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

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

Fourth Quarter, 2022 HCPCS Coding Cycle

This document presents a summary of each HCPCS code application and CMS' coding decision for each application processed in CMS' Fourth Quarter 2022 Drug and Biological HCPCS code application review cycle. Each individual summary includes the request number; topic/issue; summary of the applicant's request as written by the applicant with occasional non-substantive editorial changes made by CMS; and CMS' final HCPCS coding decision. All new coding actions will be effective April 1, 2023, unless otherwise indicated.

The HCPCS coding decisions below will also be included in the January 2023 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.

Final Determinations for the Fourth Quarter 2022 Drug and Biological HCPCS Applications.

Rolvedon™ - HCP2209309BRRH

Topic/Issue

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

Applicant's suggested language: JXXXX, “Injection, eflapegrastim-xnst, 13.2 mg”

Applicant’s Summary

Spectrum Pharmaceuticals submitted a request to establish a new HCPCS Level II code to identify Rolvedon™ (eflapegrastim-xnst). Rolvedon™ was approved by the Food and Drug Administration (FDA) under the Biologics License Application (BLA) pathway on September 9, 2022. Rolvedon™ is a recombinant human granulocyte growth factor that binds to granulocyte colony stimulating factor receptors on myeloid progenitor cells and neutrophils, triggering signaling pathways that control cell differentiation, proliferation, migration and survival. Rolvedon™ is indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in adult patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with clinically significant incidence of febrile neutropenia. Rolvedon™ is not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation. The dosage for Rolvedon™ is a single subcutaneous injection of 13.2 mg administered by a healthcare professional once per chemotherapy cycle, approximately 24 hours after cytotoxic chemotherapy. The entire contents of the 13.2 mg prefilled syringe are administered. Rolvedon™ is packaged in a dispensing pack containing one sterile 13.2 mg/0.6 mL prefilled syringe. According to the applicant, existing HCPCS codes do not identify this product; and given that Rolvedon™ is a single source biological as defined by section 1847A(c)(6)(D) of the Social Security Act, it should be assigned a new HCPCS Level II code and paid separately by Medicare consistent with statute and CMS policy.

CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code J1449, “Injection, eflapegrastim-xnst, 0.1 mg”

Stimufend® - HCP220927WMFN0

Topic/Issue

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

Applicant's suggested language: QXXXX, “Injection, pegfilgrastim-fpgk, biosimilar, (stimufend), 0.5 mg”

Applicant’s Summary

Fresenius Kabi submitted a request to establish a new HCPCS Level II code to identify Stimufend® (pegfilgrastim-fpgk). Stimufend® was approved by the Food and Drug Administration (FDA) under the Biologics License Application (BLA) pathway on September 1, 2022. Stimufend® is a leukocyte growth factor indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia. Stimufend® is a colony-stimulating factor that acts on hematopoietic cells by binding to specific cell surface receptors, thereby stimulating proliferation, differentiation, commitment, and end cell functional activation. The recommended dosage of Stimufend® is a single subcutaneous injection of 6 mg administered once per chemotherapy cycle. Stimufend® should not be administered between 14 days before and 24 hours after administration of cytotoxic chemotherapy. Stimufend® is a clear, colorless, preservative-free solution that will be supplied in a prefilled single-dose syringe for manual use containing 6 mg pegfilgrastim-fpgk, Stimufend® will be provided in a dispensing pack containing one sterile 6 mg/0.6 mL prefilled syringe. According to the applicant, neither current HCPCS coding for pegfilgrastim originator (J2506) nor biosimilars (Q5108, Q5111, Q5120, Q5122) appropriately or uniquely identify Stimufend®, as the J codes would not identify the product as a biosimilar and the biosimilar codes tend to have the brand name and different unique suffixes within the descriptors. According to the applicant, biosimilars are considered single source products, so Stimufend® should receive a unique HCPCS code that will enable all payers to readily process claims for each biosimilar.

CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code Q5127, “Injection, pegfilgrastim-fpgk (stimufend), biosimilar, 0.5 mg”

Cimerli™ - HCP22100307D0L

Topic/Issue

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

Applicant's suggested language: QXXXX, “Injection, ranibizumab-eqrn, biosimilar (Cimerli), 0.1 mg”

Applicant’s Summary

Coherus BioSciences submitted a request to establish a new HCPCS Level II code to identify Cimerli™ (ranibizumab-eqrn) injection. Cimerli™ is a vascular endothelial growth factor inhibitor for intraocular injection. Cimerli™ was approved by the Food and Drug Administration (FDA) under the Biologics License Application (BLA) pathway on August 2, 2022. Cimerli™ is interchangeable with Lucentis® (ranibizumab injection) for the treatment of neovascular (wet) age-related macular degeneration, macular edema following retinal vein occlusion, diabetic macular edema, diabetic retinopathy, and myopic choroidal neovascularization. Cimerli™ binds to and inhibits the biologic activity of human vascular endothelial growth factor A. Cimerli™ is a colorless to pale yellow solution. Each single-dose glass vial provides 0.05 mL for intravitreal injections. It is available in two strengths including 10 mg/mL solution (Cimerli™0.5 mg) and 6 mg/mL solution (Cimerli™ 0.3 mg) and may be administered approximately every 28 days. Specific dosing will depend on diagnosis. According to the applicant, Cimerli™ is a single source biological that requires separate payment under Section 1847A of the Social Security Act; as such, a unique, product-specific HCPCS code should be established to ensure appropriate and adequate payment under this section of the Act.

CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code Q5128, “Injection, ranibizumab-eqrn (cimerli), biosimilar, 0.1 mg”

Vegzelma® - HCP221003G5MAB

Topic/Issue

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

Applicant's suggested language: XXXXX, “Injection, bevacizumab-adcd, biosimilar, (Vegzelma), 10 mg”

Applicant’s Summary

Celltrion USA, Inc. submitted a request to establish a new HCPCS Level II code to identify Vegzelma® (bevacizumab-adcd). Vegzelma® is a vascular endothelial growth factor inhibitor that is indicated for treatment in the following: metastatic colorectal cancer, in combination with intravenous fluorouracil-based chemotherapy for first- or second-line treatment; metastatic colorectal cancer, in combination with fluoropyrimidine-irinotecan or fluoropyrimidine-oxaliplatin-based chemotherapy for second-line treatment in patients who have progressed on a first-line bevacizumab product-containing regimen. Vegzelma® was approved by the Food and Drug Administration (FDA) under the Biologics License Application (BLA) pathway on September 27, 2022. Vegzelma® is dosed based on body weight and varies by indication and chemotherapy regimen. Vegzelma® is supplied in strengths of 100 mg/4 mL and 400 mg/16 mL as a clear to opalescent, colorless to pale brown, sterile solution for intravenous infusion supplied in a single-dose vial packaged within cartons with four packaging configurations. According to the applicant, existing HCPCS codes are unique to each bevacizumab biosimilar and none are applicable for Vegzelma® (bevacizumab-adcd).

CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code Q5129, “Injection, bevacizumab-adcd (vegzelma), biosimilar, 10 mg”

SurGraft® FT - HCP221003LJVKV

Topic/Issue

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

Applicant's suggested language: QXXXX, “SurGraft FT, per sq. cm”

Applicant’s Summary

Surgenex, LLC submitted a request to establish a new HCPCS Level II code to identify SurGraft® FT. SurGraft® FT is a full thickness dehydrated amniotic and chorionic tissue allograft derived from donated human amniotic and chorionic membrane. SurGraft® FT is intended to act as a barrier and provide protective coverage from the surrounding environment for acute and chronic wounds such as; partial and full thickness wounds, pressure sores/ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds trauma wounds and draining wounds. According to the applicant, there is currently no HCPCS code available to describe SurGraft® FT. Following standard wound preparation, SurGraft® FT is applied directly to the wound, adheres to the wound bed without fixation and it is fully resorbable. SurGraft® FT is sterile and it is supplied in a single use package in a variety of 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, “SurGraft® FT, when intended for use as a barrier or cover for acute and chronic wounds, appears to meet the criteria for regulation solely under section 361 of the Public Health Service (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 Q4268, "Surgraft ft, per square centimeter"

SurGraft® XT - HCP221003PR30T

Topic/Issue

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

Applicant's suggested language: QXXXX, “SurGraft® XT, per sq. cm”

Applicant’s Summary

Surgenex, LLC submitted a request to establish a new HCPCS Level II code to identify SurGraft® XT. SurGraft® XT is a dual layer dehydrated amniotic allograft derived from donated human amniotic membrane. SurGraft® XT is intended to act as a barrier and provide protective coverage from the surrounding environment for acute and chronic wounds such as; partial and full thickness wounds, pressure sores/ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds, trauma wounds and draining wounds. Following standard wound preparation, SurGraft® XT is applied directly to the wound, adheres to the wound bed without fixation and it is fully resorbable. SurGraft® XT is sterile and supplied in a single use package in a variety of 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, “it appears SurGraft® XT, when intended for use as barrier or cover for acute and chronic wounds, meets the criteria for regulation solely under section 361 of the Public Health Service (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 Q4269, "Surgraft xt, per square centimeter"

Complete™ SL - HCP220927DVCAR

Topic/Issue

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

Applicant's suggested language: QXXXX, “Complete SL, per sq. cm”

Applicant’s Summary

Samaritan Biologics, LLC submitted a request to establish a new HCPCS Level II code to identify Complete™ SL. Complete™ SL is a single layer amnion derived allograft that serves as a barrier and provides protective coverage from the surrounding environment to acute and chronic wounds. Complete™ SL is a sterile, single use, dehydrated allograft derived from donated amniotic membrane. Complete™ SL is a fully resorbable graft that acts by providing a physical barrier to the wound. Complete™ SL dosage is per sq. cm., depending on the size of the wound. Complete™ SL graft can be reapplied as needed. Complete™ SL is intended for external application. Following standard wound preparation, Complete™ SL is applied directly to the wound, it adheres to the wound bed without fixation. Complete™ SL is fully resorbable and does not have to be removed from the wound bed.

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, “Complete™ SL, when intended for use as a barrier or cover for acute and chronic wounds, appears to meet the criteria for regulation solely under section 361 of the Public Health Service (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 Q4270, "Complete sl, per square centimeter"

Complete™ FT - HCP220927TMA2F

Topic/Issue

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

Applicant's suggested language: QXXXX, “Complete FT, per sq. cm”

Applicant’s Summary

Samaritan Biologics LLC submitted a request to establish a new HCPCS Level II code to identify Complete™ FT. Complete™ FT is a full thickness amnion-chorion derived allograft that serves as a barrier and provides protective coverage from the surrounding environment to acute and chronic wounds. Complete™ FT is a sterile, single use, dehydrated allograft derived from donated human amnion-chorion membrane. Complete™ FT is a fully resorbable graft that acts by providing a physical barrier to the wound. Complete™ FT dosage is per sq. cm, depending on the size of the wound. Complete™ FT graft can be reapplied as needed. Complete™ FT is intended for external application. Following standard wound preparation, Complete™ FT is applied directly to the wound, it adheres to the wound bed without fixation. Complete™ FT is fully resorbable and does not have to be removed from the wound bed.

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, “Complete™ FT, when intended for use as a barrier or cover for acute and chronic wounds, appears to meet the criteria for regulation solely under section 361 of the Public Health Service (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 Q4271, "Complete ft, per square centimeter"

Fylnetra® - HCP220727NMUL9

Topic/Issue

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

Applicant's suggested language: QXXXX, “Fylnetra® (pegfilgrastim-pbbk) injection, for subcutaneous use, 0.1mL”

Applicant’s Summary

Amneal Pharmaceuticals submitted a request to establish a new HCPCS Level II code to identify Fylnetra® (pegfilgrastim-pbbk) injection. Fylnetra® was approved by the Food and Drug Administration (FDA) under the Biologics License Application (BLA) pathway on May 26, 2022. Fylnetra® is a leukocyte growth factor indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anticancer drugs associated with a clinically significant incidence of febrile neutropenia. Pegfilgrastim products are colony-stimulating factors that act on hematopoietic cells by binding to specific cell surface receptors, thereby stimulating proliferation, differentiation, commitment, and end cell functional activation. The Fylnetra® prefilled syringe is not designed to allow for direct administration of doses less than 0.6 mL (6 mg). The syringe does not bear graduation marks, which are necessary to accurately measure doses of Fylnetra® less than 0.6 mL (6 mg) for direct administration to patients. Thus, the direct administration to patients requiring dosing of less than 0.6 mL (6 mg) is not recommended due to the potential for dosing errors. Fylnetra® is physician administered subcutaneously via a single-dose prefilled syringe for manual use. Fylnetra® is a single-dose prefilled syringe provided in a dispensing pack containing one sterile 6mg/0.6mL prefilled syringe. According to the applicant, no current HCPCS code adequately describes or differentiates Fylnetra® from other therapies; therefore, there is a programmatic need for CMS to create and assign a unique HCPCS code for Fylnetra®.

CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code Q5130, “Injection, pegfilgrastim-pbbk (fylnetra), biosimilar, 0.5 mg”

Spevigo® - HCP22093014EME

Topic/Issue

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

Applicant's suggested language: JXXXX, “Injection, spesolimab-sbzo, 900mg”

Applicant’s Summary

Boehringer Ingelheim Pharmaceuticals, Inc. submitted a request to establish a new HCPCS Level II code to identify Spevigo®. Spevigo® is a humanized antagonistic monoclonal immunoglobulin G1 antibody blocking human IL36R signaling. Binding of spesolimab to IL36R prevents the subsequent activation of IL36R by cognate ligands (IL36 α, β and γ) and downstream activation of pro-inflammatory and pro-fibrotic pathways. Spevigo® was approved by the Food and Drug Administration (FDA) under the Biologics License Application (BLA) pathway on September 1, 2022 for the treatment of generalized pustular psoriasis flares in adults. According to the applicant, at the time of this request, there was no HCPCS Level II code assigned for Spevigo® and using a Not-Otherwise-Classified (NOC) HCPCS code prevents concise tracking of utilization, often results in under-payment, and may result in incorrect billing.

CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code J1747, “Injection, spesolimab-sbzo, 1 mg”

XENPOZYME™ - HCP220923FK3CL

Topic/Issue

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

Applicant's suggested language: JXXXX, “Injection, olipudase alfa-rpcp, 1 mg, for intravenous use”

Applicant’s Summary

Sanofi submitted a request to establish a new HCPCS Level II code to identify XENPOZYME™. XENPOZYME™ (olipudase alfa-rpcp) is a hydrolytic lysosomal sphingomyelin-specific enzyme indicated for treatment of non-central nervous system manifestations of acid sphingomyelinase deficiency (ASMD) in adult and pediatric patients. XENPOZYME™ was approved by the Food and Drug Administration (FDA) under the Biologics License Application (BLA) pathway on August 31, 2022. ASMD is a lysosomal storage disease that results from reduced activity of the enzyme acid sphingomyelinase (ASM), caused by pathogenic variants in the sphingomyelin phosphodiesterase 1 gene. ASM degrades sphingomyelin to ceramide and phosphocholine. The deficiency of ASM causes an intra-lysosomal accumulation of SM (as well as cholesterol and other cell membrane lipids) in various tissues. According to the applicant, XENPOZYME™ provides an exogenous source of ASM. XENPOZYME™ is supplied as a sterile white to off-white lyophilized powder for reconstitution in single-dose vials for intravenous infusion. One 20 mg vial in a carton of XENPOZYME™ (olipudase alfa-rpcp) is administered as an intravenous infusion every 2 weeks as indicated for treatment of non-central nervous system manifestations of ASMD in adult and pediatric patients. XENPOZYME™ is not expected to cross the blood-brain barrier or modulate central nervous system manifestations of the disease.

CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code J0218, "Injection, olipudase alfa-rpcp, 1 mg”

PEDMARK® - HCP220930UM7F9

Topic/Issue

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

Applicant's suggested language: XXXXX, “PEDMARK® (sodium thiosulfate anhydrous injection) for intravenous use to reduce the risk of ototoxicity associated with cisplatin in patients one month of age and older with localized, non-metastatic solid tumors”

Applicant’s Summary

Fennec Pharmaceuticals, Inc. (Fennec) submitted a request to establish a new HCPCS Level II code to identify PEDMARK®. PEDMARK® (sodium thiosulfate injection) is for intravenous use to reduce the risk of ototoxicity associated with cisplatin in pediatric patients one month of age and older with localized, non-metastatic solid tumors, as there is currently no J-code associated with the existing formulation of sodium thiosulfate solution for the indication of interest. PEDMARK® was approved by the Food and Drug Administration (FDA) under a New Drug Application (NDA) on September 21, 2022. PEDMARK® is indicated to reduce the risk of ototoxicity associated with cisplatin in pediatric patients one month of age and older with localized, non-metastatic solid tumors. The efficacy of PEDMARK® in reducing the risk of cisplatin-associated ototoxicity was evaluated in two multicenter studies: SIOPEL 6 and COG ACCL0431. Cisplatin-induced ototoxicity is caused by irreversible damage to hair cells in the cochlea hypothesized to be due to a combination of reactive oxygen species (ROS) production and direct alkylation of DNA leading to cell death. Sodium thiosulfate interacts directly with cisplatin to produce an inactive platinum species. In addition, sodium thiosulfate can enter cells through the sodium sulfate cotransporter 2 and cause intracellular effects such as the increase in antioxidant glutathione levels and inhibition of intracellular oxidative stress. PEDMARK® has a recommended dosing as follows: 10 g/m2 (Actual Body Weight less than 5 kg), 15 g/m2 (Actual Body Weight 5 to 10 kg), 20 g/m2 (Actual Body Weight greater than 10 kg). PEDMARK® is to be administered as an intravenous infusion over 15 minutes, starting 6 hours after completion of cisplatin infusion. For multi-day cisplatin regimens, administer PEDMARK® 6 hours after each cisplatin infusion but at least 10 hours before starting the next cisplatin infusion. Each PEDMARK® vial contains the equivalent of 12.5 grams of sodium thiosulfate pentahydrate (provided as sodium thiosulfate anhydrous 8 grams) in 100 mL solution (125 mg/mL). Each mL contains the equivalent of 125 mg of sodium thiosulfate pentahydrate (provided as sodium thiosulfate anhydrous 80 mg) and 0.25 mg boric acid. In turn, existing code categories do not accurately characterize PEDMARK®. According to the applicant, there are currently no available therapies for preventing cisplatin-induced ototoxicity in pediatric patients one month of age and older and current management strategies (e.g., hearing aids) do not replace normal hearing. According to the applicant, PEDMARK®'s novel formulation, indication and administration necessitate a new code category as to date no suitable code currently exists.

CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code J0208, "Injection, sodium thiosulfate, 100 mg”

Elucirem™ - HCP220930JQQ56

Topic/Issue

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

Applicant's suggested language: AXXXX, “Injection, gadopiclenol, 1 ml”

Applicant’s Summary

Guerbet LLC submitted a request to establish a new HCPCS Level II code to identify Elucirem™. Elucirem™ (gadopiclenol) vial injection is a gadolinium-based contrast agent indicated in adults and children aged 2 years and older for contrast enhanced magnetic resonance imaging (MRI) to improve detection, visualization, and assist in detection and visualization of lesions with abnormal vascularity in the central nervous system (brain, spine, and associated tissues) and the body (head and neck, thorax, abdomen, pelvis, and the musculoskeletal system). Elucirem™ (gadopiclenol) injection was approved by the Food and Drug Administration (FDA) under a New Drug Application (NDA) on September 21, 2022. Elucirem™ is available in various vial sizes and each vial. According to the applicant, there is no HCPCS code assigned for Elucirem™ (gadopiclenol) and when new-to-market it will be reported with a Not-Otherwise-Classified (NOC) HCPCS code. The applicant mentioned that using a NOC HCPCS code prevents concise tracking of utilization, often results in under-payment, and may result in incorrect billing.

CMS Final HCPCS Coding Decision

This request is being deferred to a subsequent coding cycle because the scope of the request necessitates that additional consideration be given before CMS reaches a final decision.

Elucirem™ -HCP22093037EYE

Topic/Issue

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

Applicant's suggested language: AXXXX, “Injection, gadopiclenol, per 1 ml, prefilled syringe”

Applicant’s Summary

Guerbet LLC submitted a request to establish a new HCPCS Level II code to identify Elucirem™. Elucirem™ (gadopiclenol) prefilled syringe injection is a gadolinium-based contrast agent indicated in adults and children aged 2 years and older for contrast enhanced magnetic resonance imaging (MRI) to improve detection, visualization, and assist in detection and visualization of lesions with abnormal vascularity in the central nervous system (brain, spine, and associated tissues) and the body (head and neck, thorax, abdomen, pelvis, and the musculoskeletal system). Elucirem™ (gadopiclenol) injection was approved by the Food and Drug Administration (FDA) under a New Drug Application (NDA) on September 21, 2022. Elucirem™ is available in three sizes and packaging. According to the applicant, there is no HCPCS code assigned for Elucirem™ (gadopiclenol) and when new-to-market it will be reported with a Not-Otherwise-Classified (NOC) HCPCS code. The applicant mentioned that using a NOC HCPCS code prevents concise tracking of utilization, often results in under-payment, and may result in incorrect billing.

CMS Final HCPCS Coding Decision

This request is being deferred to a subsequent coding cycle because the scope of the request necessitates that additional consideration be given before CMS reaches a final decision.

VUEWAY™ - HCP221003PJLCW

Topic/Issue

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

Applicant's suggested language: AXXXX, “Injection, gadopiclenol, 1 ml”

Applicant’s Summary

JR Associates submitted a request to establish a new HCPCS Level II code to identify VUEWAY™. This product is a gadolinium-based contrast agent (GBCA). VUEWAY™ (gadopiclenol) was approved by the Food and Drug Administration (FDA) under a New Drug Application (NDA) on September 21, 2022. VUEWAY™ solution for injection, 485.1 mg/mL is indicated in adults and children age 2 years and older for contrast enhanced magnetic resonance imaging (MRI) to improve detection, visualization and assist in characterization of lesions in the central nervous system (brain, spine, and associated tissues) and the body (head and neck, thorax, abdomen, pelvis, and the musculoskeletal system). According to the applicant, this product provides approximately 2-3 times the contrast enhancement per molecule vs. all other marketed GBCAs and has been approved by the FDA to be administered at a weight-based dose of 0.05 mmol/kg, which is half that of the approved doses of all other general-use GBCAs (0.1 mmol/kg). Gadopiclenol is a paramagnetic macrocyclic non-ionic complex gadolinium that develops a magnetic moment when placed in a magnetic field. The magnetic moment alters the relaxation rates of water protons in its vicinity in the body, leading to an increase in signal intensity (brightness) of tissues. It presents a high relaxivity in water due to its specific chemical structure. It can exchange two water molecules, which are linked to the gadolinium to complete its coordination number in addition to the four nitrogens and the three oxygens of the carboxylate functions of the gadopiclenol chelate. Gadopiclenol solution for injection demonstrates the highest relaxivity in water and serum vs. all currently approved linear and macrocyclic GBCAs at all field strengths. It is due to its high relaxivity, it can be given at half-dose of gadolinium compared to other non-specific GBCAs, while providing the same contrast enhancement. VUEWAY™ is available in single-dose vials, in single-dose pre-filled syringes, and in pharmacy bulk packages. According to the applicant, current HCPCS codes describe specific general use GBCA products. The applicant stated the HCPCS code for unspecified gadolinium products has been reported for several general use GBCAs, all of which lack the contrast enhancement properties that allow for gadopiclenol’s different weight-based dose. According to the applicant, gadopiclenol’s properties warrant a specific HCPCS code.

CMS Final HCPCS Coding Decision

This request is being deferred to a subsequent coding cycle because the scope of the request necessitates that additional consideration be given before CMS reaches a final decision.

NeoStim TL Membrane - HCP221003EG483

Topic/Issue

Request to establish a new HCPCS Level II code to identify NeoStim TL.

Applicant's suggested language: QXXXX, “NST, per sq. cm”

Applicant’s Summary

NeoStim, LLC submitted a request to establish a new HCPCS Level II code to identify NeoStim TL. NeoStim TL is a triple layer dehydrated amnion membrane allograft derived from donated human amniotic membrane. It serves as a barrier or provides a protective coverage from the surrounding environment for acute and chronic wounds such as; partial and full thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds and trauma wounds. Following standard wound preparation, NeoStim TL is applied directly to the wound, adheres to the wound bed without fixation and it is fully resorbable. NeoStim TL is sterile and it is supplied in a single use package. According to the applicant, there is currently no HCPCS code available to describe NeoStim TL

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, “NeoStim TL, when intended for use over the wound and as a barrier or protective coverage, from the surrounding environment, to acute and chronic wounds, appears to meet the criteria for regulation solely under section 361 of the Public Health Service (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 Q4265, “Neostim tl, per square centimeter”

NeoStim Membrane - HCP2210035R3E4

Topic/Issue

Request to establish a new HCPCS Level II code to identify NeoStim Membrane.

Applicant's suggested language: QXXXX, “NSM, per sq. cm”

Applicant’s Summary

NeoStim, LLC submitted a request to establish a new HCPCS Level II code to identify NeoStim Membrane. NeoStim Membrane is a single layer dehydrated amnion membrane allograft derived from donated human amniotic membrane. It serves as a barrier or provides a protective coverage from the surrounding environment for acute and chronic wounds such as; partial and full thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds and trauma wounds. Following standard wound preparation, NeoStim is applied directly to the wound, adheres to the wound bed without fixation and it is fully resorbable. NeoStim is sterile and it is supplied in a single use package. According to the applicant, there is currently no HCPCS code available to describe NeoStim.

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, “NeoStim, when intended for use over the wound and as a barrier or protective coverage, from the surrounding environment, to acute and chronic wounds, appears to meet the criteria for regulation solely under section 361 of the Public Health Service (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 Q4266, “Neostim membrane, per square centimeter”

NeoStim DL - HCP221003YJFT2

Topic/Issue

Request to establish a new HCPCS Level II code to identify NeoStim DL.

Applicant's suggested language: QXXXX, “NSD, per sq. cm”

Applicant’s Summary

NeoStim, LLC submitted a request to establish a new HCPCS Level II code to identify NeoStim DL. NeoStim DL is a double layer dehydrated amnion membrane allograft derived from donated human amniotic membrane. It serves as a barrier or provides a protective coverage from the surrounding environment for acute and chronic wounds such as; partial and full thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds and trauma wounds. Following standard wound preparation, NeoStim DL is applied directly to the wound, adheres to the wound bed without fixation and it is fully resorbable. NeoStim DL is sterile and it is supplied in a single use package. According to the applicant, there is currently no HCPCS code available to describe NeoStim DL.

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, “NeoStim DL, when intended for use over the wound and as a barrier or protective coverage, from the surrounding environment, to acute and chronic wounds, appears to meet the criteria for regulation solely under section 361 of the Public Health Service (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 Q4267, "Neostim dl, per square centimeter"

AmnioTX™ Amniotic Membrane - HCP221003CXMLB

Topic/Issue

Request to establish a new HCPCS Level II code to identify AmnioTX™, Amniotic Membrane.

Applicant's suggested language: XXXXX, "amnioTX, Amniotic Membrane, per sq centimeter"

Applicant's Summary

Revogenbio submitted a request to establish a new HCPCS Level II code to identify AmnioTX™. AmnioTX™ is intended to be used as a protective wound cover or barrier to offer protection from the surrounding environment in wounds, including surgically created wounds such as ocular repair and reconstruction. According to the applicant, this intended use is consistent with the homologous uses of amniotic membrane that the Food and Drug Administration (FDA) explicitly identified in its guidance on minimal manipulation and homologous uses of human cells, tissues, and cellular and tissue-based products (HCT/P). The dosage for amnioTX™ amniotic membrane allograft is per square centimeter. amnioTX™ is available in the following sizes: 2cm x 2cm, 2cm x 4cm, 4cm x 4cm, 4cm x 6cm, 4cm x 7cm, 5cm x 5cm, 4cm x 8cm, 10cm x 10cm, 20cm x 20cm. AmnioTX™ is for topical application in one patient on a single occasion. AmnioTX™ is supplied as a dehydrated amniotic allograft membrane packaged in an outer pouch, sealed in an inner pouch. Each pouch features a peel back seal and is also heat sealed to provide a sterile barrier. The package label includes graft details such as dimensions. The allograft is stored at room temperature throughout transport and storage.

CMS Final HCPCS Coding Decision

After review of the FDA's Tissue Reference Group (TRG) letter submitted by the applicant for AmnioTX™, the company/manufacturer referenced in the letter differs from the current applicant, Revogenbio. As a result, CMS refers the applicant to the FDA to obtain the FDA's feedback regarding the manufacturing of AmnioTX™. The applicant is welcome to submit a complete HCPCS Level II application in a subsequent coding cycle where the product manufacturer information presented to CMS in the application is consistent with written feedback obtained from the FDA's TRG. Information for submitting questions to the FDA's TRG is located at: https://www.fda.gov/vaccinesblood-biologics/tissue-tissue-products/tissue-reference-group.

Paragard® T380A 10 Years - HCP220928R14AW

Topic/Issue

Request to revise an existing HCPCS Level II code J7300 to identify Paragard® T380A 10 Years.

Applicant's suggested language: J7300, “Intrauterine copper contraceptive Paragard® T380A 10 year Duration”

Applicant’s Summary

CooperSurgical submitted a request to revise an existing HCPCS Level II code J7300 to identify Paragard® T380A 10 Years. Paragard® is copper-containing intrauterine system (IUS) indicated for prevention of pregnancy in females of reproductive potential for up to 10 years. Paragard® T380A IUS was approved by the FDA in 1984. The mechanism of action for Paragard® is that copper is continuously released into the uterine cavity which contributes to the contraceptive effectiveness of Paragard®. Mechanism(s) by which copper enhances contraceptive efficacy include interference with sperm transport and fertilization of an egg, and possibly prevention of implantation. Paragard® is an intrauterine system inserted by a licensed provider. Each Paragard® is white, T-shaped and measures 32 mm horizontally and 36 mm vertically with approximately 176 mg of copper wire wrapped around the vertical arm and approximately 68.7 mg copper wire collar placed on each side of horizontal arms, and with monofilament polyethylene thread tides through the tip of the vertical arm. The T-Body is made of polyethylene with barium sulfate. Each Paragard® is packaged together with the insertion tube with blue flange and solid white rod in a Tyvek polyethylene pouch. According to the applicant, HCPCS code J7300, “intrauterine copper contraceptive”, is the current HCPCS code that describes Paragard®. According to the applicant, the existing code is inadequate due to lack of description for IUS. The applicant claims the current coding does not include duration or amount of copper. The applicant commented that payors cannot identify Paragard® in the IUS category. Unlike hormonal IUSs, which include both brand name and dosage of levonorgestrel, HCPCS code J7300 does not include either dosage or duration. Examples of hormonal IUS coding include HCPCS code J7296, “Levonorgestrel-releasing intrauterine contraceptive system, (kyleena), 19.5 mg”, HCPCS code J7297, “Levonorgestrel-releasing intrauterine contraceptive system (liletta), 52 mg”, HCPCS code J7298, “Levonorgestrel-releasing intrauterine contraceptive system (mirena), 52 mg”, and HCPCS code J7301, “Levonorgestrel-releasing intrauterine contraceptive system (skyla), 13.5 mg.”

CMS Final HCPCS Coding Decision

CMS is denying the applicant’s request to revise existing HCPCS Level II code J7300 to identify Paragard® T380A 10 Years. This product is the only NDA-approved intrauterine copper contraceptive device/system available for distribution and use at this time; therefore, the current descriptor for HCPCS code J7300 adequately describes the product. The product names are included in J7296, J7297, J7298, and J7301 to mitigate confusion with claims for multiple units of a lower-dosed system, for instance a claim for 4 units of J7301 when the claimant should instead submit for one unit of a 52 mg system. Furthermore, all four of the drugs described by HCPCS codes J7296, J7297, J7298, and J7301 were approved by the FDA under separately assigned NDAs.

IHEEZO™ - HCP221001VTUYX

Topic/Issue

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

Applicant's suggested language: JXXXX, “IHEEZO™ (chloroprocaine hydrochloride ophthalmic gel) 3% with a billing unit of 1mg”

Applicant’s Summary

Harrow Eye, LLC. submitted a request to establish a new HCPCS Level II code to identify IHEEZO™ (chloroprocaine hydrochloride ophthalmic gel). IHEEZO™ (chloroprocaine hydrochloride ophthalmic gel) 3% contains 24 mg of chloroprocaine hydrochloride per vial (800 mg of gel) and is physician administered on the surface of the eye. IHEEZO™ was approved by the Food and Drug Administration (FDA) under a New Drug Application (NDA) on September 26, 2022. IHEEZO™ is an ester anesthetic that blocks the generation and the conduction of nerve impulses, presumably by increasing the threshold for electrical excitation in the nerve, by slowing the propagation of the nerve impulse, and by reducing the rate of rise of the action potential. It contains chloroprocaine hydrochloride as the active pharmaceutical ingredient. IHEEZO™ is indicated for ocular surface anesthesia. In general, the progression of anesthesia is related to the diameter, myelination, and conduction velocity of affected nerve fibers. Clinically, the order of loss of nerve function is as follows: (1) pain, (2) temperature, (3) touch, (4) proprioception, and (5) skeletal muscle tone. The recommended dose of IHEEZO™, as per the FDA label, is three (3) drops applied topically to the ocular surface in the area of the planned procedure. IHEEZO™ may be reapplied as needed to maintain anesthetic effect. IHEEZO™ is indicated for administration under the direct supervision of a healthcare provider. IHEEZO™ is not intended for patient self-administration. IHEEZO™ should not be injected or intraocularly administered. IHEEZO™ (chloroprocaine hydrochloride ophthalmic gel) 3% is supplied as a sterile, clear, colorless to light yellow gel in a single-patient use vial. Each single-patient use vial contains 24 mg chloroprocaine in 800 mg of gel, in one aluminum pouch containing one (1) LDPE single-patient use vial of IHEEZO™. The outer surface of the vial is not sterile. According to the applicant, there is a programmatic need for CMS to create and assign a unique HCPCS Level II code for IHEEZO™ as it was approved under the 505(b)(2) pathway and as such is a single-source drug.

CMS Final HCPCS Coding Decision

Establish a new HCPCS Level II code J2403, “Chloroprocaine hcl ophthalmic, 3% gel, 1 mg”

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

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

In order to conform with the general approach used for the assignment of products paid under section 1847A of the Social Security Act (the Act) to HCPCS codes as described at the following CMS link: https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Downloads/051807_coding_annoucement.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 a "multiple source drug" in section 1847A(c)(6) of the Act, CMS will remove the brand name of the drug from any existing HCPCS 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-NDC crosswalk[2] to identify the correct billing and payment code for each applicable product.

CMS Final HCPCS Coding Decision

1. Establish six new HCPCS Level II codes 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.

2. Revise or delete existing HCPCS Level II codes, as needed, to separately identify multiple source drugs and single source drugs.

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

[1] The FDA's Orange Book, officially entitled, *Approved Drug Products With Therapeutic Equivalence Evaluations*, identifies drug products approved on the basis of safety and effectiveness by the FDA, and is published at the following FDA link: https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm.
[2] The ASP crosswalks are maintained by CMS on a quarterly basis to support ASP-based Medicare Part B payments only. The quarterly ASP crosswalks are published at the following CMS link: https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/2022-asp-drug-pricing-files.

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

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

HCPCS Code	Action	Long Descriptor
J0610	Delete	Injection, calcium gluconate (fresenius kabi), per 10 ml
J0611	Delete	Injection, calcium gluconate (wg critical care), per 10 ml
J0612	Add	Injection, calcium gluconate (fresenius kabi), per 10 mg
J0613	Add	Injection, calcium gluconate (wg critical care), per 10 mg
J9196	Add	Injection, gemcitabine hydrochloride (accord), not therapeutically equivalent to J9201, 200 mg
J9294	Add	Injection, pemetrexed (hospira) not therapeutically equivalent to j9305, 10 mg
J9296	Add	Injection, pemetrexed (accord) not therapeutically equivalent to j9305, 10 mg
J9297	Add	Injection, pemetrexed (sandoz), not therapeutically equivalent to j9305, 10 mg