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

First 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' First 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 July 1, 2022, unless otherwise indicated.

The HCPCS coding decisions below will also be included in the July 2022 HCPCS Quarterly Update, pending publication by CMS in the coming weeks at:
https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update

For inquiries regarding coverage, please contact the insurer(s) in whose jurisdiction(s) claim(s) would be filed. Specifically, contact the Medicaid agency in the state in which a Medicaid claim is filed, the individual private insurance entity, the Department of Veterans Affairs, or, for local Medicare coverage determinations, contact the Medicare contractor in the jurisdiction the claim would be filed. For detailed information describing CMS' 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. The dose descriptors assigned to codes established in this quarterly coding cycle are in alignment with this policy.

FYARRO™ - HCP22010408VCD

Topic/Issue

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

Applicant's suggested language: JXXXX, "Injection, sirolimus protein-bound particles, 1 mg"

Applicant's Summary

Aadi submitted a request to establish a new HCPCS Level II code to identify FYARRO™ (sirolimus protein-bound particles for injectable suspension) (albumin-bound). FYARRO™ is indicated for the treatment of adult patients with locally advanced unresectable or metastatic malignant perivascular epithelioid cell tumor (PEComa). FYARRO™ is sirolimus formulated as albumin-bound nanoparticles. The active ingredient is sirolimus bound to albumin which exists in the nanoparticles in a non-crystalline amorphous state. FYARRO™ is administered by a healthcare provider as an intravenous infusion over 30 minutes on days 1 and 8 of a 21-day cycle until disease progression or unacceptable toxicity. The recommended dose of FYARRO™ is 100 mg/m^2. FYARRO™ is supplied as a white to yellow, sterile lyophilized powder for reconstitution with 20 mL of 0.9% sodium chloride injection, USP prior to intravenous infusion. Each single-dose vial contains 100 mg of sirolimus (bound to human albumin) and approximately 850 mg of human albumin (containing sodium caprylate and sodium acetyltryptophanate). Each milliliter (mL) of reconstituted suspension contains 5 mg sirolimus formulated as albumin-bound particles. FYARRO™ in advanced malignant PEComa, a rare disease with unmet medical need, was granted Orphan Drug, Fast Track, and Breakthrough Therapy designations. The NDA application was granted Priority Review classification on July 21, 2021 with a Prescription Drug User Fee Act (PDUFA) action date of November 26, 2021. The NDA was primarily supported by the PEC-001 study (AMPECT), a multi-center, single-arm clinical trial in 34 patients with locally advanced unresectable or metastatic malignant PEComa. FYARRO™ demonstrated efficacy and safety in the intended patient population, and therefore, met the evidentiary standard for effectiveness under the law. No permanent or temporary HCPCS code currently exists that describes FYARRO™ and its unique active ingredient. A unique code is needed to recognize and ensure appropriate average sales price (ASP)-based payment for FYARRO™ as a single source drug under section 1847A of the Social Security Act.

Final Decision

1. Establish new HCPCS Level II code J9331, "Injection, sirolimus protein-bound particles, 1 mg"

   Effective: 7/1/2022

2. Discontinue existing HCPCS Level II code C9091, "Injection, sirolimus protein-bound particles, 1 mg"

   Effective: 6/30/2022

LEQVIO® - HCP2201032RY14

Topic/Issue

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

Applicant's suggested language: J9XXX, "Injection, inclisiran, 1 mg"

Applicant's Summary

Novartis submitted a request to establish a new HCPCS Level II code to identify LEQVIO®. LEQVIO® contains inclisiran sodium, a small interfering RNA (siRNA) directed to PCSK9 (proprotein convertase subtilisin-kexin type 9) mRNA. Inclisiran contains a covalently linked ligand containing three N-acetylgalactosamine (GalNAc) residues to facilitate delivery to hepatocytes. Novartis received approval for LEQVIO® from the Food and Drug Administration (FDA) on December 22, 2021. No existing HCPCS code specifically describes this product. A unique J code is necessary to identify and reimburse LEQVIO® and appropriately implement current Medicare payment policy for single source drugs. LEQVIO® is indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia (HeFH)] or clinical atherosclerotic cardiovascular disease (ASCVD), who require additional lowering of low-density lipoprotein cholesterol (LDL-C). Inclisiran is a double-stranded small interfering ribonucleic acid (siRNA), conjugated on the sense strand with triantennary N-Acetylgalactosamine (GalNAc) to facilitate uptake by hepatocytes. In hepatocytes, inclisiran utilizes the RNA interference mechanism and directs catalytic breakdown of mRNA for PCSK9. This increases LDL-C receptor recycling and expression on the hepatocyte cell surface, which increases LDL-C uptake and lowers LDL-C levels in the circulation. The recommended dose for LEQVIO®, in combination with maximally tolerated statin therapy, is 284 mg initially, again at 3 months, and then every 6 months, administered through a single subcutaneous injection. LEQVIO® is supplied in a single-dose prefilled syringe containing 284 mg/1.5 mL (189 mg/mL) of inclisiran.

Final Decision

Establish new HCPCS Level II code J1306, "Injection, inclisiran, 1 mg"

Effective: 7/1/2022

celera™ - HCP2112299C8CG

Topic/Issue

Request to establish a new HCPCS Level II code to identify celera™ Dual Membrane and celera™ Dual Layer.

Applicant's suggested language: QXXXX "celera™ Dual Membrane and celera™ Dual Layer"

Applicant's Summary

Nvision Biomedical Technologies, Inc. submitted a request to establish a new HCPCS Level II code to identify celera™ Dual Membrane and celera™ Dual Layer. celera™ Dual Membrane and celera™ Dual Layer products are minimally manipulated human amniotic and/or chorionic membrane products derived from 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. These products consist primarily of extracellular matrix proteins and serves as a natural, biologic barrier. The typical patient population includes patients requiring a wound cover or skin substitute for cutaneous wounds. The celera™ Dual Membrane and celera™ Dual Layer products are used by qualified health care professionals in a physician office, outpatient, or inpatient setting. The dosage is per centimeter square (cm^2), depending on the size of the injury or site of application. celera™ Dual Membrane and celera™ Dual Layer products are supplied in various size and configuration sheets with a total of 1 to 49 cm^2 and are stored at ambient temperature. There is currently a generic, nonspecific HCPCS Level II code (Q4100) that is reported for the use of these types of products as well as brand specific codes. A new code is warranted so that it may be readily identified for third party claims processing.

Final Decision

Based on written feedback from the FDA's Tissue Reference Group (TRG), celera™ Dual Layer and celera™ Dual Membrane, "when intended to serve as a wound cover or skin substitute for cutaneous wounds, appear to meet all the criteria for regulation solely under section 361 of the Public Health Service 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 new HCPCS Level II code Q4259, "Celera dual layer or celera dual membrane, per square centimeter"

Effective: 7/1/2022

Signature APatch - HCP2112294NVQN

Topic/Issue

Request to establish a new HCPCS Level II code to identify Signature APatch.

Applicant's suggested language: XXXXX "Signature APatch, per square centimeter or Signature APatch per sqcm"

Applicant's Summary

Signature Biologics submitted a request to establish a new HCPCS Level II code to identify Signature APatch. Signature APatch is a cryopreserved, minimally manipulated amniotic membrane allograft for homologous use as a wound barrier (cover) or covering (physical barrier). The hexagon shape allows for coverage over many wound shapes and multi-directional expansion to cover unique wound sizes and morphology. Signature APatch is produced in a single size configuration: hexagon patch with 2.5 cm sides, measuring 5.0 cm in diameter, and a total surface area of 16 cm squared. Signature APatch is a precision cut matrix, designed for application directly to acute or chronic wounds to establish a cover or barrier. This includes but is not limited to: venous leg ulcers, pressure ulcers, diabetic foot ulcers, surgical wounds, burns, and wounds with exposed tendon, muscle, and/or bone. It is directly applied to the wound weekly for up to 12 weeks or until the wound is closed as a part of a semi-wet dressing standard of care. Signature APatch is supplied as a cryopreserved tissue, prepared and packaged aseptically in a 15 mL cryovial. Signature APatch is thawed in a sterile gloved hand for 5 minutes, applied to a wound or injury site using sterile forceps following wound preparation. Signature APatch may be cut and shaped to appropriate size for application, may be used with tissue adhesives or semi-wet dressings to apply the allograft to the site if necessary.

Final Decision

Based on written feedback from the FDA's Tissue Reference Group (TRG), Signature APatch, "when intended to serve as a barrier and covering, meets the criteria for regulation solely under section 361 of the Public Health Service 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 new HCPCS Level II code Q4260, "Signature apatch, per square centimeter"

Effective: 7/1/2022

TAG - HCP220103HMRM4

Topic/Issue

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

Applicant's suggested language: Q4XXX "TAG, per sq cm"

Applicant's Summary

Conventus Flower Orthopedics submitted a request to establish a new HCPCS Level II code to identify TAG. TAG is a sterile, dehydrated, triple layer amniotic allograft composed solely from the amniotic membrane of donated human placental tissue. TAG is intended to serve as a barrier and provide protective coverage from the surrounding environment for acute and chronic wounds. Following standard wound preparation, TAG may be applied directly to the wound. If rehydration is desired, place the graft on the area of intended application and re-hydrate in-situ with sterile water or 0.9% saline. TAG may be secured in place using a secondary dressing. TAG is available in the following sizes: 2.56cm x 2.56cm and 10cm x 13cm. It is packaged in a primary foil pouch and a secondary Tyvek pouch and sterilized by e-beam to meet a sterility assurance level (SAL) of 10-6. A single sterile, double pouched membrane is provided in a paperboard shelf box.

Final Decision

Based on written feedback from the FDA's Tissue Reference Group (TRG), TAG, when intended for use "as a barrier and provides protective coverage, from the surrounding environment, to acute and chronic wounds," meets the criteria for regulation solely under section 361 of the Public Health Service 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 new HCPCS Level II code Q4261, "Tag, per square centimeter"

Effective: 7/1/2022

SUSVIMO™ - HCP2112208WD5G

Topic/Issue

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

Applicant's suggested language: XXXXX "Injection, via SUSVIMO™ ocular implant, ranibizumab, 1 mg"

Applicant's Summary

Genentech submitted a request to establish a new HCPCS Level II code to describe SUSVIMO™ (ranibizumab injection) via SUSVIMO™ ocular implant. SUSVIMO™ intraocular drug delivery system is designed to be used specifically with SUSVIMO™. The system consists of an intraocular implant along with ancillary devices used to fill, insert, and explant (if needed) the implant. SUSVIMO™, a vascular endothelial growth factor (VEGF) inhibitor, is indicated for the treatment of patients with neovascular (wet) age-related macular degeneration (AMD) who have previously responded to at least two intravitreal injections of a VEGF inhibitor. The recommended dose of SUSVIMO™ is 2 mg (0.02 mL of 100mg/mL solution) continuously delivered via the SUSVIMO™ ocular implant with refills administered every 24 weeks (approximately 6 months). Each SUSVIMO™ initial fill needle kit (NDC 50242-078-55) contains one SUSVIMO™ 100mg/mL single-dose glass vial and one SUSVIMO™ initial fill needle (for initial fill and implant procedure). Each SUSVIMO™ (ranibizumab injection) carton (NDC 50242-078-12) contains one SUSVIMO™ 100mg/mL single-dose glass vial (for refill-exchange procedure). Each SUSVIMO™ refill needle carton contains a SUSVIMO™ refill needle. There is currently no unique HCPCS Level II code that describes SUSVIMO™.

Final Decision

1. Establish new HCPCS Level II code J2779, "Injection, ranibizumab, via intravitreal implant (susvimo), 0.1 mg"

   Effective: 7/1/2022

2. Discontinue existing HCPCS Level II code C9093, "Injection, ranibizumab, via intravitreal implant (susvimo), 0.1 mg"

   Effective: 6/30/2022

RYPLAZIM® - HCP211217F1694

Topic/Issue

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

Applicant's suggested language: XXXXX "Plasminogen, human-tvmh lyophilized powder for reconstitution, for intravenous use Injection, RYPLAZIM"

Applicant's Summary

Kedrion Biopharma Inc. submitted a request to establish a new HCPCS Level II code to identify RYPLAZIM®. RYPLAZIM® is a Glu-plasminogen (> 95% purity) which is the native circulating form of plasminogen in the blood. RYPLAZIM® is a sterile, white to off-white, lyophilized preparation of purified, plasma-derived plasminogen (human) to be reconstituted and administered by the intravenous route. Each vial of RYPLAZIM® contains 68.8 mg of plasminogen. Following reconstitution with 12.5 mL of sterile water for injection (SWFI), the RYPLAZIM® solution contains 5.5 mg/mL plasminogen and the following inactive ingredients: sodium citrate, sodium chloride, glycine, and sucrose. RYPLAZIM® contains no preservatives. Biological potency of the plasminogen is determined by a chromogenic assay calibrated with a standard plasminogen deficiency type 1 and is characterized by decreased plasminogen levels that cause formation of fibrin-rich, ligneous pseudomembranous lesions on mucous membranes that can impair normal tissue and organ function. Replacement therapy increases the plasma level of plasminogen enabling a temporary correction of the plasminogen deficiency and reduction or resolution of extravascular fibrinous lesions. No current HCPCS code adequately describes or differentiates RYPLAZIM® from other therapies; therefore, there is a programmatic need for CMS to create and assign a unique HCPCS code. As mentioned previously, RYPLAZIM® was FDA approved under a BLA. Therefore, it meets CMS' current definition of single source drug and for purposes of implementing the ASP statute, must be assigned its own unique billing code. RYPLAZIM® indicated for the treatment of patients with plasminogen deficiency type 1 (hypoplasminogenemia). Treatment with RYPLAZIM temporarily increases plasminogen levels in blood. The recommended dosage of RYPLAZIM is 6.6 mg/kg body weight administered intravenously every 2 to 4 days (Q2D to Q4D).

Final Decision

1. Establish new HCPCS Level II code J2998, "Injection, plasminogen, human-tvmh, 1 mg"

   Effective: 7/1/2022

   Existing modifier "JA" "administered intravenously" is available for use to specify the route of administration.

2. Discontinue existing HCPCS Level II code C9090, "Injection, plasminogen, human-tvmh, 1 mg"

   Effective: 6/30/2022

XIPERE™ - HCP211223EDH33

Topic/Issue

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

Applicant's suggested language: JXXXX, "triamcinolone acetonide injectable suspension, for suprachoroidal use, each"

Applicant's Summary

Bausch & Lomb submitted a request to establish a new HCPCS Level II code to identify XIPERE™. XIPERE™ is a sterile, preservative-free, injectable suspension of triamcinolone acetonide, a synthetic corticosteroid for use with the SCS Microinjector®. The chemical name for triamcinolone acetonide is 9-fluoro-11β,16α,17,21-tetrahydroxypregna-1,4-diene-3,20-dione cyclic 16,17-acetal with acetone. Triamcinolone acetonide is a synthetic glucocorticoid (glucocorticoids are often referred to as corticosteroids) with immunosuppressive and anti-inflammatory activity. XIPERE™ (triamcinolone acetonide injectable suspension) 40 mg/mL is indicated for the treatment of macular edema associated with uveitis. Triamcinolone acetonide is a synthetic glucocorticoid (glucocorticoids are often referred to as corticosteroids) with immunosuppressive and anti-inflammatory activity. The primary mechanism of action for triamcinolone acetonide is as a corticosteroid hormone receptor agonist. It is to be use for suprachoroidal injection using the SCS Microinjector®. The recommended dose of XIPERE™ is 4 mg (0.1 mL of the 40 mg/mL injectable suspension). Suprachoroidal injection using the SCS Microinjector®, which is part of the larger package as described above and below. The suprachoroidal injection procedure should be carried out under controlled aseptic conditions, which include the use of sterile gloves, a sterile drape, a sterile eyelid speculum (or equivalent), and a sterile cotton swab. Adequate anesthesia and a broad-spectrum microbicide applied to the periocular skin, eyelid, and ocular surface are recommended to be given prior to the suprachoroidal injection. Please see attached FDA label for further detail on the 19 steps required to safely administer XIPERE™ via the microinjector syringe with vial adapter. XIPERE™ is supplied as part of a larger package with the following sterile components for administration, sealed in a Tyvek covered tray, and one single-dose glass vial, in a carton with a package insert (NDC71565-040-01): One SCS Microinjector® syringe with vial adapter attached; One 30-G x 900-µm needle; One 30-G x 1100-µm needle; One single-dose vial of triamcinolone acetonide injectable suspension 40 mg/mL (NDC 71565-040-25), which is not separately commercially available.

Final Decision

1. Establish new HCPCS Level II code J3299, "Injection, triamcinolone acetonide (xipere), 1 mg"

   Effective: 7/1/2022

2. Discontinue existing HCPCS Level II code C9092, "Injection, triamcinolone acetonide, suprachoroidal (xipere), 1 mg"

   Effective: 6/30/2022

VYVGART™ - HCP211230EK51H

Topic/Issue

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

Applicant's suggested language: "Injection, efgartigimod alfa-fcab, 10 mg"

Applicant's Summary

Ar genx submitted a request to establish a new HCPCS Level II code to identify VYVGART™ (efgartigimod alfa-fcab) with the descriptor "Injection, efgartigimod alfa-fcab, 10 mg." VYVGART™ was approved by the FDA on December 17, 2021 and is indicated for the treatment of adult patients with generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody positive. Efgartigimod alfa-fcab is a human immunoglobulin G1 (IgG1)-derived Fc fragment of the za allotype that binds to the neonatal Fc Receptor (FcRn), resulting in the reduction of circulating IgG. The recommended dose of VYVGART™ in gMG patients is 10 mg/kg as a 1-hour intravenous infusion to be administered in treatment cycles of once weekly infusions for 4 weeks. In patients weighing 120 kg or more, the recommended dose of VYVGART™ is 1200 mg (3 vials) per infusion. VYVGART™ injection is a preservative free, sterile, colorless to slightly yellow, clear to slightly opalescent solution supplied in one 20 mL single-dose vial per carton. Each single-dose 20 mL vial contains 400 mg efgartigimod alfa-fcab at a concentration of 20 mg/mL. No existing HCPCS code describes VYVGART™. Currently, providers must use miscellaneous/unclassified codes. Miscellaneous codes do not describe VYVGART™, nor are they appropriate for permanent use or for facilitating optimal claims processing, payment, or utilization tracking. For this reason, a unique code that adequately and specifically describes VYVGART™ is needed.

Final Decision

Establish new HCPCS Level II code J9332, "Injection, efgartigimod alfa-fcab, 2 mg"

Effective: 7/1/2022

Illuccix® - HCP2112225TDTK

Topic/Issue

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

Applicant's suggested language: A95XX "Illuccix® (kit for the preparation of Gallium Ga -68 Gozetotide injection) (Gozetotide is also known as PSMA-11) (diagnostic, per 1 millicurie)"

Applicant's Summary

Telix Pharmaceuticals (US), Inc., submitted a request to establish a new HCPCS Level II code to identify Illuccix®. Presently there is no HCPCS code assigned for Illuccix® (kit for the preparation of Gallium Ga -68 Gozetotide injection (Gozetotide is also known as PSMA-11). It will be reported with not-otherwise-classified (NOC) HCPCS code A9597 (Positron emission tomography radiopharmaceutical, diagnostic, for tumor identification, not otherwise classified) or A4641 (Radiopharmaceutical, diagnostic, not otherwise classified) as an alternative for commercial payers that will not accept A9597. Using either HCPCS code prevents concise tracking of utilization, often results in under-payment, and may result in incorrect billing. An "A" HCPCS code with verbiage such as A95XX Illuccix® (kit for the preparation of Gallium Ga -68 Gozetotide injection (Gozetotide is also known as PSMA-11) (diagnostic, per 1 millicurie) would be the most appropriate code and is being formally requested through this process. Illuccix® is a radioactive diagnostic agent indicated for positron emission tomography (PET) of prostate specific membrane antigen (PSMA) positive lesions in men with prostate cancer with suspected metastasis who are candidates for initial definitive therapy or men with suspected recurrence based on elevated serum prostate specific antigen (PSA) level, granted FDA approval on December 17, 2021. Use of Illuccix® may allow for more concise treatment planning by improving staging and restaging of prostate cancer through greater detection of metastasis outside the prostate and avoiding localized treatments such as radiation therapies (external beam or brachytherapy) or radical prostatectomy, in the presence of metastatic disease. Illuccix® is also effective in prostate cancer patients with biochemical recurrence post definitive therapy. Rising PSA indicates the patient has recurrent disease, but not the location of the disease. Illuccix® helps localize metastatic disease, which in turn allows providers to choose the appropriate treatment based on where the disease is localized. Illuccix® is administered as an intravenous bolus injection and the recommended dose is 5mCi. Illuccix® is supplied as a 3-vial kit which contains the non-radioactive ingredients needed to produce 68GA PSMA-11 Injection. There are 2 configurations available to allow preparation of Ga-68 PSMA-11 using Ga-68 from different generator or cyclotron sources. Configuration A is used for Ga-68 produced by cyclotron via GE FASTlabR or for Ga-68 obtained from a Eckert & Ziegler Galliapharm Ge 68/Ga-68 generator. Configuration B is used for Ga-68 obtained from an IRE Galli Eo® Ge 68/Ga-68 generator. Due to two options for generators, there are two NDC numbers for Illuccix®, 74725-0100-25 and 74725-0100-64.

Final Decision

Establish new HCPCS Level II code A9596, "Gallium ga-68 gozetotide, diagnostic, (illuccix), 1 millicurie"

Effective: 7/1/2022

TAUVID™ - HCP2201049130M

Topic/Issue

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

Applicant's suggested language: A95XX "flortaucipir F 18 injection, diagnostic, per study dose, up to 10 mCi"

Applicant's Summary

Eli Lilly submitted a request to establish a new HCPCS Level II code to identify TAUVID™ (flortaucipir F 18 injection). TAUVID™ is a radioactive diagnostic agent indicated for positron emission tomography (PET) imaging of the brain to estimate the density and distribution of aggregated tau neurofibrillary tangles (NFTs) in adult patients with cognitive impairment who are being evaluated for Alzheimer's disease (AD). TAUVID™ is not indicated for use in the evaluation of patients for chronic traumatic encephalopathy. Flortaucipir F 18 binds to aggregated tau protein. In the brains of patients with AD, tau aggregates combine to form NFTs, one of two components required for the neuropathological diagnosis of AD. In vitro, flortaucipir F 18 binds to paired helical filament (PHF) tau purified from brain homogenates of donors with AD. The dissociation constant (Kd) of flortaucipir F 18 binding to PHFs is 0.57 nM. In vivo, flortaucipir F 18 is differentially retained in neocortical areas that contain aggregated tau. In vitro, tritiated flortaucipir has been reported to bind with low nanomolar affinity to monoamine oxidase-A and monoamine oxidase-B, which could contribute to off target binding. The recommended amount of radioactivity to be administered for PET imaging is 370 MBq (10 mCi), administered as an intravenous bolus injection in a total volume of 10 mL or less. Approximately 80 minutes after the TAUVID™ intravenous injection, a 20-minute PET image with the patient supine is obtained. TAUVID™ injection is supplied by Eli Lilly in a 30 mL or 50 mL multiple-dose vial (30 mL: NDC 0002-1210-30 (IC1210) and 50 mL: NDC 0002-1210-50 (IC1210)) containing a clear, colorless solution free of visible particulate matter at a strength of 300 MBq/mL to 1,900 MBq/mL (8.1 mCi/mL to 51 mCi/mL) flortaucipir F 18 at end of synthesis. Each vial contains multiple doses and is enclosed in a shield container to minimize external radiation exposure. Per the FDA label, the recommended dose for each patient is a fixed dose of 10 mCi (not weight-based dosing). Eli Lilly supplies TAUVID™ in a multi-dose (not single-dose) vial to the radiopharmacy. The radiopharmacy provides enough TAUVID™ in a patient-specific syringe, each with the necessary amount of product to be 10 mCi at the time of administration calculated at the time of distribution to the imaging facility to account for the level of anticipated radioactive decay during transit. At the place of service, all patient doses administered are calculated at 10 mCi at the time of administration. This further supports the request for "per dose" HCPCS units dosage.

Final Decision

Establish new HCPCS Level II code A9601, "Flortaucipir f 18 injection, diagnostic, 1 millicurie"

Effective: 7/1/2022

cutaquig® - HCP220104DXPL8

Topic/Issue

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

Applicant's suggested language: J15XX "Injection, Immune Globulin Subcutaneous (Human) – hipp, (cutaquig), per 100 mg"

Applicant's Summary

Octapharma USA, Inc. submitted a request to establish a new HCPCS Level II code to identify cutaquig®. cutaquig® is a solvent/detergent-treated, sterile preparation of highly purified immunoglobulin G (IgG) derived from large pools of human plasma. cutaquig® prevents infections of a wide variety of bacterial and viral agents in immunodeficient adults by temporarily restoring IgG levels in circulating plasma. cutaquig® was approved under a unique biologics license application (BLA) and has no therapeutic equivalents. Thus, cutaquig® is a biological under the average sales price (ASP) statute and warrants a unique code under CMS's implementation of that statute. The existing subcutaneous immune globulin (SCIG) codes (J1555, J1559, J1575) cannot be used for cutaquig® because each code includes a different product name and because it would set payment for cutaquig® based on ASP information for other products. cutaquig® is indicated as replacement therapy for primary humoral immunodeficiency (PI) in adults and pediatric patients 2 years of age and older. This includes, but is not limited to, common variable immunodeficiency (CVID), X-linked agammaglobulinemia, congenital agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies. cutaquig® supplies a broad spectrum of opsonizing and neutralizing IgG antibodies against a wide variety of bacterial and viral agents. For patients switching to cutaquig® from intravenous immune globulin (IVIG) the weekly dose is calculated by dividing the monthly IVIG dose in grams by the number of weeks between IVIG infusions and then multiply this value with a dose adjustment factor of 1.30. For patients switching to cutaquig® from SCIG, it is recommended to maintain the same weekly dosing (in grams) as was used for the previous SCIG product. cutaquig® is intended for the subcutaneous route of administration.

Final Decision

Establish new HCPCS Level II code J1551, "Injection, immune globulin (cutaquig), 100 mg"

Effective: 7/1/2022

Existing modifier "JB" "administered subcutaneously" is available for use to specify the route of administration.

TEZSPIRE™ - HCP211222BJ3E1

Topic/Issue

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

Applicant's suggested language: "Injection, tezepelumab-ekko 1 mg"

Applicant's Summary

Amgen submitted a request to establish a new HCPCS Level II code to identify TEZSPIRE™ (tezepelumab-ekko). TEZSPIRE™ is indicated for the add-on maintenance treatment of adult and pediatric patients aged 12 years and older with severe asthma. TEZSPIRE™ is not for relief of acute bronchospasm or status asthmaticus. The U.S. Food and Drug Administration (FDA) approved the biologics license application (BLA) for TEZSPIRE™ on December 17, 2021. TEZSPIRE™ (tezepelumab-ekko) is a thymic stromal lymphopoietin (TSLP) blocker, human monoclonal antibody (IgG2λ) that binds to human TSLP with a dissociation constant of 15.8 pM and blocks its interaction with the heterodimeric TSLP receptor. TSLP is a cytokine mainly derived from epithelial cells and occupies an upstream position in the asthma inflammatory cascade. A unique code is needed to recognize the approval of TEZSPIRE™ under an original BLA and ensure appropriate average sales price (ASP)-based payment under section 1847A of the Social Security Act. TEZSPIRE™ is administered by a healthcare provider as a subcutaneous injection. The recommended dose of TEZSPIRE™ is 210 mg administered once every four weeks. TEZSPIRE™ is a clear to opalescent, colorless to light yellow solution available in two forms: a single-dose vial with a carton containing one 210 mg/1.91 mL (110 mg/mL) glass vial, and a single-dose pre-filled syringe with a carton containing one 210 mg/1.91 mL (110 mg/mL). TEZSPIRE™ was granted breakthrough therapy designation by the FDA on September 6, 2018 for patients with severe asthma without an eosinophilic phenotype based on the tezepelumab Phase 2b PATHWAY data which demonstrated a significant reduction in the annual asthma exacerbation rate compared with placebo in a broad population of severe asthma patients independent of baseline blood eosinophil count or other type 2 inflammatory biomarkers. Additionally, TEZSPIRE™ was granted priority review by the FDA on July 7, 2021 based on results from the PATHFINDER clinical trial program, including results from the pivotal NAVIGATOR Phase 3 trial, in which tezepelumab demonstrated superiority across every primary and key secondary endpoint compared to placebo in a broad population of patients with uncontrolled asthma while receiving treatment with medium- or high-dose inhaled corticosteroids (ICS) plus at least one additional controller medication with or without oral corticosteroids (OCS).

Final Decision

Establish new HCPCS Level II code J2356, "Injection, tezepelumab-ekko, 1 mg"

Effective: 7/1/2022

APRETUDE - HCP211221DFP27

Topic/Issue

Request to establish a new HCPCS Level II Code to identify APRETUDE.

Applicant's suggested language: JXXXX "Injection, cabotegravir, (PrEP use), 600-mg (APRETUDE)"

Applicant's Summary

Charles River Associates, Inc. submitted a request to establish a new HCPCS Level II code to identify the APRETUDE kit for injection. APRETUDE contains cabotegravir extended-release injectable suspension, a human immunodeficiency virus integrase strand transfer inhibitor (INSTI). APRETUDE is FDA-approved to reduce the risk of sexually acquired HIV-1 infection. No currently available codes describe APRETUDE as it is newly approved via a new drug application (NDA). APRETUDE is indicated in at-risk adults and adolescents weighing at least 35 kg for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection. Individuals must have a negative HIV-1 test prior to initiating APRETUDE (with or without an oral lead-in with oral cabotegravir) for HIV-1 PrEP. APRETUDE must be administered by a healthcare provider by gluteal intramuscular injection. APRETUDE is supplied in a kit containing one 600-mg/3-mL single-dose (200-mg/mL) vial of cabotegravir extended-release injectable suspension, 1 syringe, 1 vial adapter, and 1 needle for intramuscular injection (23 gauge, 1 ½ inch) (NDC 49702-264-23).

Final Decision

Establish new HCPCS Level II code J0739, "Injection, cabotegravir, 1 mg"

Effective: 7/1/2022

RETHYMIC® - HCP2112166WLC3

Topic/Issue

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

Applicant's suggested language: J33XX "Allogeneic processed thymus tissue - agdc, per treatment"

Applicant's Summary

Enzyvant Therapeutics GmbH submitted a request to establish a new HCPCS Level II code to identify RETHYMIC® (Allogeneic processed thymus tissue – agdc). RETHYMIC® is engineered human thymus tissue designed to regenerate the thymic function children with congenital athymia are missing and is administered as a one-time regenerative tissue-based therapy for immune reconstitution in pediatric patients with congenital athymia, an ultra-rare disease with an estimated incidence in the U.S. of seventeen (17) to twenty-four (24) live births each year. Patients are born without a thymus, a condition that causes profound immunodeficiency, life-threatening immune dysregulation, and high susceptibility to potentially fatal infections and before RETHYMIC® there was no effective treatment for congenital athymia, and most patients die by two years of age. RETHYMIC® was granted FDA approval on October 8, 2021. RETHYMIC® therapy consists of slices of processed tissue and the dosage is determined by the surface area of the RETHYMIC® slices and recipient body surface area (BSA). The recommended dose range is 5000 to 22,000 mm2 of RETHYMIC® surface area/m2 recipient BSA. The manufacturer calculates the dose for the specific patient, the amount of product provided is adjusted at the manufacturing facility to ensure the maximum dose for the patient cannot be exceeded. Surgical implantation of allogeneic processed thymus tissue product (RETHYMIC®) should be done by a qualified surgeon. RETHYMIC® should be implanted in the quadriceps muscle and implantation requires a healthy bed of muscle tissue.

Final Decision

RETHYMIC® is not suitable for HCPCS Level II coding as it is used exclusively in hospital inpatient settings. CMS is not aware of the need for a unique HCPCS Level II code for use by other payers to track utilization.

Lidocidex™ - HCP220104KMKEW

Topic/Issue

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

Applicant's suggested language: XXXXX "Lidocidex™ I dexamethasone phosphate with lidocaine HCl Injection, USP 5mg/10mg/1.5mL (3.33mg/6.67mg/mL) 1.5mL Single Use Vial"

Applicant's Summary

Nubratori Inc. submitted a request to establish a new HCPCS Level II code to identify Lidocidex™. Lidocidex™ is a unique sterile injection compounded by FDA registered outsourcing facility function: The function is to allow the combination of a short acting anesthetic and short acting corticosteroid in a single use vial for licensed provider use. The reason for the request is that there are currently no codes for premixed combinations of local anesthetics and corticosteroids. Indications for use: local anesthesia and local anti-inflammatory response. It is a corticosteroid pre-mixed with lidocaine. Dosage is as follows; 5mg/10mg/1.5mL (3.33mg/6.67mg/mL) and route of administration; for intra-articular, subcutaneous, and soft tissue injection. It is packaged as 1.5 mL sterile solution in a 2 mL amber vial. Single use vial, stored in carton.

Final Decision

Lidocidex™ is not suitable for HCPCS Level II coding as CMS does not establish unique HCPCS Level II codes for compounded drugs.

Cocoon - HCP220103Y9VDR

Topic/Issue

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

Applicant's suggested language: QXXXX "Cocoon Dual-Layer and Single-Layer Membranes, per square centimeter"

Applicant's Summary

Pinnacle Transplant Technologies submitted a request to establish a new HCPCS Level II code to identify minimally manipulated human amnion allografts; Cocoon Single-Layer and Dual-Layer Membranes. Cocoon Membranes are intended for homologous use as a treatment of soft tissue injury, which include full and partial-thickness, chronic, acute and hard to heal wounds. They are indicated for the covering of full and partial-thickness, chronic, acute and hard-to-heal wounds. After preparation of the wound site, the human amnion allograft is surgically applied to the wound surface, extended beyond the wound margins and secured in place using the clinician's choice of fixation. As determined by the physician, a reapplication may be necessary. The Tissue Reference Group (TRG) at the FDA, Office of Tissues and Advanced Therapies, confirmed Cocoon Dual-Layer Membrane is a human cells, tissues, and cellular and tissue-based product (HCT/P) regulated solely under section 361 of the Public Health Service (PHS) Act and the regulations identified in 21 CFR 1271.

Final Decision

After review of the TRG letter submitted by the applicant, the Cocoon Membrane product information submitted to CMS appears to differ from the information that was submitted to the FDA's TRG. Based on written feedback from the TRG, the Cocoon Membrane, when intended for use "as a wound covering" and "to act as a barrier" for "full and partial-thickness, chronic and acute wounds" appears to meet the criteria for regulation solely under section 361 of the PHS Act and the regulations in 21 CFR part 1271. However, in the HCPCS Level II application for Cocoon Membrane, the applicant referenced additional intended uses. The application stated that "Cocoon Membranes are intended for homologous use as a treatment of soft tissue injury, which include full and partial-thickness, chronic, acute and hard to heal wounds." Based on this information, it appears that the Cocoon Membrane may not be suitable for registration as an HCT/P.

CMS refers the applicant back to the FDA's TRG to obtain written feedback regarding how the product, consistent with its intended uses described in the HCPCS Level II application, is appropriately regulated. After obtaining the FDA's written feedback, the applicant is welcome to submit a complete HCPCS Level II application in a subsequent coding cycle. Information for submitting questions to the FDA's TRG is located at: https://www.fda.gov/vaccines-bloodbiologics/tissue-tissue-products/tissue-reference-group.

PalinGen® - HCP21121043D84

Topic/Issue

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

Applicant's suggested language: XXXXX "PalinGen® Dual Layer Membranes, per square centimeter"

Applicant's Summary

Amnio Technology submitted a request to establish a new HCPCS Level II code to identify PalinGen®. PalinGen® Dual Layer Membranes are dehydrated, human allografts derived from the placenta. They contain extracellular matrix components to support wound management. They are minimally manipulated, preserving many of the natural growth factors normally present in amniotic tissue. PalinGen® Dual Layer Membrane products are used for children and adults suffering from non-healing acute and chronic wounds (diabetic, venous, mixed venous-arterial, pressure ulcers), complex and/or open surgical wounds and burns. PalinGen® Dual Layer Membranes are intended for homologous use and support the repair of soft tissue injury, which include full and partial-thickness, and hard to heal wounds. PalinGen® Dual Layer Membranes are used to cover the wounds and offer protection from the surrounding environment and serve as a selective barrier for the movement of nutrients. The size of the membrane is determined by the physician and should be large enough to completely cover the wound. After preparation of the wound site, the human amnion allograft is applied to the wound surface, extended beyond the wound margins, and secured in place using the clinician's choice of fixation. As determined by the physician, reapplication may be necessary. PalinGen® Dual Layer Membrane is supplied in the following sizes: 2cm x 3cm, 2cm x 4cm, 4cm x 4cm, 4cm x 6cm, and 4cm x 8cm sizes.

Final Decision

After review of the Tissue Reference Group (TRG) letter submitted by the applicant, the PalinGen® product information submitted to CMS appears to differ from the information that was submitted to the FDA's TRG. Based on written feedback from the TRG, PalinGen®, when intended for use "as a barrier", meets all the criteria for regulation solely under section 361 of the Public Health Service (PHS) Act and the regulations in 21 CFR part 1271. However, in the HCPCS Level II application for PalinGen®, the applicant referenced additional intended uses. The application stated that "PalinGen® Dual Layer Membranes are intended for homologous use and support the repair of soft tissue injury, which include full and partial-thickness, and hard to heal wounds." Based on this information, it appears that PalinGen® may not be suitable for registration as a human cells, tissues, and cellular and tissue-based product (HCT/P).

CMS refers the applicant back to the FDA's TRG to obtain written feedback regarding how the product, consistent with its intended uses described in the HCPCS Level II application, is appropriately regulated. After obtaining the FDA's written feedback, the applicant is welcome to submit a complete HCPCS Level II application in a subsequent coding cycle. Information for submitting questions to the FDA's TRG is located at: https://www.fda.gov/vaccines-bloodbiologics/tissue-tissue-products/tissue-reference-group.

Esano AAA - HCP220103WHQVT

Topic/Issue

Request to establish a new HCPCS Level II code to identify Esano AAA.

Applicant's suggested language: Q42XX "Esano AAA, per sq. cm"

Applicant's Summary

Evolution Biologyx, LLC submitted a request to establish a new HCPCS Level II code to identify Esano AAA. Esano AAA is a triple layer decellularized, dehydrated human amniotic membrane allograft, derived from donated, normal, healthy, human, full-term placentas. Esano AAA is intended for use as a membrane covering, provides protection from the surrounding environment and can be used as a barrier. Esano AAA provides an extracellular matrix ("ECM") while supporting the repair of damaged tissue including, but not limited to, partial- and full-thickness, acute and chronic wounds (such as, for example, traumatic and complex wounds, burns, surgical and Mohs surgery sites; and diabetic, venous, arterial, pressure and other ulcers). Esano AAA is supplied in a single patient, single use, double peel pouch in the following sizes: 10mm disc, 12mm disc, 15mm disc, 1cm x 1cm, 1cm x 2cm, 2cm x 2cm, 2cm x 3cm, 2cm x 4cm, 3cm x 3cm, 3cm x 6cm, 3cm x 8 cm, 4cm x 4cm, 4cm x 6cm, 4cm x 8 cm, 5cm x 5cm, 6cm x 6cm, 7cm x 7cm, 10cm x 10cm and 10cm x 12cm. There is no existing HCPCS code to describe Esano AAA, tri-layer, decellularized, dehydrated human amniotic membrane allograft. Esano AAA can be used to treat patients who present with acute and chronic wounds and in surgical applications including, but not limited to, partial- and full-thickness acute and chronic wounds (such as, for example, traumatic and complex wounds, burns, surgical and Mohs surgery sites; and diabetic, venous, arterial, pressure and other ulcers).

Final Decision

After review of the Tissue Reference Group (TRG) letter submitted by the applicant, the Esano AAA product information submitted to CMS appears to differ from the information that was submitted to the FDA's TRG. Based on written feedback from the TRG, Esano AAA, when intended for use "as a cover or to protect from the surrounding environment" and for "use as a barrier," meets all the criteria for regulation solely under section 361 of the Public Health Service Act and the regulations in 21 CFR part 1271. However, in the HCPCS Level II application for Esano AAA, the applicant referenced additional intended uses. The application stated that "Esano AAA can be used to treat patients who present with acute and chronic wounds and in surgical applications including, but not limited to, partial- and full-thickness acute and chronic wounds." Based on this information, it appears that Esano AAA may not be suitable for registration as a human cells, tissues, and cellular and tissue-based product (HCT/P).

CMS refers the applicant back to the FDA's TRG to obtain written feedback regarding how the product, consistent with its intended uses described in the HCPCS Level II application, is appropriately regulated. After obtaining the FDA's written feedback, the applicant is welcome to submit a complete HCPCS Level II application in a subsequent coding cycle. Information for submitting questions to the FDA's TRG is located at: https://www.fda.gov/vaccines-bloodbiologics/tissue-tissue-products/tissue-reference-group.

Sanopellis - HCP220104WH2VX

Topic/Issue

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

Applicant did not provide suggested language

Applicant's Summary

ReNu LLC submitted a request to establish a new HCPCS Level II code to identify Sanopellis. Sanopellis are dehydrated, human allografts derived from the placenta, specifically it is two layers of amniotic membrane. They contain extracellular matrix components to support cellular attachment and proliferation for tissue repair. They are minimally manipulated, preserving many of the natural growth factors normally present in amniotic tissue. The patient population for use of the Sanopellis products include children and adults suffering from non-healing acute and chronic wounds (diabetic, venous, mixed venous-arterial, pressure ulcers), complex and/or open surgical wounds and burns. Sanopellis are intended for homologous use and support the repair of soft tissue injury, which include full and partial-thickness, chronic, acute and hard to heal wounds. Sanopellis are used to cover the wounds and offer protection from the surrounding environment and serve as a selective barrier for the movement of nutrients. The size of the membrane is determined by the physician and should be large enough to completely cover the wound. After preparation of the wound site, the human amnion allograft is applied to the wound surface, extended beyond the wound margins and secured in place using the clinician's choice of fixation. As determined by the physician, a reapplication may be necessary. Sanopellis is available in multiple sizes: 2cm x 3cm, 4cm x 4cm, and 4cm x 6cm. The smallest available size is a 2cm x 3cm allograft for covering small wounds.

Final Decision

After review of the Tissue Reference Group (TRG) letter submitted by the applicant, the Sanopellis product information submitted to CMS appears to differ from the information that was submitted to the FDA's TRG. Based on written feedback from the TRG, Sanopellis, when intended for use "as a wound covering" and "to act as a barrier" for "full and partial-thickness, chronic and acute 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. However, in the HCPCS Level II application for Sanopellis, the applicant referenced additional intended uses. The application stated that "Sanopellis, are intended for homologous use and support the repair of soft tissue injury, which include full and partial-thickness, chronic, acute and hard to heal wounds." Based on this information, it appears that Sanopellis may not be suitable for registration as a human cells, tissues, and cellular and tissue-based product (HCT/P).

CMS refers the applicant back to the FDA's TRG to obtain written feedback regarding how the product, consistent with its intended uses described in the HCPCS Level II application, is appropriately regulated. After obtaining the FDA's written feedback, the applicant is welcome to submit a complete HCPCS Level II application in a subsequent coding cycle. Information for submitting questions to the FDA's TRG is located at: https://www.fda.gov/vaccines-bloodbiologics/tissue-tissue-products/tissue-reference-group.

3L Biovance® - HCP2201040GE1J

Topic/Issue

Request to establish a new HCPCS Level II code to identify 3L Biovance®.

Applicant's suggested language: Q41XX "3L Biovance, 1 sq cm. Sizes ranging from 10mm to 120 sq cm"

Applicant's Summary

Celularity Inc. submitted a request to establish a new HCPCS Level II code to identify Biovance® Tri-Layer and 3L Biovance®. The processing of the tissue involves the separation of the amniotic membrane from the chorionic membrane followed by cleaning using a mild detergent, scraping, and rinsing. The membrane is folded upon itself to create a tri-layer thickness, dehydrated, packaged, then sterilized using e-beam irradiation. The name is 3L Biovance® Human Amniotic Membrane Allograft (referred to as 3L throughout document). Dehydrated human membrane allografts are human tissue allograft intended for use as a cover or to protect from the surrounding environment in wound and surgical repair and reconstruction procedures. Applications include, but are not limited to, application to partial- and full-thickness, acute and chronic wounds (such as traumatic and complex wounds, burns, surgical, and Mohs surgery sites; and diabetic, venous, arterial, pressure, and other ulcers), including wounds with exposed tendon, muscle, bone, or other vital structures. For many uncomplicated wounds, traditional surgical dressings will suffice and enable a wound to heal in an orderly and timely manner. However, in various areas of medicine, wound care physicians often encounter chronic non-healing wounds that have poor rates of healing or are entirely resistant to closure. It is for these difficult-to-heal wounds and patients with a history of delayed healing that advanced biologic products such as 3L are particularly well-suited. The quantity and size of the product used will vary based upon wound size and physician recommendation. 3L is packaged as a sterile product in sealed, single-use pouches.

Final Decision

After review of the Tissue Reference Group (TRG) letter submitted by the applicant, the 3L Biovance® product information submitted to CMS appears to differ from the information that was submitted to the FDA's TRG. Based on written feedback from the TRG, 3L Biovance®, when intended for use as "a cover or to protect from the surrounding environment," meets all the criteria for regulation solely under section 361 of the Public Health Service (PHS) Act and the regulations in 21 CFR part 1271. However, in the HCPCS Level II application for 3L Biovance®, the applicant referenced additional intended uses. The application stated that "It is for these difficult-to-heal wounds and patients with a history of delayed healing that advanced biologic products such as 3L are particularly well-suited." Based on this information, it appears that 3L Biovance® may not be suitable for registration as a human cells, tissues, and cellular and tissue-based product (HCT/P).

CMS refers the applicant back to the FDA's TRG to obtain written feedback regarding how the product, consistent with its intended uses described in the HCPCS Level II application, is appropriately regulated. After obtaining the FDA's written feedback, the applicant is welcome to submit a complete HCPCS Level II application in a subsequent coding cycle. Information for submitting questions to the FDA's TRG is located at: https://www.fda.gov/vaccines-bloodbiologics/tissue-tissue-products/tissue-reference-group.

Pemetrexed - HCP220103RRTDJ

Topic/Issue

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

Applicant's suggested language: J9XXX, "Injection, pemetrexed (teva), per 10 MG"
Recommended short descriptor: "inj. pemetrexed (teva), 10 MG"

Applicant's Summary

Teva Pharmaceuticals submitted a request to establish a new HCPCS Level II code to identify Pemetrexed. Pemetrexed Injection is a folate analog metabolic inhibitor that disrupts folate-dependent metabolic processes essential for cell replication, and is indicated as a single agent in the treatment of locally advanced and metastatic non-squamous non-small cell lung cancer. The number of vials needed for a given patient to administer in a single dose is calculated based on body surface area (BSA). The recommended dose of Pemetrexed in patients with a creatinine clearance (calculated by Cockcroft-Gault equation) of 45 mL/min or greater is 500 mg/m2 administered as an intravenous infusion over 10 minutes on day 1 of each 21-day cycle. There is no recommended dose for patients whose creatinine clearance is less than 45 mL/min (see package insert for use in specific populations). Pemetrexed Injection is a clear, colorless to slightly yellowish or slightly yellow-greenish solution available in sterile single-dose vials containing 100 mg/4 mL, 500 mg/20 mL, and 1 g/40 mL of Pemetrexed. Pemetrexed Injection, solution is a unique single source drug that was FDA approved under a section 505(b)(2) new drug application (NDA) and is not therapeutically equivalent or interchangeable to the other FDA-approved pemetrexed products.

Final Decision

CMS reviewed the FDA's website at the time of the application submission, which listed the NDA for Pemetrexed as discontinued. This application is considered incomplete, as CMS will not issue a HCPCS Level II code for a drug with a discontinued NDA. The applicant is welcome to submit a complete HCPCS Level II application in a subsequent coding cycle.