG Letter dated June 20, 2024, when intended as a “barrier or cover.”

Palisade™ DM Matrix - HCP240626P4U9X

Topic/Issue

Request to establish a new HCPCS Level II code to identify Palisade™ DM Matrix.

Applicant suggests language: XXXXX, “Palisade™ DM Matrix, per cm2”

Summary of Applicant's Submission

Sequence LifeScience Inc. submitted a request to establish a new HCPCS Level II code to identify Palisade™ DM Matrix. Palisade™ DM Matrix is regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) solely under section 361 of the Public Health Service (PHS) Act and 21 CFR Part 1271 when intended for use as a “barrier or cover.” Palisade™ DM Matrix is a dual membrane, minimally manipulated, human amniotic and chorionic membrane product derived from placental tissue that retain the structural and functional characteristics of the tissue. The final product is dehydrated, packaged in different size sheets and terminally sterilized by irradiation. Palisade™ DM Matrix is composed of extracellular matrix proteins and is intended for use over wounds and as a barrier or protective coverage for acute and chronic wounds. The product is typically used for individuals with full thickness acute and chronic wounds where a biologic barrier or wound cover is required. The dosage is per centimeter square, depending on the size of the injury or site of application. Palisade™ DM Matrix is supplied in various sizes.

CMS Final HCPCS Coding Decision

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

Establish a new HCPCS Level II code Q4350, “Palisade dm matrix, per square centimeter"

This coding decision applies to the Palisade™ DM Matrix product described in the application and accompanying FDA TRG Letter dated June 20, 2024, when intended as a “barrier or cover.”

Enclose™ TL Matrix - HCP2406262LE03

Topic/Issue

Request to establish a new HCPCS Level II code to identify Enclose™ TL Matrix.

Applicant suggests language: XXXXX, “Enclose™ TL Matrix, per cm2”

Summary of Applicant's Submission

Sequence LifeScience Inc. submitted a request to establish a new HCPCS Level II code to identify Enclose™ TL Matrix. Enclose™ TL Matrix is regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) solely under section 361 of the Public Health Service (PHS) Act and 21 CFR Part 1271 when intended for use as a “barrier or cover.” Enclose™ TL Matrix is a tri-layered minimally manipulated human placental membrane product derived from donated placental tissues that retain the structural and functional characteristics of the tissues. The final product is dehydrated, packaged in different size sheets and terminally sterilized by irradiation. Enclose™ TL Matrix is composed of extracellular matrix proteins and serves as a natural, biological barrier or wound cover. The product is typically used for individuals with chronic full thickness ulcers and other skin defects where a biological barrier or cover is required. Enclose™ TL Matrix is used by or on order for a licensed physician for single patient use. The dosage is per centimeter square, depending on the size of the injury or site of application. Enclose™ TL Matrix is supplied in various size and configuration sheets.

CMS Final HCPCS Coding Decision

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

Establish a new HCPCS Level II code Q4351, “Enclose tl matrix, per square centimeter"

This coding decision applies to the Enclose™ TL Matrix product described in the application and accompanying FDA TRG Letter dated June 20, 2024, when intended as a “barrier or cover.”

Overlay™ SL Matrix - HCP240626MRK7N

Topic/Issue

Request to establish a new HCPCS Level II code to identify Overlay™ SL Matrix.

Applicant suggests language: XXXXX, “Overlay™ SL Matrix, per cm2”

Summary of Applicant's Submission

Sequence LifeScience, submitted a request to establish a new HCPCS Level II code to identify Overlay™ SL Matrix. Overlay™ SL Matrix is regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) solely under section 361 of the Public Health Service (PHS) Act and 21 CFR Part 1271 when intended for use as a “barrier or cover.” Overlay™ SL Matrix is a single layer, minimally manipulated, human amniotic membrane product derived from placental tissue that retain the structural and functional characteristics of the tissue. The final product is dehydrated, packaged in different size sheets and terminally sterilized by irradiation. Overlay™ SL Matrix is composed of extracellular matrix proteins and is intended for use over wounds and as a barrier or protective coverage for acute and chronic wounds. The product is typically used for individuals with full thickness acute and chronic wounds where a biologic barrier or wound cover is required. The dosage is per centimeter square, depending on the size of the injury or site of application. Overlay™ SL Matrix is supplied in various sizes.

CMS Final HCPCS Coding Decision

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

Establish a new HCPCS Level II code Q4352, “Overlay sl matrix, per square centimeter"

This coding decision applies to the Overlay™ SL Matrix product described in the application and accompanying FDA TRG Letter dated June 20, 2024, when intended as a “barrier or cover.”

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

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

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

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

Due to the complexity and nuanced nature of the differences between each product, we encourage providers to rely on the Average Sales Price (ASP) HCPCS-National Drug Code (NDC) crosswalk[3] to identify the correct billing and payment code for each applicable product.

CMS Final HCPCS Coding Decision

Establish eleven new HCPCS Level II codes, revise one HCPCS Level II code, and discontinue eight 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 in an upcoming biannual public meeting.

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[2] The FDA's Orange Book, officially entitled, *Approved Drug Products With Therapeutic Equivalence Evaluations,* identifies drug products approved on the basis of safety and effectiveness by the FDA, and is published at the following FDA link: https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm.

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

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

Appendix A: HCPCS Level II Codes for Products Approved by the FDA Under the 505(b)(2) NDA or BLA Pathways and Products "Not Otherwise Classified" [4, 5]

HCPCS Code	Action	Long Descriptor
J9259*	delete	Injection, paclitaxel protein-bound particles (american regent) not therapeutically equivalent to j9264, 1 mg
J0135*	delete	Injection, adalimumab, 20 mg
J0139**	add	Injection, adalimumab, 1 mg
J1552	add	Injection, immune globulin (alyglo), 500 mg
J2290	add	Injection, nafcillin sodium, 20 mg
J2796*	delete	Injection, romiplostim, 10 micrograms
J2802	add	Injection, romiplostim, 1 microgram
J2806*	delete	Injection, sincalide (maia), not therapeutically equivalent to j2805, 5 micrograms
J9033	revise	Revise "Injection, bendamustine hcl (treanda), 1 mg" to instead read "Injection, bendamustine hydrochloride, 1 mg"
J9058*	delete	Injection, bendamustine hydrochloride (apotex), 1 mg
J9059*	delete	Injection, bendamustine hydrochloride (baxter), 1 mg
Q0155	add	Dronabinol (syndros), 0.1 mg, oral, fda approved prescription anti-emetic, for use as a complete therapeutic substitute for an iv anti-emetic at the time of chemotherapy treatment, not to exceed a 48 hour dosage regimen
Q5131*	delete	Injection, adalimumab-aacf (idacio), biosimilar, 20 mg
Q5132*	delete	Injection, adalimumab-afzb (abrilada), biosimilar, 10 mg
Q5140	add	Injection, adalimumab-fkjp, biosimilar, 1 mg
Q5141	add	Injection, adalimumab-aaty, biosimilar, 1 mg
Q5142	add	Injection, adalimumab-ryvk biosimilar, 1 mg
Q5143	add	Injection, adalimumab-adbm, biosimilar, 1 mg
Q5144**	add	Injection, adalimumab-aacf (idacio), biosimilar, 1 mg
Q5145**	add	Injection, adalimumab-afzb (abrilada), biosimilar, 1 mg

*The effective date for the discontinuation of this code is December 31, 2024.
**Due to juvenile dosing and consistency across adalimumab products, the dose descriptor is being reduced to 1 mg.

[4] Updated on October 4, 2024 to remove HCPCS Level II code J2253, as the long description is the same since this code became effective on 10/1/2024.
[5] Updated on October 30, 2024 to revise the HCPCS Level II code J1552 long description from "Injection, immune globulin (alyglo), 100 mg" to instead read "Injection, immune globulin (alyglo), 500 mg".