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

Third Quarter, 2020 Coding Cycle for Drug and Biological Products

This HCPCS Code Application Summary document presents, in request number sequence, a summary of each HCPCS code application and CMS' HCPCS coding decision for each application processed in CMS' Third Quarter 2020 Drug and Biological HCPCS code application review cycle. Each individual summary includes: the application number; topic; summary of the applicant's request as written by the applicant with occasional minor, non-substantive editorial changes made by CMS; CMS' HCPCS coding decision; and the effective date of any coding action which, for the purpose of this publication, refers to the date the code is first available to be billed on claims. These HCPCS coding decisions will also be included in the January 2021 HCPCS Quarterly Update, pending publication by CMS in the coming weeks at: https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Alpha-Numeric-HCPCS.

We have received inquiries regarding coding of hyaluronic acid products and the First Quarter 2020 HCPCS coding decisions relating to these products. We are working to assess these coding decisions and will further address these decisions in an upcoming quarter relative to our current policies and procedures. Please see information at https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Downloads/051807_coding_announcement.pdf for more information.

Request # 20.101

Topic/Issue

Request to establish a new Level II HCPCS code to identify SPRAVATO (esketamine)

Applicant's suggested language: JXXXX: Nasal spray, esketamine, 28 mg

Applicant's Summary

SPRAVATO (esketamine) nasal spray, CIII, is an N-methyl D-aspartate (NMDA) receptor antagonist approved in March 2019 by the FDA for use, in conjunction with an oral antidepressant, for treatment-resistant depression in adults. Treatment-resistant depression (TRD) was defined in the completed phase 3 program, as a DSM-5 diagnosis of Major Depressive Disorder (MDD) in adults who have not responded adequately to at least two different antidepressants of adequate dose and duration in the current depressive episode. SPRAVATO nasal spray is administered, under the direct supervision of a healthcare provider, with monitoring by the provider under a Risk Evaluation and Mitigation Strategy. CMS recently established two G-codes for SPRAVATO: G2082 Office, or other outpatient visit for the evaluation and management of an established patient that requires the supervision of a physician or other qualified health care professional and provision of up to 56 mg of esketamine nasal self-administration, includes 2 hours post-administration observation; and G2083 Office or other outpatient visit for the evaluation and management of an established patient that requires the supervision of a physician or other qualified health care professional and provision of greater than 56 mg esketamine nasal self-administration, includes 2 hours post-administration observation.

Janssen Pharmaceutical Companies of Johnson & Johnson sincerely appreciates the establishment of these codes, and is not asking CMS to eliminate, or revise the G codes because they help CMS address specific Medicare programmatic needs. Nevertheless, Janssen Pharmaceutical Companies of Johnson & Johnson remains concerned that some commercial payers may have difficulty adjudicating claims for this service because the G codes includes both a medical service and the drug which can have different payment methodologies. For example, we have identified fourteen (large national, regional and Medicaid) payers that have either informed Janssen Pharmaceutical Companies of Johnson & Johnson that they are not using the G codes, or have published coding guidance in 2020 indicating that providers should use miscellaneous HCPCS codes rather than the G codes. In addition, we have included documentation of nine additional commercial and Medicaid payers that continue to instruct providers to use miscellaneous codes, with no reference to G codes, based on guidance published before 2020. In many cases, these coding policies reflect how those payers contract and reimburse separately for professional mental health services and drug therapies. Issuance of a specific J code will facilitate more efficient claims processing by those payers.

Final Decision

CMS appreciates the claims adjudication issues of other insurers and payers. As such, CMS establishes new Level II HCPCS code S0013 "Esketamine, nasal spray, 1 mg"

For Medicare, the drug is packaged in a G code to report the drug/service combination and S0013 would not be included on the claim.

CMS also recommends that the applicant approach the AMA for a CPT code to report the REMS service of administering esketamine when the drug is reported separately.

Effective: 1/1/2021

Request # 20.116

Topic/Issue

Request to establish a new Level II HCPCS code to identify UPLIZNA (inebilizumab-cdon)

Applicant's suggested language: J13XX (inebilizumab-cdon, per 300mg)

Applicant's Summary

Viela Bio requests to establish a new Level II HCPCS code to identify UPLIZNA (inebilizumab-cdon).

UPLIZNA (inebilizumab-cdon) was granted FDA approval on June 11, 2020 for the treatment of adults with neuromyelitis optica spectrum disorders (NMOSD) who are anti-aquaporin-4 (AQP4) antibody positive. Inebilizumab-cdon, the active ingredient in UPLIZNA, is a humanized afucosylated monoclonal antibody that targets CD19+ B-cells. NMOSD is the first and only indication for UPLIZNA; it is also being studied for the treatment of myasthenia gravis, IgG4-related disease, and highly-sensitized kidney transplant candidates. Prior to the first dose, Hepatitis B virus, quantitative serum immunoglobulins, and tuberculosis screening is required. UPLIZNA must be diluted in 250mL of 0.9% Sodium Chloride Injection, USP prior to administration and is administered as an intravenous (IV) infusion titrated to completion, approximately 90 minutes. The recommended dose is: Initial dose: 300mg intravenous infusion followed two weeks later by a second 300mg intravenous infusion. Subsequent doses (starting 6 months from the first infusion) of a single 300mg intravenous infusion every 6 months. Monitor patients closely during the infusion and for at least one hour after completion of the infusion. UPLIZNA is supplied in single-use vials (100 mg/10 mL), three vials contained in one carton. All three vials must be used to constitute one patient dose.

Final Decision

Establish new Level II HCPCS code J1823 "Injection, inebilizumab-cdon, 1 mg"

CMS has a long-standing convention to assign dose descriptors in the smallest amount that could be billed in multiple units to accommodate a variety of doses, making coding more robust, facilitate accurate payment and reporting of exact dose administered.

Effective: 01/01/2021

Request # 20.117

Topic/Issue

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

Applicant's suggested language: "Injection, sacituzumab govitecan-hziy, per 1 mg".

Applicant's Summary

lmmunomedics, Inc. requests a new Level II HCPCS code with the description of "Injection, sacituzumab govitecan-hziy, per 1 mg". TRODELVY is a Trop-2-directed antibody and topoisomerase inhibitor conjugate indicated for the treatment of adult patients with metastatic triple-negative breast cancer (mTNBC) who have received at least two prior therapies for metastatic disease. TRODELVY was approved by the FDA on April 22, 2020 under Accelerated Approval based on tumor response rate and duration of response and is the first and only Trop-2 antibody drug conjugate (ADC) approved for the treatment of mTNBC. On April 6, 2020, an independent Data Safety Monitoring Committee unanimously recommended the Phase 3 confirmatory study be halted due to compelling evidence of efficacy. TRODELVY is supplied as a sterile, off-white to yellowish lyophilized powder in a single-dose vial, 180 mg each. The recommended dose is 10 mg/kg administered as an intravenous infusion once weekly on Days 1 and 8 of a 21-day treatment cycles. A dose may be reduced by 25% or 50% should severe neutropenia or severe non-neutropenic toxicity be encountered.

As per the applicant, there are currently no available Level II HCPCS code that describes sacituzumab govitecan-hziy. According to the applicant, without a unique HCPCS code, use of a miscellaneous or unclassified HCPCS code will be required. Additionally, use of a miscellaneous or unclassified HCPCS code will require manual claims submission and/or manual claims review resulting in increased workload for both providers and payers. These manual claims submission and/or manual claims review processes lead to significant delay and possibly inaccurate payment rates for providers. This can have a negative impact on physician, clinic, and hospital outpatient adoption because of billing and reimbursement confusion. A delay or reluctance in adoption of sacituzumab govitecan-hziy will have a negative clinical impact on women with mTNBC, a very aggressive disease with median survival of 10-13 months.

Final Decision

Establish new Level II HCPCS code J9317 "Injection, sacituzumab govitecan-hziy, 2.5 mg"

CMS has a long-standing convention to assign dose descriptors in the smallest amount that could be billed in multiple units to accommodate a variety of doses, making coding more robust, facilitate accurate payment and reporting of exact dose administered. However, in this case, the limitations presented by Medicare claims processing system necessitate that we assign a dose descriptor that will enable the code to be billed in multiple units and not exceed the maximum number of digits that can be recorded on a single claim line.

Effective: 01/01/2021

Request # 20.118

Topic/Issue

Request to establish a new Level II HCPCS code to identify cerianna

Applicant's suggested language: A95XX: Fluoroestradiol F 18 injection, diagnostic, per 1 mCi

Applicant's Summary

Zionexa requests one new HCPCS code to identify cerianna (Fluoroestradiol F 18) Injection, for intravenous use.

Cerianna is a radioactive drug indicated for use with positron emission tomography (PET) imaging for the detection of estrogen receptor (ER)-positive lesions as an adjunct to biopsy in patients with recurrent or metastatic breast cancer. Fluoroestradiol F 18 binds ER (binding affinity: Kd = 0.13 ± 0.02 nM; Bmax = 1901 ± 89 fmol/mg; IC50 = 0.085 nM) in ER-positive human breast cancer tissue. Fluoroestradiol F 18 uptake measured by PET in human tumors is directly proportional to tumor ER expression measured by in vitro assays. The recommended amount of radioactivity to be administered for PET imaging is 222 MBq (6 mCi), with a range of 111 MBq to 222 MBq (3 mCi to 6 mCi), administered as a single intravenous injection of 10 mL or less over 1 to 2 minutes. Cerianna is supplied as a 50 mL multiple-dose glass vial (NDC# 72874-001-01) containing a clear, colorless injection solution at a strength of 148 MBq/mL to 3,700 MBq/mL (4 mCi/mL to 100 mCi/mL) fluoroestradiol F 18 at the end of synthesis. Each vial contains multiple doses and is enclosed in a shield container to minimize external radiation exposure.

As per the applicant, no current Level II HCPCS code currently identifies this product. The applicant further states, current CMS policy1 eliminated billing for PET scans in conjunction with HCPCS code A4641 (Radiopharmaceutical, diagnostic, not otherwise classified), effective 2008.

Final Decision

Establish new Level II HCPCS code A9591 "Fluoroestradiol F 18, diagnostic, 1 millicurie"

Effective: 01/01/2021

Request # 20.119

Topic/Issue

Request to revise an existing Level II HCPCS code Q4126 to include SimpliDerm in the language.

Applicant's suggested revision language: Q4126 “MemoDerm, DermaSpan, TranZgraft InteguPly, or SimpliDerm, per sq cm”.

Applicant’s Summary

Aziyo Biologics, Inc. is requesting that Level II HCPCS code Q4126, be revised to include SimpliDerm. All of the products currently listed in the descriptor for Q4126 are HADMs manufactured by Aziyo Biologics Inc using the same processing technique used to manufacture SimpliDerm. The only difference is that MemoDerm, DermaSpan, InteguPly and TranZgraft are freeze-dried, whereas SimpliDerm is pre-hydrated.

SimpliDerm is a human acellular dermal matrix (HADM) allograft with a sterility assurance level of 10-6. It is derived from human skin that has been aseptically processed and terminally sterilized to preserve the native collagen microstructure, while removing potential immunogenic cells and epidermis. SimpliDerm is used for the repair or replacement of damaged or insufficient integumental tissue. Per its labeling, SimpliDerm “is to be used for the replacement of damaged or insufficient integumental tissue or for the repair, reinforcement, or supplemental support of soft tissue defects.” SimpliDerm functions as a framework to support cellular repopulation and vascularization at the surgical site. Like native dermis, SimpliDerm contains key extracellular matrix components such as collagen, elastin, and glycosaminoglycan, which provide an optimal microenvironment for tissue remodeling during regenerative medicine applications. Available in over 60 combinations of varying lengths, widths, and thicknesses, the size of SimpliDerm selected depends on the clinical procedure and amount of tissue requiring repair. The graft is supplied inside a sterile inner pouch, which is then enclosed in a secondary outer pouch. It is implanted into the surgical site as directed by the surgeon. According to the applicant, the current descriptor of Q4126 is insufficient to describe SimpliDerm because it lacks the brand name “SimpliDerm”.

Final Decision

After review of FDA’s guidance, it does not appear to CMS that SimpliDerm, used exclusively for surgical implantation, is suitable for registration as a human cells, tissues, and cellular tissue-based product (HCT/P). CMS refers the applicant to the FDA’s Tissue Reference Group or the Office of Combination Products to obtain written feedback regarding how the product is appropriately regulated. After obtaining the FDA’s written feedback, the applicant is welcome to submit a complete HCPCS code application in a subsequent coding cycle.

Information for submitting questions to the TRG is located at:

https://www.fda.gov/vaccines-blood-biologics/tissue-tissue-products/tissue-reference-group

Request # 20.121

Topic/Issue

Request to establish a new Level II HCPCS code to identify FETROJA (cefiderocol).

Applicant's suggested language: JXXXX “Injection, cefiderocol, 1 mg.”

Applicant’s Summary

Shionogi, Inc is requesting a new HCPCS code be created for the recently FDA approved drug FETROJA (cefiderocol).

FETROJA is a cephalosporin antibacterial drug product consisting of cefiderocol sulfate tosylate for intravenous infusion. FETROJA is an antibacterial indicated in patients 18 years of age or older who have limited or no alternative treatment options, for the treatment of complicated urinary tract infections (cUTI), including pyelonephritis caused by susceptible Gram-negative microorganisms. Approval of this indication is based on limited clinical safety and efficacy data for FETROJA. To reduce the development of drug-resistant bacteria and maintain the effectiveness of FETROJA and other antibacterial drugs, FETROJA should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria. FETROJA is administered via intravenous infusion after reconstitution. The recommended dosage of FETROJA is 2 gm every 8 hours infused over 3 hours with dosage adjustment dependent on renal function. FETROJA 1 gram (cefiderocol) for injection is supplied as a white to off-white sterile lyophilized powder for reconstitution in single-dose, clear glass vials sealed with a rubber stopper (not made with natural rubber latex) and an aluminum seal with flip-off cap.

Final Decision

Establish new Level II HCPCS code J0693 "Injection, cefiderocol, 5 mg"

CMS has a long-standing convention to assign dose descriptors in the smallest amount that could be billed in multiple units to accommodate a variety of doses, making coding more robust, facilitate accurate payment and reporting of exact dose administered. However, in this case, the limitations presented by Medicare claims processing system necessitate that we assign a dose descriptor that will enable the code to be billed in multiple units and not exceed the maximum number of digits that can be recorded on a single claim line.

Effective: 01/01/2021

Request # 20.122

Topic/Issue

Request to establish a new Level II HCPCS code to identify Darzalex Faspro.

Applicant's suggested language: JXXXX Injection daratumumab, 1800 mg and hyaluronidase, 30,000 units, for subcutaneous injection

Applicant's Summary

DARZALEX FASPRO is a combination of daratumumab, a CD38-directed cytolytic antibody, and hyaluronidase, an endoglycosidase, for the treatment of adult patients with multiple myeloma:

- in combination with bortezomib, melphalan and prednisone in newly diagnosed patients who are ineligible for autologous stem cell transplant
- in combination with lenalidomide and dexamethasone in newly diagnosed patients who are ineligible for autologous stem cell transplant and in patients with relapsed or refractory multiple myeloma who have received at least one prior therapy
- in combination with bortezomib and dexamethasone in patients who have received at least one prior therapy
- as monotherapy, in patients who have received at least three prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent or who are double-refractory to a PI and an immunomodulatory agent.

Currently, there is a HCPCS code for intravenous DARZALEX. However, DARZALEX FASPRO (daratumumab and hyaluronidase-fihj) is for subcutaneous use only and has different dosage and administration instructions than intravenous daratumumab. The subcutaneous formulation is distinct from the intravenous formulation.

After pre-medication with corticosteroids, antipyretics and antihistamines, 15 ml DARZALEX FASPRO should be administered into the subcutaneous tissue of the abdomen over approximately 3 to 5 minutes, according to the recommended schedule.

Final Decision

Establish new Level II HCPCS code J9144 "Injection, daratumumab, 10 mg and hyaluronidase-fihj".

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, making coding more robust, facilitate accurate payment and reporting of exact dose administered.

Effective: 01/01/2021

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

Request # 20.124

Topic/Issue

Request to establish a new Level II HCPCS code for sevenfact [coagulation factor VIIa (recombinant)-jncw] lyophilized powder for solution, for intravenous (IV) use.

Applicant's suggested language: JXXXX factor VIIa antihemophilic factor, (recombinant)-jncw, 1mcg

Applicant's Summary

Sevenfact is indicated for the treatment and control of bleeding episodes occurring in adults and adolescents (12 years of age and older) with hemophilia A or B with inhibitors. Its active ingredient is a recombinant analog of human coagulation factor VIIa that activates factor X to factor Xa, bypassing factors VIII and IX, initiating the common pathway of the coagulation cascade.

Sevenfact is a single-source biological product approved by the U.S. Food and Drug Administration (FDA) under an original biologics license application (BLA), as defined under 42 Code of Federal Regulation (CFR) § 447.502.[1] No existing HCPCS code specifically describes sevenfact, and therefore a unique J-Code is necessary to appropriately identify and reimburse sevenfact as well as to implement current Medicare payment policy for single-source drugs and biologics. Existing HCPCS codes for other products used for treatment within sevenfact's approved indication do not describe sevenfact and cannot be used to report its use. Sevenfact is dosed according to the severity of the bleeds:

After reconstitution, sevenfact is for IV use only. sevenfact is supplied as a lyophilized powder in single-use vials containing 1 or 5 mg of coagulation factor VIIa (recombinant)-jncw.

Final Decision

1. Establish new Level II HCPCS code J7212 "factor viia (antihemophilic factor, recombinant)-jncw (sevenfact), 1microgram"

Effective: 01/01/2021

2. Revise existing Level II HCPCS code J7189 which currently reads: "Factor viia (antihemophilic recombinant), per 1 microgram" to instead read: "Factor viia (antihemophilic factor, recombinant), (novoseven rt), 1 microgram".

3. Revise short descriptor of code J7189: Factor viia recomb novoseven

Request # 20.125

Topic/Issue

Request to establish a new Level II HCPCS code to identify FENSOLVI (leuprolide acetate) for injectable suspension for subcutaneous use.

Applicant's suggested language: JXXXX Injection, leuprolide acetate (FENSOLVI), 45 mg, for subcutaneous use

Applicant's Summary

FENSOLVI is a sterile polymeric matrix formulation of leuprolide acetate that is administered subcutaneously by a healthcare professional for the treatment of pediatric patients 2 years of age and older with central precocious puberty. Leuprolide acetate is a synthetic nonapeptide analog of naturally occurring gonadotropin-releasing hormone that possesses greater potency than the natural hormone.

FENSOLVI is supplied in a kit that includes 2 prefilled syringes; 1 contains 45 mg of lyophilized leuprolide acetate powder and the other contains the *in-situ* polymeric gel delivery system. The *in-situ* polymeric gel (non-gelatin-containing) delivery system consists of a biodegradable poly (DL-lactide-co-glycolide) (PLG) polymer formulation dissolved in the biocompatible solvent, N-methyl-2-pyrrolidone (NMP). Once every 6 months, FENSOLVI 45 mg is administered subcutaneously, where it forms a solid drug delivery depot.

Current HCPCS codes for other leuprolide acetate products are not appropriate for FENSOLVI due to differences in route of administration, formulation, reconstitution process, targeted patient population/therapeutic indication, dosing, absorption, metabolism, needle gauge, needle size, injection volume, and cost.

Final Decision

CMS plans to continue to consider this code request for FENSOLVI during a subsequent coding cycle. CMS is reviewing the public comments to the calendar year 2021 physician fee schedule (PFS) final rule pertaining to proposed policy regarding drugs approved through section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

Request # 20.126

Topic/Issue

Request to establish new Level II HCPCS code to identify BioNextMatrix.

Applicant's suggested language: BioNextMatrix, per 0.1.cc

Applicant's Summary

BioNextMatrix is a three-dimensional scaffold of soluble ECM that supports cellular activity and that provides cushioning and physical support to tissue when used in patients with acute, chronic or non-healing wounds, burns, or surgical wounds. It is intended for homologous use only.

Final Decision

After review of FDA's guidance, it does not appear to CMS that BioNextMatrix is suitable for registration as an HCT/P. CMS refers the applicant to the FDA's Tissue Reference Group or the Office of Combination Products to obtain written feedback regarding how the product is appropriately regulated. After obtaining the FDA's written feedback, the applicant is welcome to submit a complete HCPCS code application in a subsequent coding cycle.

Information for submitting questions to the TRG is located at:

https://www.fda.gov/vaccines-blood-biologics/tissue-tissue-products/tissue-reference-group

Request # 20.127

Topic/Issue

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

Applicant's suggested language: PlacenTX placental tissue allograft, per 0.1 cc

Applicant's Summary

PlacenTX provides a scaffold of soluble proteins that provides physical support and cushioning to tissue, while serving as a conduit that connects and supports cells and cellular activity. It is intended for homologous use only. PlacenTX provides a three-dimensional structure that supports healing when used in a variety of wounds, burns and tissue defects, such as in patients with acute, chronic or non-healing wounds, burns, or surgical wounds and in patients with soft tissue injuries or inflammatory conditions.

Final Decision

After review of FDA's guidance, it does not appear to CMS that PlacenTX is suitable for registration as an HCT/P. CMS refers the applicant to the FDA's Tissue Reference Group or the Office of Combination Products to obtain written feedback regarding how the product is appropriately regulated. After obtaining the FDA's written feedback, the applicant is welcome to submit a complete HCPCS code application in a subsequent coding cycle.

Information for submitting questions to the TRG is located at:

https://www.fda.gov/vaccines-blood-biologics/tissue-tissue-products/tissue-reference-group

Request # 20.128

Topic/Issue

Request to establish a new Level II HCPCS code to identify the novel SCENESSE (Afamelanotide) orphan medication.

Applicant's suggested language: JXXXX- Subcutaneous and intradermal Injection, Afamelanotide, 16 mg

Applicant's Summary

CLINUVEL, INC. requests to establish a new Level II HCPCS code to specifically designate and describe SCENESSE (Afamelanotide). SCENESSE (Afamelanotide) implant is a hormonal therapy with a controlled release for subcutaneous/intradermal administration. The SCENESSE® implant is a solid white to off-white, bioresorbable and sterile rod approximately 1.7 cm in length and 1.45 mm in diameter. Afamelanotide is a melanocortin receptor agonist and binds selectively to melanocortin 1 receptor (MC1-R). This leads to increased production of eumelanin in the skin providing protection from exposure to sunlight or artificial light sources, which provokes phototoxicity in patients with EPP. SCENESSE (Afamelanotide) is a first-in-class drug that is not therapeutically equivalent to any other product and hence no current, specific, permanent code adequately describes it. SCENESSE (Afamelanotide) is a melanocortin 1 receptor (MC1-R) agonist indicated to increase pain free light exposure in adult patients with a history of phototoxic reactions from erythropoietic protoporphyria (EPP). Afamelanotide is thought to mimic the endogenous alpha-melanocyte stimulating hormone's pharmacological activity by activating the synthesis of eumelanin mediated by the MC1R receptor.

The dosage is one SCENESSE (Afamelanotide) implant (containing 16 mg of afamelanotide) every 60 days. The route of administration for the SCENESSE® (Afamelanotide) is subcutaneous/intradermal. The SCENESSE® (Afamelanotide) implant is packaged in a Type I amber glass vial sealed with a PTFE coated rubber stopper. Each vial contains one implant and packaged individually in a cardboard box.

Final Decision

Establish new Level II HCPCS code J7352 "Afamelanotide implant, 1 mg"

CMS has a long-standing convention to assign dose descriptors in the smallest amount that could be billed in multiple units to accommodate a variety of doses, making coding more robust, facilitate accurate payment and reporting of exact dose administered.

Effective: 01/01/2021

Request # 20.129

Topic/Issue

Request to establish a new Level II HCPCS code to identify HCPCS code to identify NYVEPRIA

Applicant's suggested language: QXXXX: Injection, pegfilgrastim-apgf, biosimilar, (nyvepria), 0.5 mg

Applicant's Summary

NYVEPRIA is a covalent conjugate of recombinant methionyl human G-CSF and monomethoxypolyethylene glycol. Recombinant methionyl human G-CSF is a water-soluble 175 amino acid protein. Recombinant methionyl human G-CSF is obtained from the bacterial fermentation of a strain of E. coli transformed with a genetically engineered plasmid containing the human G-CSF gene.

NYVEPRIA is a biosimilar to the US-licensed pegfilgrastim reference product NEULASTA (Amgen Inc.). NYVEPRIA requires a new HCPCS code to apply the specified biosimilar payment amount.

NYVEPRIA is a single-source pegfilgrastim biosimilar, and should receive a unique code. Approved biosimilar biological products with a common reference product are not grouped into the same HCPCS code, and should be assigned separate HCPCS codes.

NYVEPRIA 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.

NYVEPRIA (pegfilgrastim-apgf) for subcutaneous injection is a clear, colorless solution supplied in a prefilled single-dose syringe for manual use containing 6 mg pegfilgrastim-apgf, supplied with a 27-gauge 1/2-inch needle and a BD UltraSafe Plus Passive Needle Guard.

Final Decision

Establish new Level II HCPCS code Q5122 "Injection, pegfilgrastim-apgf, biosimilar, (nyvepria), 0.5 mg"

Effective: 01/01/2021

Request # 20.130

Topic/Issue

Request to establish a new Level II HCPCS code to identify ZEPZELCA (lurbinectedin) injection, for intravenous use.

Applicants suggested language: Injection, lurbinectedin, 1 mg

Applicant's Summary

EPZELCA (lurbinectedin) is an alkylating drug indicated for the treatment of adult patients with metastatic small cell lung cancer (SCLC) with disease progression on or after platinum-based chemotherapy. ZEPZELCA was approved by the FDA on June 15, 2020, under Accelerated Approval based on overall response rate and duration of response. Previously, ZEPZELCA was granted Orphan Drug Designation.

ZEPZELCA is supplied as a sterile, preservative-free, white to off-white lyophilized powder in a 4 mg single-dose clear glass vial. The recommended dose is 3.2 mg/m2 by intravenous infusion over 60 minutes repeated every 3 weeks until disease progression or unacceptable toxicity. A dose may be reduced to 2.6 mg/m2 or 2.0 mg/m2 should certain adverse events occur.

The majority of SCLC treated patients show disease relapse and are eligible for second-line therapy. However, few options exist after failure of first-line therapy. There is no currently available Level II HCPCS code that describes lurbinectedin. Without a unique HCPCS code identifying ZEPZELCA, use of a miscellaneous or unclassified HCPCS code is required. Additionally, use of a miscellaneous or unclassified HCPCS code requires manual claims submission and/or manual claims review resulting in increased workload for both providers and payers.

Final Decision

Establish new Level II HCPCS code J9223 "Injection, lurbinectedin, 0.1 mg"

CMS has a long-standing convention to assign dose descriptors in the smallest amount that could be billed in multiple units to accommodate a variety of doses, making coding more robust, facilitate accurate payment and reporting of exact dose administered.

Effective: 01/01/2021

Request # 20.131

Topic/Issue

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

Applicant's Summary

Bracco Diagnostics is requesting a new Level II HCPCS Code**:** Barium Sulfate 40% w/v for use in Computed Tomography Colonography (CTC). The applicant comments that barium sulfate is not part of the practice expense as per CMS file CMS-1715-F_PUF_Supply.

Trade name: TAGITOL V (BARIUM SULFATE) ORAL SUSPENSION, 40% w/v. There is no existing code for any FDA-approved barium-based x-ray contrast media products.

TAGITOL V is a low-volume, stool-tagging contrast agent used to opacify residual stool in the colon for CTC imaging for adults. It blends into the stool as it forms, resulting in immediate visible identification of retained feces. TAGITOL V should be taken one dose (20 mL) per meal at breakfast, lunch and dinner the day before the exam to create the contrast needed for an effective scan. Each patient pack includes 3 x 20 mL bottles. TAGITOL V is the only FDA approved barium sulfate product on the market that is indicated for use in CTC as a fecal tagging agent.

Final Decision

This item is factored into the practice expense. CMS previously referred the applicant to the American Medical Association (AMA). We did not see any information in the repeat code application submitted to CMS regarding an AMA response. CMS again refers the applicant to the AMA for guidance regarding consideration of oral barium suspension by the American Medical Association/Specialty Society Relative Value Scale Update Committee (RUC).

To the extent the applicant has concerns regarding the accuracy of prices used in the physician fee schedule, the applicant is welcome to submit pricing information to CMS at MedicarePhysicianFeeSchedule@cms.hhs.gov for consideration in future rulemaking.

In addition, the applicant cited information in chapters 1 and 17 of the Medicare Claims Processing manual as support for establishment of a separate Level II HCPCS code when reporting certain hospital claims or cost reporting information. Our decision that supplies are included in the procedure is consistent with the manual provisions that addresses how to report drug products with and without product-specific HCPCS codes.

Request # 20.132

Topic/Issue

Request to establish a new Level II HCPCS code to identify VARIBAR HONEY (BARIUM SULFATE) ORAL SUSPENSION, 40% w/v.

Applicant's Summary

VARIBAR THIN HONEY is a radiopaque contrast agent administered orally to evaluate swallowing during a Modified Barium Swallow Study (MBSS). It is used sequentially with other VARIBAR products of increasing viscosities that simulate various liquids and foods. The VARIBAR THIN HONEY is designed to represent liquids that flow slower than the lower viscosity liquids and is typically used as an intervention strategy for patients who aspirate the other viscosity levels due to impaired swallowing function. It has also been used in the pediatric population to represent a stage I or stage II baby food.

The radiopaque property of VARIBAR® THIN HONEY allows for visualization of the swallowing process during fluoroscopy. Dosage and administration: For oral use only – administered by infant bottle, syringe or spoon. The recommended dose: Adults: 5 mL, Pediatric patients 1 to 3 ml. During a single MBSS, multiple doses may be administered with maximum cumulative dose: 30 mL Available in 250 mL bottle

Final Decision

This item is factored into the practice expense. CMS previously referred the applicant to the American Medical Association (AMA). We did not see any information in the repeat code application submitted to CMS regarding an AMA response. CMS again refers the applicant to the AMA for guidance regarding consideration of oral barium suspension by the American Medical Association/Specialty Society Relative Value Scale Update Committee (RUC).

To the extent the applicant has concerns regarding the accuracy of prices used in the physician fee schedule, the applicant is welcome to submit pricing information to CMS at MedicarePhysicianFeeSchedule@cms.hhs.gov for consideration in future rulemaking.

In addition, the applicant cited information in chapters 1 and 17 of the Medicare Claims Processing manual as support for establishment of a separate Level II HCPCS code when reporting certain hospital claims or cost reporting information. Our decision that supplies are included in the procedure is consistent with the manual provisions that addresses how to report drug products with and without product-specific HCPCS codes.

Request # 20.133

Topic/Issue

Request to establish a new Level II HCPCS code to identify VARIBAR NECTAR (BARIUM SULFATE) ORAL SUSPENSION, 40% w/v.

Applicant's Summary

VARIBAR NECTAR is a radiopaque contrast agent administered orally to evaluate swallowing during a Modified Barium Swallow Study (MBSS). It is used sequentially with other VARIBAR products of increasing viscosities that simulate various liquids and foods. The VARIBAR NECTAR is designed to represent liquids that flow slightly slower than everyday thin liquids and is typically used as an intervention strategy for patients who aspirate thin liquids due to impaired swallowing function. It also may represent naturally viscous beverages, such as tomato juice. The radiopaque property of VARIBAR NECTAR allows for visualization of the swallowing process during fluoroscopy. Dosage and administration: For oral use only – administered by infant bottle, syringe or spoon. The recommended dose: Adults: 5 mL, Pediatric patients 6 months and older: 1 to 3 ml. Pediatric patients younger than 6 months: 0.5 to 1mL. During a single MBSS, multiple doses may be administered with Maximum cumulative dose: 30 mL Available in 240 mL bottle

Final Decision

This item is factored into the practice expense. CMS previously referred the applicant to the American Medical Association (AMA). We did not see any information in the repeat code application submitted to CMS regarding an AMA response. CMS again refers the applicant to the AMA for guidance regarding consideration of oral barium suspension by the American Medical Association/Specialty Society Relative Value Scale Update Committee (RUC).

To the extent the applicant has concerns regarding the accuracy of prices used in the physician fee schedule, the applicant is welcome to submit pricing information to CMS at MedicarePhysicianFeeSchedule@cms.hhs.gov for consideration in future rulemaking.

In addition, the applicant cited information in chapters 1 and 17 of the Medicare Claims Processing manual as support for establishment of a separate Level II HCPCS code when reporting certain hospital claims or cost reporting information. Our decision that supplies are included in the procedure is consistent with the manual provisions that addresses how to report drug products with and without product-specific HCPCS codes.

Request # 20.134

Topic/Issue

Request to establish a new Level II HCPCS code to identify Barium Sulfate oral paste (40% w/v) with a viscosity of 5000 cPs for Modified Barium Swallow Studies (MBSS). Trade name: VARIBAR PUDDING (BARIUM SULFATE) ORAL PASTE.

Applicant's Summary

VARIBAR PUDDING is a radiopaque contrast agent administered orally to evaluate swallowing during MBSS. It is used sequentially with other VARIBAR products of various viscosities and textures that simulate various liquids and foods. The radiopaque property of VARIBAR PUDDING allows for visualization of the swallowing process during fluoroscopy. Dosage and administration: For oral use only – administered by syringe or spoon. The recommended dose: Adults: 5mL, Pediatric patients: 1 to 3 mL. During a single MBSS, multiple doses may be administered with maximum cumulative dose: 30 mL. Available in 230 mL tube

Final Decision

This item is factored into the practice expense. CMS previously referred the applicant to the American Medical Association (AMA). We did not see any information in the repeat code application submitted to CMS regarding an AMA response. CMS again refers the applicant to the AMA for guidance regarding consideration of oral barium suspension by the American Medical Association/Specialty Society Relative Value Scale Update Committee (RUC).

To the extent the applicant has concerns regarding the accuracy of prices used in the physician fee schedule, the applicant is welcome to submit pricing information to CMS at MedicarePhysicianFeeSchedule@cms.hhs.gov for consideration in future rulemaking.

In addition, the applicant cited information in chapters 1 and 17 of the Medicare Claims Processing manual as support for establishment of a separate Level II HCPCS code when reporting certain hospital claims or cost reporting information. Our decision that supplies are included in the procedure is consistent with the manual provisions that addresses how to report drug products with and without product-specific HCPCS codes.

Request # 20.135

Topic/Issue

Request to establish a new Level II HCPCS code to identify VARIBAR THIN HONEY (BARIUM SULFATE) ORAL SUSPENSION, 40% w/v.

Applicant's Summary

VARIBAR THIN HONEY is a radiopaque contrast agent administered orally to evaluate swallowing during a Modified Barium Swallow Study (MBSS). It is used sequentially with other VARIBAR products of increasing viscosities that simulate various liquids and foods. The VARIBAR THIN HONEY is designed to represent liquids that flow slower than every-day thin liquids and nectar-like liquids and is typically used as an intervention strategy for patients who aspirate the first two viscosity levels (thin and nectar) due to impaired swallowing function. The radiopaque property of VARIBAR THIN HONEY allows for visualization of the swallowing process during fluoroscopy. Dosage and administration: For oral use only – administered by infant bottle, syringe or spoon. The recommended dose: Adults: 5 mL, Pediatric patients 1 to 3 mL. During a single Modified Barium Swallow Study, multiple doses may be administered with maximum cumulative dose: 30 mL Available in 250 mL bottle.

Final Decision

This item is factored into the practice expense. CMS previously referred the applicant to the American Medical Association (AMA). We did not see any information in the repeat code application submitted to CMS regarding an AMA response. CMS again refers the applicant to the AMA for guidance regarding consideration of oral barium suspension by the American Medical Association/Specialty Society Relative Value Scale Update Committee (RUC).

To the extent the applicant has concerns regarding the accuracy of prices used in the physician fee schedule, the applicant is welcome to submit pricing information to CMS at MedicarePhysicianFeeSchedule@cms.hhs.gov for consideration in future rulemaking.

In addition, the applicant cited information in chapters 1 and 17 of the Medicare Claims Processing manual as support for establishment of a separate Level II HCPCS code when reporting certain hospital claims or cost reporting information. Our decision that supplies are included in the procedure is consistent with the manual provisions that addresses how to report drug products with and without product-specific HCPCS codes.

Request # 20.136

Topic/Issue

Request to establish a new Level II HCPCS code to identify VARIBAR THIN LIQUID (BARIUM SULFATE) FOR ORAL SUSPENSION, 81% w/w.

Applicant's Summary

VARIBAR THIN LIQUID is a radiopaque contrast agent administered to evaluate swallowing during a Modified Barium Swallow Study (MBSS). It is used sequentially with other VARIBAR products of various viscosities and textures that simulate various liquids and foods. The thin liquid is specifically designed to represent every-day beverages that are thin, such as water, coffee, soft drinks, etc. The radiopaque property of VARIBAR THIN LIQUID allows for visualization of the swallowing process during fluoroscopy. Dosage and administration: For oral use only – administered by infant bottle, syringe or spoon. The recommended dose: Adults: 5mL, Pediatric patients 6 months and older: 1 to 3 mL. Pediatric patients younger than 6 months: 0.5 to 1 mL. During a single MBSS, multiple doses may be administered with Maximum cumulative dose: 80 mL. Available in 148 g bottle (powder to be reconstituted with water).

Final Decision

This item is factored into the practice expense. CMS previously referred the applicant to the American Medical Association (AMA). We did not see any information in the repeat code application submitted to CMS regarding an AMA response. CMS again refers the applicant to the AMA for guidance regarding consideration of oral barium suspension by the American Medical Association/Specialty Society Relative Value Scale Update Committee (RUC).

To the extent the applicant has concerns regarding the accuracy of prices used in the physician fee schedule, the applicant is welcome to submit pricing information to CMS at MedicarePhysicianFeeSchedule@cms.hhs.gov for consideration in future rulemaking.

In addition, the applicant cited information in chapters 1 and 17 of the Medicare Claims Processing manual as support for establishment of a separate Level II HCPCS code when reporting certain hospital claims or cost reporting information. Our decision that supplies are included in the procedure is consistent with the manual provisions that addresses how to report drug products with and without product-specific HCPCS codes.

Request # 20.137

Topic/Issue

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

Applicant's suggested language: Q4XXX, Vendaje, per square centimeter

Applicant's Summary

VENDAJE is dehydrated human amniotic membrane composed of amnion and Wharton's jelly. This single layered product, which lacks immunogenicity, preserves the scaffold of extracellular matrix proteins, active growth factors and cytokines. Utilizing these crucial restorative components on superficial dermal wounds promotes non-fibrotic tissue repair, allows tissue regeneration, and infection control at a faster healing rate. No existing code adequately describes VENDAJE. VENDAJE is indicated for augmenting and repairing the integumentary system concerning chronic and acute ulcers related to disease processes, superficial burns, surgical incisions, and traumatic lacerations. The product acts on the patient by creating a moist microenvironment which protects wounds and exposed nerve endings from pathogens and irritants. The amniotic membrane provides a vapor barrier preventing unwanted water loss from excessive evaporation at the wound thus reducing pain and inflammation. Our product's protective structure and reparative components are effective for regenerating various dermal wounds with minimal scarring. The route of administration is topical by applying the membrane over the wound or within the surgical site. It is affixed by hydrostatic tension with or without sutures. VENDAJE is aseptically packaged and sealed in an im1er poly/foil peel pouch.

Final Decision

After review of FDA's guidance, it does not appear to CMS that VENDAJE, is suitable for registration as an HCT/P. CMS refers the applicant to the FDA's Tissue Reference Group or the Office of Combination Products to obtain written feedback regarding how the product is appropriately regulated. After obtaining the FDA's written feedback, the applicant is welcome to submit a complete HCPCS code application in a subsequent coding cycle.

Information for submitting questions to the TRG is located at:

https://www.fda.gov/vaccines-blood-biologics/tissue-tissue-products/tissue-reference-group

Request # 20.138

Topic/Issue

Request to establish a new Level II HCPCS code to identify VENDAJE Optic

Applicant's suggested language: Q4XXX, Vendaje Optic, per millimeter

Applicant's Summary

VENDAJE Optic is dehydrated amniotic membrane composed of amnion and Wharton's jelly. The product is functioned to treat ophthalmic conditions pertaining to corneal and conjunctival surface reconstruction through the preservation of extracellular matrix components, growth factors, and cytokines which are present in amniotic membrane. These crucial healing roles synthesizes tissue repair, augmentation, and regeneration at a faster healing rate. No existing code adequately describes VENDAJE Optic. VENDAJE Optic is indicated as a scaffold for repairing and reconstructing the structural quality and surface of the ocular system such as minimizing abnormal epithelium development, reduce scarring and inflammation, treat non-healing corneal ulcers, perforations, and conjunctival reconstruction. The product is utilized in conjunction with corrective ophthalmic surgeries for regenerating epithelium. VENDAJE Optic acts on the patient as a non-immunogenic graft, promotes non-fibrotic healing and creates an ideal microenvironment similar to that of the host tissue as they provide permeable anti-microbial barriers thus, protecting the eye from pathogens and irritants. The product provides a vapor barrier preventing moisture loss thus reducing pain and inflammation caused by friction of the eyelids. VENDAJE Optic is available in sizes of 8mm, 10mm, and 12mm discs, and dosage is based on the size of the wound. The route of administration is topical without specification to orientation. The product is applied on the ocular surface and is affixed through hydrostatic tension. VENDAJE Optic is aseptically packaged and sealed in an inner poly/foil peel pouch.

Final Decision

After review of FDA's guidance, it does not appear to CMS that VENDAJE Optic, is suitable for registration as an HCT/P. CMS refers the applicant to the FDA's Tissue Reference Group or the Office of Combination Products to obtain written feedback regarding how the product is appropriately regulated. After obtaining the FDA's written feedback, the applicant is welcome to submit a complete HCPCS code application in a subsequent coding cycle.

Information for submitting questions to the TRG is located at:

https://www.fda.gov/vaccines-blood-biologics/tissue-tissue-products/tissue-reference-group

Request # 20.139

Topic/Issue

Request to establish a new Level II HCPCS code to identify VENDAJE AC

Applicant's suggested language: Q4XXX, Vendaje AC, per square centimeter

Applicant's Summary

VENDAJE AC is a dehydrated human amnion and chorion membrane allograft. The product utilizes the preserved extracellular matrix components, growth factors, and cytokines present in amniotic membrane and synthesizes these crucial healing roles for tissue repair and regeneration. No existing HCPCS code adequately describes VENDAJE AC. VENDAJE AC is indicated as a scaffold for repairing and reconstructing the integumentary system concerning chronic and acute dermal wounds from 1st to 3rd degree burns, pressure ulcers, abrasions and lacerations. The product acts on the patient by creating a moist environment which protects wounds from pathogens and irritants. The dual layer membrane provides a vapor barrier preventing fluid loss from excessive evaporation at the wound thus reducing pain and inflammation. The protective structure and reparative components are effective for regenerating various dermal wounds with minimal scarring. The route of administration is topically applying membrane over the wound. It is affixed by hydrostatic tension. VENDAJE AC is aseptically packaged and sealed in an inner poly/foil peel pouch. An irradiation indicator is fixed on the inner package and then sealed with an outer poly/foil peel pouch. The packaged allograft is terminally sterilized by electric beam, labeled, and sealed in a dust cover containing an IFU (Instruction for Use), patient labels and a tissue tracking card.

Final Decision

After review of FDA's guidance, it does not appear to CMS that VENDAJE AC, is suitable for registration as an HCT/P. CMS refers the applicant to the FDA's Tissue Reference Group or the Office of Combination Products to obtain written feedback regarding how the product is appropriately regulated. After obtaining the FDA's written feedback, the applicant is welcome to submit a complete HCPCS code application in a subsequent coding cycle.

Information for submitting questions to the TRG is located at:

https://www.fda.gov/vaccines-blood-biologics/tissue-tissue-products/tissue-reference-group

Request # 20.140

Topic/Issue

Request to establish a new Level II HCPCS code to identify Maxx Ultra Cord.

Applicant's suggested language: Maxx Ultra Cord, per square centimeter.

Applicant's Summary

Maxx Ultra Cord is a semi transparent, collagenous membrane allograft. It is derived from the umbilical cord. The product serves as a wound cover or a soft tissue barrier. Maxx Ultra Cord is typically used for chronic non-healing wounds such as diabetic foot ulcers and venous leg ulcers. It is applied directly to the wound. There are various sizes, the provider uses the size that most closely matches the wound, applies to graft directly to the wound bed, and then covers with a bandage. Maxx Ultra Cord comes in a sterile pouch.

Final Decision

After review of FDA's guidance, it does not appear to CMS that Maxx Ultra Cord is suitable for registration as an HCT/P. CMS refers the applicant to the FDA's Tissue Reference Group or the Office of Combination Products to obtain written feedback regarding how the product is appropriately regulated. After obtaining the FDA's written feedback, the applicant is welcome to submit a complete HCPCS code application in a subsequent coding cycle.

Information for submitting questions to the TRG is located at:

https://www.fda.gov/vaccines-blood-biologics/tissue-tissue-products/tissue-reference-group

Request # 20.141

Topic/Issue

Request to establish a new Level II HCPCS code to identify ExEm Foam

Applicant's Summary

A new HCPCS Level II Q-Code is requested for ExEm Foam (air polymer-type A) intrauterine foam, a drug product indicated for use as a contrast agent for Sonohysterosalpingography, a transvaginal ultrasound imaging procedure that can be used to assess fallopian tube patency (openness). Assessment of fallopian tube patency is a fundamental test in a fertility work-up; occluded (non-patent) tubes could prevent sperm from reaching the ova. ExEm Foam is a new molecular entity with no equivalent drug products on the market and is the only currently marketed drug product approved for its indication for use. There are no existing HCPCS Level I or II Codes that adequately describe ExEm Foam. There are HCPCS Level I CPT Codes that are used to bill for Hysterosalpingography procedures (CPT Codes 74740 and 58340), but those codes do not include any practice expense supplies for contrast material used when performing the imaging procedure. Accordingly, a new Q-Code for Air polymer-type A intrauterine foam, for use in imaging, per dose, is needed. Sonohysterosalpingography is a transvaginal ultrasound imaging procedure that can be used to assess fallopian tube patency in women with known or suspected infertility. Transvaginal ultrasound imaging with ExEm Foam is performed in outpatient hospital, physician's office, infertility clinic, and imaging center settings. ExEm Foam is administered through the uterine cavity into the fallopian tubes via an intrauterine infusion process using a 5-Fr or larger gynecological catheter prior to the performance of Sonohysterosalpingography. The recommended initial dose of ExEm Foam is 2 to 3 mL, with repeated doses in increments of 2 to 3 mL (up to a total of 10 mL) to achieve visualization of the fallopian tubes. ExEm Foam is packaged in a single dose kit, including prefilled syringes of gel (ExEm Gel) and diluent (ExEm Water), and one Combifix Adapter (coupling device).

Final Decision

CMS carefully reconsidered this repeat application. This type of product would typically be included in the practice expense for a procedure and not separately coded.

The company has identified two CPT codes as relevant: CPT code 58340 "Catheterization and introduction of saline or contrast material for saline infusion sonohysterography (SIS) or hysterosalpingography (HSG)" and CPT code 74740 "Hysterosalpingography, radiological supervision and interpretation", but indicated that these two CPT codes do not include ExEm foam in the practice expense as a rationale for CMS to develop a separate code. CMS does not believe that these two codes specifically identify the fallopian tube ultrasound procedure for which ExEm foam is used. We believe the appropriate starting point for correct coding is for the applicant to approach the AMA for coding guidance.

Request # 20.143

Topic/Issue

Request to establish a new Level II HCPCS code to identify pertuzumab, trastuzumab, and hyaluronidase-zzxf, brand name, PHESGO.

Applicant's suggested language: Subcutaneous Injection, pertuzumab, trastuzumab, and hyaluronidase, 10 mg

Applicant's Summary

PHESGO is a combination of pertuzumab and trastuzumab, HER2/neu receptor antagonists, and hyaluronidase, an endoglycosidase. PHESGO is indicated for the treatment of: 1) Early Breast Cancer (EBC) a) in combination with chemotherapy for the neoadjuvant treatment of adult patients with HER2- positive, locally advanced, inflammatory, or early stage breast cancer (either greater than 2 cm in diameter or node positive) as part of a complete treatment regimen for early breast cancer; b) in combination with chemotherapy for the adjuvant treatment of adult patients with HER2- positive early breast cancer at high risk of recurrence. 2) Metastatic Breast Cancer (MBC) in combination with docetaxel for the treatment of adult patients with HER2-positive metastatic breast cancer who have not received prior anti-HER2 therapy or chemotherapy for metastatic disease. PHESGO is administered by a healthcare professional as a subcutaneous injection and is supplied as 1,200 mg pertuzumab, 600 mg trastuzumab, and 30,000 units hyaluronidase per 15 mL in a single-dose vial (recommended initial dose) and as 600 mg pertuzumab, 600 mg trastuzumab and 20,000 units hyaluronidase per 10 mL in a single-dose vial (recommended maintenance dose). Subcutaneous administration of PHESGO takes approximately eight minutes for the initial loading dose and approximately five minutes for each subsequent maintenance dose, which is recommended for every three weeks.

Final Decision

Establish new Level II HCPCS code J9316 "Injection, pertuzumab, trastuzumab, and hyaluronidase-zzxf, per 10 mg"

Effective: 01/01/2021

Request # 20.144

Topic/Issue

Request to establish a new Level II HCPCS code to identify REViV

Applicant's Summary

REViV is an amniotic fluid that is a minimally manipulated human tissue allograft suspension product that serves to provide a barrier/support function to aid in the healing of a defect. The fluid is intended to provide the extracellular matric needed for the infiltration, attachment and proliferation of cells required for the repair of damaged tissue. Amniotic membrane tissue-based products have been shown to reduce scarring, fibrosis, and adhesions in surgical and wound sites. It is administered through a syringe directly to the defect and the amount is determined by the licensed clinician based on the size and severity of the defect. Each human tissue product distributed by New Life Medical Services is identified by a computer generated unique serial number bar code that contains the donor number, release date and expiration date of each vial allowing traceability from donor to recipient back to donor. The product containing vial is then packaged in a transportable protective pouch which also includes the product label. Included in the pouch are instructions for use, storage requirements, quality assurance check list and packing slip. All products are shipped in a cryogenic container that has been validated to maintain the appropriate temperature for seventy-two or ninety-six hours (depending on number of deposits being sent). Products are aseptically processed. Current available HCPC codes for amniotic products are brand specific and at the present there is no code that identifies REViV.

Final Decision

After review of FDA's guidance, it does not appear to CMS that REViV is suitable for registration as an HCT/P. CMS refers the applicant to the FDA's Tissue Reference Group or the Office of Combination Products to obtain written feedback regarding how the product is appropriately regulated. After obtaining the FDA's written feedback, the applicant is welcome to submit a complete HCPCS code application in a subsequent coding cycle.

Information for submitting questions to the TRG is located at:

https://www.fda.gov/vaccines-blood-biologics/tissue-tissue-products/tissue-reference-group

Request # 20.145

Topic/Issue

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

Applicant's Summary

RENyTE obtained from the Wharton's Jelly of the umbilical cord and is regulated by the FDA as a human cell tissue product subject to Section 361 of the Public Service Act and 21 CFR 1271. RENyTE serves to provide aid in the healing of chronic wounds and soft tissue defect. The product is intended to provide the extracellular matric needed for the infiltration, attachment and proliferation of cells required for the repair of damaged tissue. Wharton's Jelly has been shown to reduce scarring, fibrosis, and adhesions in surgical and wound sites. It is administered through a syringe directly to the defect and the amount is determined by the licensed clinician based on the size and severity of the defect. Each human tissue product distributed by New Life Medical Services is identified by a computer generated unique serial number bar code that contains the donor number, release date and expiration date of each vial allowing traceability from donor to recipient back to donor. The product containing vial is then packaged in a transportable protective pouch which also includes the product label. Included in the pouch are instructions for use, storage requirements, quality assurance check list and packing slip. All products are shipped in a cryogenic container that has been validated to maintain the appropriate temperature for seventy-two or ninety-six hours (depending on number of deposits being sent). Products are aseptically processed in a cGMP facility. Sterility testing of the final product is performed by a third-party licensed facility. Current available HCPC codes for these products are brand specific and at the present there is no code that identifies RENyTE.

Final Decision

After review of FDA's guidance, it does not appear to CMS that RENyTE is suitable for registration as an HCT/P. CMS refers the applicant to the FDA's Tissue Reference Group or the Office of Combination Products to obtain written feedback regarding how the product is appropriately regulated. After obtaining the FDA's written feedback, the applicant is welcome to submit a complete HCPCS code application in a subsequent coding cycle.

Information for submitting questions to the TRG is located at:

https://www.fda.gov/vaccines-blood-biologics/tissue-tissue-products/tissue-reference-group

Request # 20.146

Topic/Issue

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

Applicants suggested language: J9XXX, Injection, Romidepsin non-lyophilized (e.g. liquid), per 1MG. Recommended short descriptor: Romidepsin Injection, liquid.

Applicant's Summary

Romidepsin Injection, liquid is a histone deacetylase (HDAC) inhibitor drug. Romidepsin Injection, liquid is a drug used in the treatment of certain types of lymphoma cancer. A new HCPCS code for Romidepsin Injection, non-lyophilized liquid is needed because it is a single source drug approved under a unique NDC number, and it needs to be differentiated from the existing HCPCS code for a multi-sourced romidepsin drug in lyophilized powder form. Romidepsin Injection, liquid is indicated for treatment of cutaneous T-cell lymphoma (CTCL) in adult patients who have received at least one prior systemic therapy; and treatment of peripheral T-cell lymphoma (PTCL) in adult patients who have received at least one prior therapy. The mechanism of the antineoplastic effect of romidepsin has not been fully characterized. The recommended dosage of romidepsin is 14 mg/m2 administered intravenously over a 4-hour period on days 1, 8, and 15 of a 28-day cycle. Cycles should be repeated every 28 days provided that the patient continues to benefit from and tolerates the drug. Romidepsin Injection, liquid is administered intravenously. Romidepsin Injection, liquid is supplied in single-dose vials.

Final Decision

CMS plans to continue to consider this code request for Romidepsin during a subsequent coding cycle pending the outcome of the PFS final rule pertaining to policy regarding drugs approved through section 505(b)(2) of the FD&C Act.

Request # 20.147

Topic/Issue

Request to establish a new Level II HCPCS code to identify Nitro Al Flowable Amnion.

Applicant's suggested language: Q41XX- Nitro Al Flowable Amnion, per 0.5 cc.

Applicant's Summary

Nitro Al Flowable Amnion is a minimally manipulated amniotic membrane allograft regulated under Section 361 of the Public Health Service Act. Nitro Al Flowable Amnion is amniotic membrane suspended in a saline solution, intended for homologous use only. Its inherent structural makeup allows it to act also as a cushion in dynamic environments. Its flowable format is specifically designed for treatment of deep dermal wounds, irregularly shaped, crevassing and tunneling wounds, augmentation of deficient/inadequate soft tissue, and other complex wound cases where a patch form of amniotic membrane may not provide complete wound coverage. Existing codes do not adequately describe Nitro Al Flowable Amnion because they are all brand specific. A new code is warranted for Nitro Al Flowable Amnion so that it may be readily identifiable for third party claims processing and tracking.

Final Decision

After review of FDA's guidance, it does not appear to CMS that Nitro Al Flowable Amnion is suitable for registration as an HCT/P. CMS refers the applicant to the FDA's Tissue Reference Group or the Office of Combination Products to obtain written feedback regarding how the product is appropriately regulated. After obtaining the FDA's written feedback, the applicant is welcome to submit a complete HCPCS code application in a subsequent coding cycle.

Information for submitting questions to the TRG is located at:

https://www.fda.gov/vaccines-blood-biologics/tissue-tissue-products/tissue-reference-group

Request # 20.148

Topic/Issue

Request to establish new Level II HCPCS code to identify AlloMend Acellular Dermal Matrix (ADM).

Applicant's suggested language Q41XX AlloMend per cm2 [acellular dermal matrix allograft, irradiated]

Applicant's Summary

AlloMend Acellular Dermal Matrix (ADM) is biological cadaveric dermis which is decellularized and further processed, extensively tested, cleansed, and irradiated to provide an acellular tissue allograft. AlloMend allograft is a natural skin replacement that can be used as a scaffold for regeneration of tissue to achieve wound closure of partial or full-thickness wounds due to tissue loss from burns, trauma and chronic wounds, such as venous and arterial ulcers, diabetic foot ulcers and pressure ulcers. It can be stored at room temperature to meet the wound coverage needs of many out-patient wound care centers and doctor offices that do not have a cryo freezer. When used in wound care applications, AlloMend tissue allograft is surgically applied and secured to the skin by the anchoring method chosen by the surgeon (sutures, staples, adhesive glue, etc.) Clinical application will vary by the type of wound or defect requiring the allograft. Most wounds respond with one application. However, the graft can be reapplied if needed. AlloMend can also be applied surgically for soft tissue repair and reconstruction. In these applications, AlloMend may be used for the repair or replacement of damaged or inadequate integumental tissue or for other homologous uses, such as supplemental support, protection, reinforcement, or covering.

Final Decision

After review of FDA's guidance, it does not appear to CMS that AlloMend Acellular Dermal Matrix (ADM) is suitable for registration as an HCT/P. CMS refers the applicant to the FDA's Tissue Reference Group or the Office of Combination Products to obtain written feedback regarding how the product is appropriately regulated. After obtaining the FDA's written feedback, the applicant is welcome to submit a complete HCPCS code application in a subsequent coding cycle.

Information for submitting questions to the TRG is located at:

https://www.fda.gov/vaccines-blood-biologics/tissue-tissue-products/tissue-reference-group

Request # 20.183

Topic/Issue

Request to establish a new Level II HCPCS code to identify mitomycin gel.

Applicant's suggested language: JXXXX, Instillation, mitomycin gel (JELMYTO) for pyelocalyceal solution and kit, per instillation.

Applicant's Summary

UroGen Pharma seeks one new HCPCS "J" code for JELMYTO™, with recommended descriptor: JXXXX, Instillation, mitomycin gel (JELMYTO) for pyelocalyceal solution and kit, per instillation.

JELMYTO (mitomycin) for pyelocalyceal solution is the first FDA-approved therapy to treat low-grade Upper Tract Urothelial Cancer (LG-UTUC) in adults. It uses UroGen's proprietary RTGel, which converts from liquid into gel form at body temperature following instillation. Function is as an alkylating drug to treat LG-UTUC. It is designed to enable longer exposure of urinary tract tissue to mitomycin to facilitate treatment of tumors with non-surgical means. Indicated for treatment of adults with LG-UTUC.

Mitomycin inhibits synthesis of deoxyribonucleic acid (DNA). The guanine and cytosine content correlates with the degree of mitomycin-induced cross-linking. At high concentrations of the drug, cellular RNA and protein synthesis are also suppressed.

Dosage is 4 mg per mL, with total instillation volume based on measurements using pyelography, not to exceed 15 mL (60 mg mitomycin). Instillation is once weekly for six weeks. Route of administration is instillation into pyelocalyceal system via ureteral catheter or nephrostomy tube.

Final Decision

Establish new Level II HCPCS code J9281 using the same language and dose descriptor as existing code C9064 "Mitomycin pyelocalyceal instillation, 1 mg"
Existing modifier JW "Drug Amount Discarded, Not Administered to Any Patient" may be used as appropriate to report any drug wastage, for example: the 20 mg difference between the 80 mg dose supplied in the kit ((2) 40 mg vials), and the 60 mg recommended dose.

New code J9281 will be effective 1/1/2021, and existing C9064 will be discontinued 12/31/2020, to avoid billing confusion/redundancy.