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

First 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' First 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.

These HCPCS coding decisions will also be included in the July 2020 HCPCS Quarterly Update, pending publication by CMS in the coming weeks at: https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Alpha-Numeric-HCPCS

Request# 20.001

Topic/Issue:

Request to establish a new Level II HCPCS code to identify ZOLGENSMA (onasemnogene abeparvovec-xioi), a suspension for intravenous infusion, Trade Name: ZOLGENSMA

Applicant's suggested language: Onasemnogene abeparvovec-xioi for infusion, per kit

Applicant's Summary

AveXis, a Novartis company, submitted a request to establish a new Level II HCPCS code to identify Zolgensma (onasemnogene abeparvovec-xioi), an injectable drug.

ZOLGENSMA is a suspension of an adeno-associated virus vector-based gene therapy and is indicated for the treatment of pediatric patients less than 2 years of age with Spinal Muscular Atrophy (SMA) with bi-allelic mutations in the survival motor neuron (SMN) 1 gene. It is a suspension for one-time, single dose intravenous infusion supplied as single use vials customized kits containing 2 to 9 vials (a combination of 5.5 mL or 8.3 mL vials) depending on body weight. All have concentrations of 2.0×10^{13} vg/mL per vial. All kits have the same WAC price without regard to the number of vials included in each kit. The recommended dose of ZOLGENSMA is 1.1×10^{14} vg/kg of body weight.

ZOLGENSMA was approved by the FDA on May 24, 2019 under Priority Review and was granted Breakthrough Therapy Designation and Orphan Drug Designation. According to the applicant, as of June 5, 2019 there was no currently available Level II HCPCS code that described ZOLGENSMA and without a unique code use of a miscellaneous or unclassified code is required.

CMS Decision

Establish new Level II HCPCS code J3399 "Injection, Onasemnogene abeparvovec-xioi, per treatment, up to $5x10^{15}$ vector genomes."

Effective: 07/01/2020

Request# 20.002

Topic/Issue:

Request to establish a new Level II HCPCS code to identify rituximab-pvvr, Trade Name: RUXIENCE™

Applicant's suggested language: QXXXX "Injection, rituximab-pvvr, biosimilar, (RUXIENCE), 10 mg

Applicant's Summary

Pfizer Inc. submitted a request to establish a new Level II HCPCS code to identify Ruxience.

Rituximab-pvvr is a genetically engineered chimeric murine/human monoclonal IgG1 kappa antibody directed against the CD20 antigen. Rituximab-pvvr is produced by mammalian cell (Chinese Hamster Ovary) suspension culture in a nutrient medium. RUXIENCE is a biosimilar to the US-licensed rituximab reference product Rituxan@ manufactured by Genentech USA, Inc. The FDA approved RUXIENCE on July 23, 2019 for adult patients with the following indications: Non-Hodgkin's Lymphoma, Chronic Lymphocytic Leukemia, Granulomatosis with Polyangiitis (Wegener's Granulomatosis) and Microscopic Polyangiitis in adult patients in combination with glucocorticoids. RUXIENCE is administered by intravenous infusion. RUXIENCE (rituximab-pvvr) injection is a sterile, preservative-free, clear to slightly opalescent, colorless to pale brownish-yellow solution for intravenous infusion supplied as a carton containing one 100 mg/l0 mL (10 ng/ml) single-dose vial or a carton containing one 500 mg/50 mL (10 mg/ml) single dose vial.

RUXIENCE requests a new HCPCS code to apply the Affordable Care Act-specified biosimilar payment amount. As per the applicant, RUXIENCE is a single-source rituximab biosimilar and should receive a unique code. According to the applicant, approved biosimilar biological products with a common reference product are no longer grouped into the same HCPCS code but should be assigned separate HCPCS code.

CMS Decision

Establish new Level II HCPCS code Q5119 "Injection, Rituximab-pvvr, biosimilar, (Ruxience), 10 mg."

Effective: 07/01/2020

Separate instructions will be issued regarding Dates of Service for Medicare.

Request# 20.003

Topic/Issue:

Request to establish a new Level II HCPCS code to identify Imipenem, cilastatin, and relebactam, Trade Name; RECARBRIO.

Applicant's suggested language: JXXXX "Injection, imipenem 4 mg, cilastatin 4 mg, and relebactam 2 mg."

Applicant's Summary

Merck requests a HCPCS code for RECARBRIO (imipenem, cilastatin and relebactam).

RECARBRIO is a combination of imipenem, cilastatin and relebactam. Imipenem is an antibacterial, cilastatin is a renal dehydropeptidase inhibitor and relebactam is a beta-lactamase inhibitor. Cilastatin limits the renal metabolism of imipenem and does not have antibacterial activity. The bacterial activity of imipenem results from binding to PBP 2 and PBP 1B in Enterobacteriaceae and Pseudomonas aeruginosa and the subsequent inhibition of penicillin binding proteins (PBPs). Inhibition of PBPs leads to the disruption of bacterial cell wall synthesis. Imipenem is stable in the presence of some beta-lactamases. Relebactam has no intrinsic antibacterial activity but protects imipenem from degradation by certain serine beta lactamases such as Sulfhydryl Variable (SHV), Temoneira, Cefotaximase-Munich, Enterobacter cloacae P99. RECARBRIO is indicated in patients 18 years of age and older who have limited or no alternative treatment options, for the treatment of complicated urinary tract infections including pyelonephritis (cUTI) and complicated intra-abdominal infections (cIAI) caused by susceptible gram negative bacteria. The recommended dose for RECARBRIO ranges from 0.5 grams to 1.25 grams and is administered by IV infusion over 30 minutes every 6 hours. It is supplied as sterile powder for constitution in a single dose vial containing imipenem 500 mg (anhydrate equivalent), cilastatin 500 mg (free acid equivalent) and relebactam 250 mg (anhydrate equivalent).

According to the applicant, currently no HCPCS code describes RECARBRIO specifically.

CMS Decision

Establish new Level II HCPCS code J0742 "Injection, imipenem 4 mg, cilastatin 4 mg and relebactam 2 mg."

Effective: 07/01/2020

Request# 20.004

Topic/Issue:

Request to establish a new Level II HCPCS code to identify pegfilgrastim-bmez, Trade name: Ziextenzo.

Applicant's suggested language: Injection, pegfilgrastim-bmez, biosimilar, (ziextenzo), 6 mg.

Applicant's Summary

Sandoz requests a new Level II HCPCS code to describe ZIEXTENZO (pegfilgrastim-bmez).

Ziextenzo is a leukocyte growth factor indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia. Ziextenzo is a biosimilar to Amgen Inc.'s Neulasta (pegfilgrastim). 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. Ziextenzo is proposed to be administered subcutaneously via a 6 mg single-dose prefilled syringe once per chemotherapy cycle. The product is provided in a 0.6 mL prefilled syringe, which contains 6 mg of the biosimilar.

According to the applicant no existing HCPCS code specifically describes this biosimilar form of pegfilgrastim and therefore a unique J code is necessary to appropriately describe and reimburse ZIEXTENZO.

CMS Decision

Establish a new Level II HCPCS code Q5120 "Injection, pegfilgrastim-bmez, biosimilar, (ziextenzo), 0.5 mg."

Effective: 07/01/2020

CMS has consistently coded Pegfilgrastim biosimilars using 0.5 mg dose descriptor.
Separate instructions will be issued regarding Dates of Service for Medicare.

Request# 20.005

Topic/Issue:

Request to establish a new Level II HCPCS code to identify crizanlizumab-tmca. Trade name: Adakveo.

Applicant's suggested language: crizanlizumab-tmca injection, for intravenous use, 100mg/10mL.

Applicant's Summary

Novartis requests a new Level II HCPCS code for ADAKVEO (crizanlizumab-tmca) injection, for intravenous use.

Adakveo is indicated to reduce the frequency of vaso-occlusive crises (VOCs) in adults and pediatric patients aged 16 years and older with sickle cell disease. It is a selectin blocker. It is a humanized IgG2 kappa monoclonal antibody that binds to P-selectin. It is produced using recombinant DNA technology in Chinese hamster ovary cells. Adakveo was approved by the FDA on November 15, 2019 under Priority Review. Previously, Breakthrough Therapy Designation and Orphan Drug Designation were granted. The recommended dose of Adakveo is 5 mg/kg of actual body weight administered by intravenous infusion over a period of 30 minutes at Week 0, Week 2 and every 4 weeks thereafter. Adakveo may be given with or without hydroxyurea. Adakveo is supplied in a 10 mL (100 mg/10mL) single-dose vial, as a sterile, preservative free, clear to opalescent, colorless to slightly brownish yellow solution for dilution.

According to the applicant, it is critical that a unique HCPCS code is made available for ADAKVEO to minimize barriers to access for patients with sickle cell disease i.e. prolonged manual claims submission or uncertainty of correct reimbursement.

CMS Decision

Establish a new Level II HCPCS code J0791 "Injection, crizanlizumab-tmca, 5 mg." New code may be reported together with existing modifier "JA" "administered intravenously", if appropriate for additional accuracy.

CMS has a long-standing convention to assign dose descriptors in the smallest amount that could be billed in multiple units to accommodate variety of doses, making coding more robust, facilitate accurate payment and reporting of exact dose administered. CMS does not typically specify route of administration e.g., Intravenous, intramuscular, or subcutaneous when appropriate modifiers could be used.

Effective: 07/01/2020

Request# 20.006

Topic/Issue:

Request to establish a new Level II HCPCS code to identify QUZYTTIR™ (cetirizine hydrochloride injection), for intravenous use.

Applicant's recommended language, JXXXX, Cetirizine hydrochloride injection, 1 mg.

Applicant's Summary

TeraSera Therapeutics LLC requests to establish a new Level II HCPCS code to identify QUZYTTIR (cetirizine hydrochloride injection), for intravenous use.

QUZYTTIR for intravenous use is a histamine1 (H_1) receptor antagonist and is indicated for the treatment of acute urticarial in adults and children 6 months of age and older. Cetirizine hydrochloride, a human metabolite of hydroxyzine, is an antihistamine; its principal effects are mediated via selective inhibition of peripheral H_1 receptors. The recommended dosage is 10 mg (1mL) for a patient 12 years of age or older; 5 mg or 10 mg for children 6 to 11 years of age; and 2.5 mg for children 6 months to 5 years of age. QUZYTTIR is administered as an intravenous push over a period of 1 to 2 minutes. It is a sterile, clear, colorless, non-pyrogenic, isotonic solution of cetrizine hydrochloride for intravenous injection; supplied in 2 mL size amber glass vials for single use.

According to the applicant, the current Level II HCPCS codes do not describe cetirizine hydrochloride injection, a single source drug administered by a healthcare professional.

CMS Decision

Establish a new Level II HCPCS code J1201 "Injection, Cetirizine hydrochloride, 0.5 mg."

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

Effective: 07/01/2020

Request# 20.007

Topic/Issue:

Request to establish a new Level II HCPCS code for AVSOLA (infliximab-axxq).

Applicant's suggested language: QXXXX Injection, infliximab-axxq, biosimilar (AVSOLA) 10 mg.

Applicant's Summary

Amgen requests a new permanent national HCPCS code for AVSOLA (infliximab-axxq).

AVSOLA is an anti-tumor necrosis factor-alpha (anti-TNF) monoclonal antibody. Infliximab products neutralize the biological activity of TNF alpha by binding with high affinity to the soluble and transmembrane forms of TNF alpha and inhibit binding of TNF alpha with its receptors. AVSOLA is approved for treatment of (i) moderate to severe fistulizing Crohn's Disease, (ii) moderate to severe Pediatric Crohn's disease (iii) moderate to severe Ulcerative Colitis,(iv)moderate to severe Pediatric Ulcerative Colitis, (v)moderate to severe Rheumatoid Arthritis (RA), (vi) Ankylosing Spondylitis, (vii) Psoriatic Arthritis, and (vii) chronic severe Plaque Psoriasis. Dosing ranges from 3 mg/kg to 10 mg/kg. Each AVSOLA for injection 20 milliliter vial is individually packaged in a carton. Each carton contains one vial. Each single dose vial contains 100 mg of lyophilized infliximab-axxq for final reconstitution volume of 10 mL. AVSOLA is administered via intravenous infusion over a period of no less than two hours and should be administered by a healthcare provider.

According to the applicant no specific HCPCS code currently describes AVSOLA and a unique code is required to distinguish it from other biosimilar biological products with the same reference products (infliximab).

CMS Decision

Establish a new Level II HCPCS code Q5121 "Injection, infliximab-axxq, biosimilar, (AVSOLA), 10 mg."

Effective: 07/01/2020

Request# 20.008

Topic/Issue:

Request to establish a new Level II HCPCS code to specifically describe GIVLAARI (givosiran)

Applicant's suggested language: JXXXX- injection, givosiran, 2.5 mg

Applicant's Summary

Alnylam requests to create a new HCPCS code to specifically describe GIVLAARI (givosiran).

GIVLAARI is an aminolevulinate synthase 1-directed small interfering RNA (siRNA) indicated for the treatment of adults with acute hepatic porphyria. It is an aminolevulinate synthase 1-directed siRNA, covalently linked to a ligand containing three N-acetylgalactosamine (GalNAc) residues to enable delivery of the siRNA to hepatocytes. GIVLAARI is a double-stranded siRNA that causes degradation of ALAS1 mRNA in hepatocytes through RNA interference, reducing the elevated levels of liver ALAS1 mRNA. This leads to reduced circulating levels of neurotoxic intermediates aminolevulinic acid (ALA) and porphobilinogen (PBG), factors associated with attacks and other disease manifestations of AHP. The recommended dose of GIVLAARI is 1 mg/kg administered via subcutaneous injection once monthly. It is packaged as a sterile, preservative free, 1 mL colorless to yellow solution for subcutaneous injection containing 189 mg givosiran in a single dose, 2 mL Type 1 glass vial.

According to the applicant GIVLAARI is a unique drug that is not therapeutically equivalent to any other product and hence no current, specific, permanent code adequately describes it.

CMS Decision

Establish a new Level II HCPCS code J0223 "Injection, givosiran, 0.5 mg." Existing modifier "JB" "administered subcutaneously" is available for use to specify route of administration.

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

Effective: 07/01/2020

Request# 20.009

Topic/Issue:

Request to establish a new Level II HCPCS code for VYONDYS 53 (golodirsen) for injection.

Applicant's suggested language: JXXXX- Injection, golodirsen, 10 mg.

Applicant's Summary

Sarepta Therapeutics, Inc. requests a new permanent level II HCPCS code for VYONDYS 53™ (golodirsen) for injection.

VYONDYS 53 is an antisense oligonucleotide of the phosphorodiamidate morpholino oligomer (PMO) subclass. It is designed to bind to exon 53 of dystrophin pre-mRNA. When VYONDYS 53 binds to exon 53 of dystrophin pre-mRNA, it results in exclusion, or "skipping", of this exon during mRNA processing in patients with genetic mutations that are amenable to exon 53 skipping. It is indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping. The recommended dose of golodirsen is 30 mg/kg administered once weekly as a 35-60 minute IV infusion. It is administered by IV infusion. Supplied in single dose vials. The solution is a clear to slightly opalescent, colorless liquid.

According to the applicant, there is currently no HCPCS code that describes VYONDYS 53.

CMS Decision

Establish a new Level II HCPCS code J1429 "Injection, golodirsen, 10 mg."

Effective: 07/01/2020

Request# 20.010

Topic/Issue:

Request to modify the descriptor for J7345 (Ameluz) from Aminolevlinic Acid HCL for Topical Administration 10%, 10 mg to Aminolevulinic Acid HCL for Topical Administration 10% 20 mg.

Applicant's Summary

Biofrontera, Inc. requests a change to the descriptor for J7345 (Ameluz) from Aminolevulinic Acid HCL for Topical Administration 10%, 10 mg to Aminolevulinic Acid HCL for Topical Administration 10% 20 mg.

Ameluz is applied directly to skin growths or lesions or entire affected area and a red light source is then shone onto the skin. It is a medicine used in adults to treat mild to moderate actinic keratosis on the face and scalp as well as the surrounding areas of the skin affected by the condition. It may also be used to treat an area of sun-induced skin damage with multiple actinic keratosis growths (field cancerization). Ameluz can also be used in adults to treat certain types of basal cell carcinoma (a type of skin cancer) when it cannot be treated by surgery. Ameluz contains the active substance 5- aminolaevulinic acid which is absorbed by cells where it acts as a photosensitizing agent (a substance that changes when exposed to light of a certain wavelength). When the affected skin is exposed to light, the photosensitizing agent is activated and reacts with oxygen in the cells to create a highly reactive and toxic type of oxygen. This kills the cells by reacting with and destroying their components, such as proteins and DNA. Ameluz should only be administered under the supervision of a physician. The dosage depends on the size of the field of cancerization in adults. Ameluz gel, 10% is a white to yellowish gel. The drug is supplied in an aluminum tube with a white, high density polyethylene screw cap. Each tube contains 2g of gel. NDC 70621-0101-01 2 g tube.

According to the applicant, existing descriptor in combination with the current Medically Unlikely Edit (MUE) of 3 essentially limits one tube of Ameluz to be used on a given day, which for many patients is not enough. The patient would be required to return for another treatment if a larger surface area needs to be treated.

CMS Decision

Existing code J7345 "Aminolevulinic acid HCL for topical administration, 10% gel, 10 mg" adequately describes the product. The 10 mg dose descriptor is consistent with CMS longstanding convention to assign small dose descriptors.

Request# 20.011

Topic/Issue:

Request to establish a new Level II HCPCS code to identify Barium sulfate 40% w/v with a viscosity of 300 cPs for Modified Barium Swallow Studies (MBSS).

Trade name: Varibar Nectar (Barium Sulfate) Oral Suspension, 40% w/v.

Applicant's Summary

Bracco Diagnostics Inc., requests a new Level II HCPCS code to identify Barium Sulfate 40% w/v with a viscosity of 300 cPs for Modified Barium Swallow Studies (MBSS).

Varibar Nectar is a radiopaque contrast agent administered orally to evaluate swallowing during a Modified Barium Swallow Study (MBSS). It is for oral use only. It is used with other Varibar products of various viscosities and textures that simulate various liquids and foods. MBSS are primarily administered to patients who have damage to the nervous system or to structures of the head and neck critical for safe and efficient swallowing. Varibar is for oral use only and administered by infant bottle, syringe or spoon. The recommended dose for adults is 5 mL, pediatric patients 6 months and older: 1 to 3mL and pediatric patients younger than 6 months: 0.5 to 1mL. During a single MBSS, multiple doses may be administered with maximum cumulative dose of 30mL.

As per the applicant, there is no existing code for any FDA barium-based x-ray contrast media products.

CMS Decision

It is our understanding that the item that is the subject of this application is factored into the practice expense. For additional details and for coding guidance, CMS refers the applicant to the American Medical Association (AMA).

Request# 20.012

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

Bracco Diagnostic Inc., requests 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).

Varibar Pudding Oral Paste is a radiopaque contrast agent administered orally to evaluate swallowing during a Modified Barium Swallow Study (MBSS). It is used with other Varibar products of various viscosities and textures that simulate various liquids and foods. MBSS are primarily administered to patients who have damage to the nervous system or to structures of the head and neck critical for safe and efficient swallowing. Varibar is for oral use only and administered by a syringe or spoon. The recommended dose for adults is 5 mL and pediatric patients is 1 to 3mL. During a single MBSS, multiple doses may be administered with maximum cumulative dose: 30mL.

As per the applicant, there is no existing code for any FDA barium-based x-ray contrast media products.

CMS Decision

It is our understanding that the item that is the subject of this application is factored into the practice expense. For additional details and for coding guidance, CMS refers the applicant to the American Medical Association (AMA).

Request# 20.013

Topic/Issue:

Request to establish a new Level II HCPCS code to identify Barium sulfate 81% w/w with a viscosity of < 15 cPs for Modified Barium Swallow Studies (MBSS).

Trade name: Varibar Thin Liquid (Barium Sulfate) Oral Suspension, 81% w/w

Applicant's Summary

Bracco Diagnostics Inc., requests a new Level II HCPCS code to identify Barium sulfate 81% w/w with a viscosity of <15 cPs for Modified Barium Swallow Studies (MBSS).

Varibar Thin Liquid is a radiopaque contrast agent administered orally to evaluate swallowing during a Modified Barium Swallow Study (MBSS). It is used with other Varibar products of various viscosities and textures that simulate various liquids and foods. MBSS are primarily administered to patients who have damage to the nervous system or to structures of the head and neck critical for safe and efficient swallowing. Varibar is for oral use only and administered by infant bottle, syringe or spoon. The recommended dose for adults is 5 mL, pediatric patients 6 months and older is 1 to 3mL and pediatric patients younger than 6 months is 0.5 to 1mL. During a single MBSS, multiple doses may be administered with maximum cumulative dose of 80mL. It is available in 148 g bottle (powder to be reconstituted with water).

As per the applicant, there is no existing code for any FDA barium-based x-ray contrast media products.

CMS Decision

It is our understanding that the item that is the subject of this application is factored into the practice expense. For additional details and for coding guidance, CMS refers the applicant to the American Medical Association (AMA).

Request# 20.014

Topic/Issue:

Request to establish a new Level II HCPCS code to identify Barium sulfate 40% w/v for use in Computed Tomography Colonography (CTC).

Trade name: Tagitol V (barium Sulfate) Oral Suspension, 40% w/v

Applicant's Summary

Bracco Diagnostics Inc., requests a new Level II HCPCS code for Barium sulfate 40% w/v for use in Computed Tomography Colonography (CTC).

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 (20mL) 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 20mL bottles.

As per the applicant, there is no existing Level II HCPCS code to identify Tagitol V and it is the only FDA approved barium sulfate product on the market that is indicated for use in CTC as a fecal tagging agent.

CMS Decision

It is our understanding that the item that is the subject of this application is factored into the practice expense. For additional details and for coding guidance, CMS refers the applicant to the American Medical Association (AMA).

Request# 20.015

Topic/Issue:

Request to establish a new Level II HCPCS code to identify Barium sulfate 40% w/v with a viscosity of 1500 cPs for Modified Barium Swallow Studies (MBSS).

Trade name: Varibar Thin Honey (Barium Sulfate) Oral Suspension, 40% w/v

Applicant's Summary

Bracco Diagnostics Inc. requests a new Level II HCPCS code to identify Barium Sulfate 40% w/v with a viscosity of 1500 cPs for Modified Barium Swallow Studies (MBSS).

Varibar Thin Honey is a radiopaque contrast agent administered orally to evaluate swallowing during a Modified Barium Swallow Study (MBSS). It is used with other Varibar products of various viscosities and textures that simulate various liquids and foods. MBSS are primarily administered to patients who have damage to the nervous system or to structures of the head and neck critical for safe and efficient swallowing. 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. Varibar is for oral use only and administered by infant bottle, syringe or spoon. The recommended dose for adults is 5 mL and pediatric patients is 1 to 3mL. During a single MBSS, multiple doses may be administered with maximum cumulative dose of 30mL. Available in 250 mL bottle.

As per the applicant, there is no existing code for any FDA barium-based x-ray contrast media products.

CMS Decision

It is our understanding that the item that is the subject of this application is factored into the practice expense. For additional details and for coding guidance, CMS refers the applicant to the American Medical Association (AMA).

Request# 20.016

Topic/Issue:

Request to establish a new Level II HCPCS code to identify Barium sulfate (40% w/v, 29% w/w) with viscosity of 3000 cPs for Modified Barium Swallow Studies (MBSS).

Trade name: Varibar Honey (Barium Sulfate) Oral Suspension, (40% w/v, 29% w/w)

Applicant's Summary

Bracco Diagnostics Inc. request a new Level II HCPCS code for Barium sulfate (40% w/v, 29% w/w) with viscosity of 3000 cPs for Modified Barium Swallow Studies (MBSS).

Varibar Honey is a radiopaque contrast agent administered orally to evaluate swallowing during a Modified Barium Swallow Study (MBSS). It is used with other Varibar products of various viscosities and textures that simulate various liquids and foods. MBSS are primarily administered to patients who have damage to the nervous system or to structures of the head and neck critical for safe and efficient swallowing. Varibar 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. It has also been used in the pediatric population to represent stage I or stage II baby food. Varibar is for oral use only and administered by infant bottle, syringe or spoon. The recommended dose for adults is 5 mL and pediatric patients is 1 to 3mL. During a single MBSS, multiple doses may be administered with maximum cumulative dose of 30mL. Available in 250 mL bottle.

As per the applicant, there is no existing code for any FDA barium-based x-ray contrast media products.

CMS Decision

It is our understanding that the item that is the subject of this application is factored into the practice expense. For additional details and for coding guidance, CMS refers the applicant to the American Medical Association (AMA).

Request# 20.017

Topic/Issue:

Request to revise existing Level II HCPCS Code Q4126 which currently reads: "Memoderm, dermaspan, tranzgraft or integuply, per square centimeter" to include SimpliDerm.

Trade name: SimpliDerm

Applicant's Summary

Aziyo Biologics, Inc. is requesting that Level II HCPCS code Q4126, "MemoDerm, DermaSpan, TranZgraft or IntéguPly, per sq cm," be revised to include SimpliDerm™. IntéguPly and TranZgraft are also manufactured by Aziyo Biologics using the same processing technique used to manufacture SimpliDerm. The only difference is that Integuply and TranZgraft are freeze dried whereas SimpliDerm is pre-hydrated.

SimpliDerm is a human acellular dermal matrix 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. It is used for the repair or replacement of damaged or insufficient integumental tissue. It functions as a framework to support cellular repopulation and vascularization at a surgical site. It contains collagen, elastin and glycosaminoglycan. SimpliDerm is 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 desired by the surgeon.

According to the applicant, the current descriptor of Q4126 is insufficient to describe SimpliDerm because it lacks the brand name "SimpliDerm. As a result, coders may not view it as an appropriate code to report its use.

CMS Decision

SimpliDerm is not suitable for coding in Level II HCPCS outside of CMS' pass-through coding process as it is used exclusively in hospital inpatient and outpatient settings. Existing codes C5271 through and including C5278 are available for assignment by insurers to report HOPPS use. Use in hospital inpatient setting would be included in surgical DRG.

Request# 20.018

Topic/Issue:

Request to establish a new Level II HCPCS code to identify luspatercept-aamt.

Trade name: Reblozyl

Applicant Summary

Celgene, Inc. requests a new Level II HCPCS code in the J9XXX series for its biological product, REBLOZYL (luspatercept-aamt) for injection, for subcutaneous use.

REBLOZYL is indicated for the treatment of anemia in adult patients with beta thalassemia who require regular red blood cell transfusions. In patients having received < 4 units of RBC transfusion within 8 weeks prior to study, the greatest Hgb increase occurred after the first dose (0.75 g/dL on average at a dose of 0.6 to 1.25 times the recommended starting dose), with additional smaller increases observed after subsequent doses. Hemoglobin levels returned to baseline approximately 8 weeks from the last dose following administration of luspatercept-aamt at a dose of 0.6 to 1.25 times the recommended starting dosage. Increasing luspatercept-aamt serum exposure was associated with greater Hgb increase in patients with beta thalassemia. Luspatercept-aamt diminishes Smad2/3 signaling and promoted erythroid maturation through differentiation of late stage erythroid precursors (normoblasts) in mice. After reconstitution with 0.68 mL sterile water for injection USP, the resulting concentration is 25 mg/0.5 mL of Luspatercept-aamt. The recommended dose is a physician administered 1 mg/l g once every 3 weeks by subcutaneous injection. REBLOZYL for injection is a white to off- white lyophilized powder supplied in a single dose vial (25 mg/ vial and 75 mg/vial). Each carton has one vial.

According to the applicant, existing codes are miscellaneous and not specific to REBLOZYL, therefore, do not adequately describe the therapy.

CMS Decision

Establish new Level II HCPCS code J0896 "Injection, Luspatercept-aamt, 0.25 mg."

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

Effective: 07/01/2020

Request# 20.019

Topic/Issue:

Request to establish a new Level II HCPCS code for XENLETA (lefamulin) 150 mg injection ("XENLETA injection")

Applicant's suggested code language: JXXXX Injection, lefamulin (Xenleta), 1 mg

Applicant's Summary

Nabriva Therapeutics US Inc. is requesting a new HCPCS Level II code for XENLETA (lefamulin) 150 mg injection (XENLETA Injection).

XENLETA injection is indicated for the treatment of adults with community-acquired bacterial pneumonia (CABP) caused by susceptible microorganisms such as Streptococcus pneumoniae, Staphylococcus aureus, Haemophilus influenza, Legionella pneumophila, Mycoplasma pneumoniae and Chlamydophila pneumoniae. XENLETA injection is a systemic pleuromutilin antibacterial. It inhibits bacterial protein synthesis through interactions with the A and P sites of the peptidyl transferase center in domain V of the 23s rRNA of the 50s subunit. The binding pocket of the bacterial ribosome closes around the mutilin core for an induced fit that prevents correct positioning of tRNA. The typical patient with community acquired bacterial pneumonia will receive one 150 mg IV dose over a 60 minute period every 12 hours or two IV doses per day. It is a clear, colorless, sterile, non-pyrogenic solution for intravenous administration containing 150 mg of lefamulin in 15 mL 0.9% sodium chloride that is supplied in a single dose vial intended for dilution in 250 mL of 10 mM citrate buffered (pH 5) 0.9% sodium chloride.

XENLETA was awarded transitional pass-through payment status and a HCPCS code C9054. The applicant states that C-codes are temporary codes typically used in the hospital outpatient department for Medicare claims only and other payers such as Medicaid and commercial plans do not typically accept C-codes for drugs. Therefore, according to the applicant, a program need exists so that patients suffering from CABP have access to care and providers can bill this treatment option.

CMS Decision

Establish a new Level II HCPCS code J0691 "Injection, lefamulin, 1 mg."

Effective: 07/01/2020

Request# 20.020

Topic/Issue:

Request to establish a new Level II HCPCS code for the AmnioCore™ amnion patch.

Applicant's suggested language: Q4XXX (AmnioCore, per square centimeter)

Applicant's Summary

Stability Biologics requests the new Level II HCPCS code for AmnioCore amnion patch.

AmnioCore is comprised of donated human tissue that has been screened, recovered and serologically tested. It is dual layer amniotic tissue allograft, providing safe, natural, biologic barrier. It is a minimally manipulated, dehydrated, non-viable cellular amniotic membrane allograft that contains multiple extracellular matrix proteins, growth factors, cytokines and other specialty proteins present in amniotic tissue to provide a barrier membrane that enhances healing. AmnioCore is intended for homologous use in the treatment of acute and chronic wounds to reduce scar tissue formation, modulate inflammation, provide a barrier and enhance healing. The tissue is for single patient use only, single occasion only and is restricted to use by a licensed physician. The AmnioCore Amniotic Membrane Allograft has been dried, sealed in its packaging container and must be stored at room temperature. It is not necessary to reconstitute AmnioCore prior to application. Once the package seal is broken, the allograft must be used within 6 hours.

According to the applicant, current HCPCS codes do not adequately describe AmnioCore. As per the applicant, providers must utilize Q4100 (skin substitute, not otherwise specified) which results in delayed claims processing, additional documentation and the inability for providers to specifically report which product is being used for treatment.

CMS Decision

Establish a new Level II HCPCS code Q4227 "Amniocore, per square centimeter."

Effective: 07/01/2020

Request# 20.021

Topic/Issue:

Request to establish a new Level II HCPCS code to identify a Wharton's jelly-derived human cell and tissue product (HCT/P). Trade name: CoreCyte

Applicant's suggested language: Q4XXX- "CoreCyte, per 0.5 mL"

Applicant's Summary

Predictive Biotech kindly requests through this application to establish a new and single Level II HCPCS code to identify a Wharton's jelly-derived human cell and tissue product (HCT/P) that is currently being sold under the trade name, CoreCyte

CoreCyte is a minimally manipulated human tissue allograft derived from the Wharton's jelly of the umbilical cord. CoreCyte is processed to preserve the cytokines, growth factors and proteins of Wharton's jelly for homologous use. It is intended for use in the repair, reconstruction, replacement or supplementation of a recipient's cells or tissues by performing the same basic function(s) of Wharton's jelly within the recipient as it would the donor. The amount and administration (injected or applied topically) of the allograft is determined by the clinician based on the intended use in each patient case. The product is distributed as a liquid allograft contained in a vial that is shipped frozen for preservation (-80C, on dry ice) and is intended to be stored in that frozen state (-60C to -80C or colder) until used or expiration date is reached. CoreCyte can be ordered in 3 different vial sizes: 0.5 mL, 1.0 mL OR 2.0 mL. The product is simply drawn up after proper thawing using a 21 G-23G needle to syringe and then prepared and applied as determined by a licensed clinician.

According to the applicant, the existing categories for products similar to CoreCyte are inadequate primarily due to variances in the way these products are received, processed and preserved, therefore, yield a potentially different consistency and activity of active components that may or may not best represent the donor source HCT/P. Payers are carefully reviewing each product and are being highly selective of those that they are willing to cover as medically necessary.

CMS Decision

Establish new level II HCPCS code Q4240 "Corecyte, for topical use only, per 0.5 cc."

After review of FDA's guidance, it does not appear to CMS that the non-topical uses such as injection for cartilage repair that are also the subject of this application are appropriate for regulation solely under section 361 of the Public Health Service Act. 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 this 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.

Information regarding the RFD Process is located at https://www.fda.gov/combinationproducts/rfdprocess/default.htm.

Request# 20.022

Topic/Issue:

Request to establish a new code Level II HCPCS code to identify an acellular liquid amnion.

Trade name: careFLO

Applicant's suggested language: QXXXX careFLO, per 0.1 cc.

Applicant's Summary

Extremity Care, LLC is requesting modification to the HCPCS code set for skin substitutes. Specifically, Extremity Care is requesting the creation of one (1) new HCPCS code for careFLO as described below:

careFLO acellular liquid amnion is an ambient temperature stored, 100% acellular liquid amniotic fluid allograft and is not a suspension on mixture of micronized amniotic membrane and saline. It is intended for homologous use to supplement a recipient's tissue. CareFLO is sterile, single use, minimally processed to preserve the native structure and biological activity of the tissue that is terminally sterilized with gamma irradiation to ensure recipient safe and effective treatment. careFLO is intended for the treatment of burn injuries and non-healing wounds including partial and full thickness wounds, pressure sores/ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/ undermined wounds, surgical wounds (e.g., donor site/grafts, post- laser surgery, post-Mohs surgery, podiatric wounds, wound dehiscence), trauma wounds, and draining wounds. careFLO acellular liquid amnion is available in three volumes 0.5 cc, 1.0 cc, 2.0 cc. and is injected though a needle on or in the wound site following wound bed preparations

Currently available HCPCS codes for synthetic and biologic wound healing technologies are product and brand specific, indicating combination configurations of human or xenograft source and synthetic materials decellularized matrices, or non-metabolically active elements. Therefore, no currently available permanent HCPCS code appropriately defines careFLO.

CMS Decision

After review of FDA's guidance, it does not appear to CMS that the product that is the subject of this application, is appropriate for regulation solely under section 361 of the Public Health Service Act. 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 this 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. Information regarding the RFD Process is located at https://www.fda.gov/combinationproducts/rfdprocess/default.htm,

Request# 20.023

Topic/Issue:

Request to establish new Level II HCPCS code to identify a sterile single use, dehydrated human amnion membrane allograft.

Trade Name: carePATCH

Suggested language: QXXXX carePATCH per sq centimeter.

Applicant's Summary

Extremity Care, LLC is requesting modification to the HCPCS code set for skin substitutes.

Specifically, Extremity Care is requesting the creation of one (1) new HCPCS code for carePATCH as described:

carePATCH is dehydrated amniotic membrane allograft used for the treatment of non-healing wounds and burn injuries. carePATCH amniotic membrane allograft delivers cytokines, proteins and growth factors to help regenerate soft tissue. Human amniotic membrane is a thin collagenous membrane that consists of collagen layers including the basement membrane and stromal matrix. The extracellular matrix (ECM) components of the amniotic tissue include collagens, growth factors fibronectin, laminins, integrins and hyaluronans. Additionally, amniotic membrane allograft is immune privileged and possesses little or no risk of foreign body reaction which can lead to fibrosis and graft failure. The dosage for carePATCH amniotic membrane allograft is per square centimeter. carePATCH is available in the following wound preparation. Absorbable/ non-absorbable suture material and/or tissue adhesives may be used to apply the graft to the site if necessary. carePATCH is supplied in the following allograft sizes: 2 cm x 2 cm, 2cm X 4cm, 4 cm x 4 cm, 4 cm x 6 cm, 5 cm x 5 cm, 4 cm x 8 cm.

According to the applicant, currently available HCPCS codes for synthetic and biologic wound healing technologies are product and brand specific, indicating combinations of human or xenograft source and synthetic materials, decellularized matrices, or non-metabolically active elements, therefore, no currently available permanent HCPCS code appropriately defines carePATCH.

CMS Decision

Establish new Level II HCPCS code Q4236 "carePATCH, per square centimeter."

Effective: 07/01/2020

Request# 20.024

Topic/Issue:

Request to establish a new Level II HCPCS code to identify enfortumab vendotin-ejfv.

Trade Name: Padcev

Applicant's suggested language: JXXXX Injection, enfortumab vendotin-ejfv, intravenous, 1 mg.

Applicant's Summary

Astellas Pharma US, Inc. submitted a request to establish a new Level II HCPCS code to identify PADCEV. PADCEV is an antibody-drug conjugate (ADC) directed against Nectin-4, an adhesion protein located on the surface of cells. PADCEV is indicated to treat adult patients with locally advanced or metastatic urothelial cancer who have previously received a programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor, and a platinum-containing chemotherapy in the neo-adjuvant/adjuvant, locally advanced or metastatic setting. Nonclinical data suggest that the anticancer activity of enfortumab vedotin is due to the binding of the ADC to nectin-4-expressing cells, followed by internalization of the ADC-nectin-4 complex, and the release of MMAE via proteolytic cleavage. Release of MMAE disrupts the microtubule network within the cell, subsequently inducing cell cycle arrest and apoptotic cell death. The recommend dose of PADCEV is 1.25 mg/kg (up to a maximum of 125 mg for patients >100 kg) administered as intravenous infusion over 30 minutes on Day 1, 8, and 15 of a 28 -day cycle until disease progression or unacceptable toxicity. PADCEV is supplied as a sterile, preservative-free, and white to off white lyophilized powder in single dose vials for reconstitution containing 20 mg or 30 mg per vial.

According to the applicant, PADCEV is a "single source drug" and is not rated as therapeutically equivalent to any other product by the FDA. As a result, as per the applicant, a unique HCPCS code for this drug would be necessary to effectuate the Medicare statute's requirement that a Part B single source drug is to be paid only on the basis of its average sales price.

CMS Decision

Establish a new Level II HCPCS code J9177 "Injection, enfortumab vedotin-ejfv, 0.25 mg."

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

Effective: 07/01/2020

Request# 20.025

Topic/Issue:

Request to establish a new Level II HCPCS code for skin substitute, BioNextFlo

Applicant's suggested language: QXXXX BioNextFlo, per 0.1 cc

Applicant's Summary

BioNextFlo Solutions, LLC is requesting to establish a new Level II HCPCS code for skin substitute, BioNextFlo. BioNextFlo is a 100% acellular liquid amniotic fluid allograft used for the treatment of non-healing wounds including partial and full thickness wounds, pressure sores/ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds, trauma wounds, draining wounds and burn injuries. It is not a suspension or mixture of micronized amniotic membrane and saline. BioNextFlo delivers cytokines, proteins and growth factors to help regenerate soft tissues. The components of the BioNextFlo acellular liquid amnion include growth factors, fibronectin, laminins, integrins and hyaluronans. It is applied on and/or deep into a wound after the wound bed is prepared with standard debridement methods. It is supplied terminally sterile in a single use package and can be mixed with saline or blood for precise syringe delivery. BioNextFlo is available in three volumes: 0.5 cc, 1 cc and 2 cc and supplied in sterile vial, for single patient use, with little to no risk of foreign body reaction which can lead to fibrosis and graft failure.

According to the applicant, currently available HCPCS codes for synthetic and biologic wound healing technologies are product and brand specific, therefore, BioNextFlo is being billed using miscellaneous code Q4100, skin substitute, not otherwise specified.

CMS Decision

After review of FDA's guidance, it does not appear to CMS that the product that is the subject of this application is 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 this 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 Information regarding the RFD Process is located at https://www.fda.gov/combinationproducts/rfdprocess/default.htm.

Request# 20.026

Topic/Issue:

Request to establish a new Level II HCPCS code for skin substitute, BioNextPATCH.

Applicant's suggested language: QXXXX BioNextPATCH per sq centimeter

Applicant's Summary

BioNext Solutions, LLC is requesting to establish a new Level II HCPCS code for skin substitute, BioNextPATCH.

BioNextPATCH is a dehydrated amniotic membrane allograft used for the treatment of non-healing wounds and burn injuries. This allograft delivers cytokines, proteins and growth factors to help regenerate soft tissue. Human amniotic membrane is a thin collagenous membrane that consists of collagen layers including the basement membrane and stromal matrix. The extracellular matrix components of the amniotic tissue include collagens, growth factors, fibronectin, laminins, integrins and hyaluronans. Additionally, amniotic membrane allograft is immune privileged and possesses little or no risk of foreign body reaction which can lead to fibrosis and graft failure. BioNextPATCH amniotic membrane allograft is available in the following sizes: 2 cm x 2 cm, 2 cm x 4 cm, 4 cm x 4cm, 5 cm x 5 cm, 4 cm x 6 cm, 4 cm x 8 cm. BioNextPATCH is applied over a wound or burn site following wound preparation in a physician office, or outpatient setting. BioNextPATCH is provided in a sterile sealed package and is intended for single use.

According to the applicant, currently available HCPCS codes for synthetic and biologic wound healing technologies are product and brand specific and Q4100 miscellaneous code is being used to bill for BioNextPATCH. As such, as per applicant, there is no currently available permanent code that appropriately describes BioNextPATCH.

CMS Decision

Establish a new Level II HCPCS code Q4228 "BioNextPATCH, per square centimeter."

Effective: 07/01/2020

Request# 20.027

Topic/Issue:

Request to establish a new Level II HCPCS code for amnion allograft product: Cogenex Amniotic Membrane.

Applicant's suggested language: "Q41XX-Cogenex Amniotic Membrane"

Applicant's Summary

Ventris Medical, LLC requests a Level II HCPCS code for its amnion allograft product: Cogenex Amniotic Membrane.

Cogenex Amniotic Membrane is a minimally manipulated amniotic membrane allograft regulated under section 361 of the Public Health Service Act. It is intended for homologous use and functions as a covering or barrier that offers protection from surrounding environment in reparative and reconstructive procedures. These procedures include but are not limited to chronic wound repair, urologic and gynecological surgeries, and burn wound reconstruction. Dosage depends on the size of the wound, injury and/or the scope of the surgery. Cogenex Amniotic Membrane is available wet or dry in 8 different sizes: 2 x 2 cm, 3 x 3 cm, 2 x 4 cm, 2 x 6 cm, 4 x 4 cm, 4 x 6 cm, 4 x 8 cm and 2 x 12 cm.

According to the applicant, existing codes do not adequately describe Cogenex Amniotic Membrane because they are all brand specific and a new code is warranted so that it may be readily identifiable for third party claims processing.

CMS Decision

Establish a new Level II HCPCS code Q4229 "Cogenex amniotic membrane, per square centimeter."

Effective: 07/01/2020

Request# 20.028

Topic/Issue:

Request to establish a new Level II HCPCS code for amnion allograft product: Cogenex Flowable Amnion.

Applicant's suggested language: "Q41XX-Cogenex Flowable Amnion, per 0.5 cc."

Applicant's Summary

Ventris Medical, LLC requests a new Level II HCPCS for its amnion allograft product: Cogenex Flowable Amnion.

Cogenex Flowable Amnion is a minimally manipulated amniotic membrane allograft regulated under section 361 of the Public Health Service Act. It is an amniotic membrane suspended in a saline solution, intended for homologous use only. Its inherent structural makeup allows it to also act 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. Cogenex Flowable Amnion is a particulate powder pre-suspended for direct application and is conveniently stored on shelf at ambient temperature. The prescribed dosage depends on size of the wound, injury and/or scope of the surgery. It is available in 3 different volumes- 0.5 cc, 1.0 cc and 3.0 cc. It is provided in a prefilled syringe and can be administered into/onto the wound or injury. Cogenex Flowable Amnion is supplied by the donation of assenting, pre-screened women at the time of an elective, live, Caesarian birth.

According to the applicant, existing codes do not adequately describe Cogenex Flowable Amnion because they are all brand specific, therefore, a new code is warranted for it so that it may be readily identifiable for third party claims processing and tracking.

CMS Decision

Establish a new Level II HCPCS code Q4230 "Cogenex flowable amnion, per 0.5 cc."

Effective: 07/01/2020

Request# 20.029

Topic/Issue:

Request to establish a new Level II HCPCS code for Corplex P

Applicant's suggested language: QXXXX- Corplex P, per cubic centimeter

Applicant's Summary

StimLabs, LLC requests a new Level II HCPCS code for Corplex P.

Corplex P is a sterile, Wharton's jelly allograft obtained from a single donated human umbilical cord, dehydrated into small pieces, and presented in a graft form. The allografts are then packaged as individual units to fill volumes of 1 cc, 2 cc and 4 cc in sterile glass vials and terminally sterilized. The allograft contains only non-viable cells that were present at the time the tissue was donated, with no supplementary viable or non-viable cells added during processing. It is minimally manipulated and intended for homologous use only. It is intended to supplement connective tissue voids in open wound environments to protect and cushion the surrounding tissue. The product must be rehydrated at the point of use and administered topically. Corplex P is to be packed into the wound environment. A dressing must be used following application as the product is not intended to be used as a wound covering or barrier membrane. The sterile Wharton's jelly allograft is presented in a dehydrated format in vials, available in three fill volumes: 1 cc, 2 cc and 4 cc. Corplex P allograft is supplied as small, sterile, lyophilized pieces packaged in a vial format. The allograft is freeze-dried and supplied in sterile vials presented in an outer pouch for easier use in aseptic environments. The outer pouch is contained in a carton. Corplex P is stored at ambient temperature (0C to 38C) until ready to use.

According to the applicant, no existing code appropriately defines Corplex P.

CMS Decision

Establish a new Level II HCPCS code Q4231 "Corplex P, per cc."

Effective: 07/01/2020

Request# 20.030

Topic/Issue:

Request to establish a new Level II HCPCS code for Corplex.

Applicant's suggested language: QXXXX Corplex, per square centimeter.

Applicant's Summary

StimLabs, LLC requests a new Level II HCPCS code for Corplex.

Corplex is a human umbilical cord allograft obtained from donated human birth tissue through the retention of both the epithelial layer and the Wharton's jelly. The sheet is processed using the Clearify process to maximize the retention of desired structural components. This process is designed to retain a thick structure optimized for use as a wound covering for deep and challenging wounds. Corplex retains key extracellular matrix components, including collagens and proteoglycans that provide a robust matrix. The product is then dehydrated, cut into various sheet sizes and presented in a dehydrated graft form and packaged as separate, individual units and terminally sterilized. The allograft only contains non-viable cells that were present at the time the tissue was donated. It is minimally manipulated and intended for homologous use only. The function of Corplex is for repair, reconstruction, replacement or supplementation of the recipient's tissue. The allograft is specifically intended to be used as a wound covering or barrier membrane over chronic and acute wounds. The route of administration is topical and is supplied as 15 mm, 2 x 2 cm, 2 x 3 cm and 3 x 5 cm sheets. Corplex is supplied in sheet form in a sterile inner pouch. The inner pouch is inside a non-permeable outer pouch contained in a carton. It should be maintained in its original packaging and stored at ambient temperature (0C to 38C) until ready for use. When stored properly Corplex allografts are shelf stable for up to 5 years.

According to the applicant, no existing code appropriately defines Corplex.

CMS Decision

Establish a new Level II HCPCS code Q4232 "Corplex, per square centimeter."

Effective: 07/01/2020

Request# 20.031

Topic/Issue:

Request to establish a new Level II HCPCS code to identify SurFactor or NuDyn, a new acellular, flowable human amniotic membrane tissue allograft.

Applicant's suggested language: QXXXX-SurFactor or NuDyn, per 0.5 cc.

Applicant's Summary

Surgenex, LLC requests to establish a new Level II HCPCS code to identify SurFactor or NuDyn, a new acellular, flowable human amniotic membrane tissue allograft.

As per the applicant, SurFactor and NuDyn are the same products, marketed under different names and any reference to SurFactor equally applies to NuDyn. These products are acellular, flowable allograft tissue matrix derived from donated human amniotic membrane. They function in support of wound healing and soft tissue repair and are indicated for use in patients with acute, chronic or non-healing wounds, burns, or surgical wounds and in patients with soft tissue injuries or inflammatory conditions such as plantar fasciitis, bursitis, tendonitis, ligament and tendon sprains, nerve entrapment and ankle capsulitis. They are available in 0.5 cc, 1 cc and 2 cc dose sizes. The vial is packaged in a foil pouch and then terminally sterilized using e-beam irradiation. The prescribed dosage depends on the size of the wound, injury and/or scope of the treatment. SurFactor and NuDyn are intended for topical application to the wound surface, to irrigate a wound bed and/or injected directly into the site of the lesion, wound margins or in surrounding tissue near the inflammation.

According to the applicant, there is no current code that includes SurFactor and NuDyn.

CMS Decision

Establish a new Level II HCPCS code Q4233 "Surfactor or Nudyn, per 0.5 cc."

Effective: 07/01/2020

Request# 20.032

Topic/Issue:

Request to establish a new Level II HCPCS code to identify ENHERTU (fam-trastuzumab deruxtecan-nxki) for injection, for intravenous use.

Applicant's suggested language: JXXXX- Injection, fam-trastuzumab deruxtecan-nxki, 1 mg.

Applicant's Summary

Daiichi Sankyo, Inc. requests a new Level II HCPCS code to identify ENHERTU (fam-trastuzumab deruxtecan-nxki) for injection, for intravenous use.

ENHERTU is a humanized anti-HER2 IgG1 attached to deruxtecan, a topoisomerase I inhibitor bound by a tetrapeptide-based cleavable linker. The ADC is stable in plasma. Following binding to HER2 on tumor cells, fam-trastuzumab deruxtecan-nxki undergoes internalization and intracellular linker cleavage by lysosomal enzymes that are upregulated in cancer cells. Upon release, the membrane permeable topoisomerase I inhibitor causes DNA damage and apoptotic cell death. The topoisomerase I inhibitor is approximately 10 times more potent than SN-38, the active metabolite of irinotecan. It is indicated for the treatment of patients of unresectable or metastatic HER2-positive breast cancer who have received two or more prior anti-HER2 therapies. The recommended dose of ENHERTU is 5.4 mg/kg given as an intravenous infusion every 3 weeks until disease progression or unacceptable toxicity. It should not be substituted for or with trastuzumab or ado-trastuzumabemtansine. The first infusion should be administered over 90 minutes. Subsequent infusions should be administered over 30 minutes if prior infusions were well tolerated. The infusion rate should be slowed or interrupted if the patient develops infusion related symptoms and infusions of ENHERTU should be permanently discontinued in cases of sever infusion reactions. It is packaged one vial per carton and supplied as a single dose vial containing 100 mg lyophilized powder.

According to the applicant, ENHERTU is a unique molecule and no current specific HCPCS code adequately describes this product.

CMS Decision

Establish a new Level II HCPCS code J9358 "Injection, fam-trastuzumab deruxtecan-nxki, 1 mg."

Effective: 07/01/2020

Request# 20.033

Topic/Issue:

Request to establish a new Level II HCPCS code to identify an intra-articular hyaluronic acid injectable product.

Trade name: VISCO-3

Applicant's suggested language: JXXXX, hyaluronan or derivative, Visco-3, fir intra-articular injection, per dose.

Applicant's Summary

Zimmer Biomet requests to establish a new Level II HCPCS code to identify an intra-articular hyaluronic acid injectable product, Trade Name: VISCO-3.

VISCO-3 is indicated for the treatment of pain in osteoarthritis of the knee in patients who have failed to respond adequately to conservative non-pharmacologic therapy and simple analgesics e.g., acetaminophen. VISCO-3 is administered via intra-articular injection by a healthcare practitioner into the joint space of the affected knee. A treatment regimen of VISCO-3 consists of injections of 2.5 mL of VISCO-3 administered once per week for three weeks for a total of three injections. VISCO-3 supplements naturally occurring hyaluronic acid in the synovial fluid within the joint capsule of the affected knee to provide cushioning and lubrication to the joint, which have been reduced due to the degradation of the joint caused by the osteoarthritis. It is a sterile, viscoelastic non-pyrogenic solution of purified, high molecular weight (620,000-1,170,000 Daltons) sodium hyaluronate (hyaluronan) having a pH of 6.8-7.8. Each one mL of VISCO-3 contains 10 mg/mL of sodium hyaluronate dissolved in a physiological saline (1.0% solution).

According to the applicant, in 2018 VISCO-3 was assigned the code J7321, the same as its predicate, SUPARTZ FX. VISCO-3 has the same composition as SUPARTZ FX; however SUPARTZ FX is approved by the FDA as a 5 injection regimen compared to VISCO-3 as a three injection treatment series. As per applicant, this case is identical to the Hyalgan (5 injection) and TRILURON (3 injection) products in the same product class. In 2019, TRILURON was assigned a new and unique code separate from Hyalgan, therefore, VISCO-3 should also be assigned a new code.

CMS Decision

1. Establish new Level II HCPCS codes J7333 "Hyaluronan or derivative, visco-3, for intra-articular injection, per dose."

2. Revise existing code J7321 which currently reads: "Hyaluronan or derivative, hyalgan, supartz or visco-3, for intra-articular injection, per dose" to instead read: "Hyaluronan or derivative, hyalgan or supartz, for intra-articular injection, per dose."

Effective: 07/01/2020

Request# 20.034

Topic/Issue:

Request to establish a new Level II HCPCS code to identify immune globulin subcutaneous, human – klhw, 20%

Trade name: Xembify

Applicant's suggested language: JXXXX, Injection, immune globulin (Xembify), 100 mg.

Applicant's Summary

GRIFOLS USA requests to establish a new Level II HCPCS code for XEMBIFY, a new biological.

XEMBIFY contains 20% human immune globulin (IG) protein for subcutaneous (SC) administration. The purity is > 98% IG class G (IgG) antibodies with a subclass distribution similar to native human plasma. The XEMBIFY manufacturing process includes caprylate precipitation and incubation, as well as additional characteristics and manufacturing steps that make XEMBIFY unique from other 20% SCIG solution and other IG products. It is an antibody replacement therapy that can restore IgG levels to the normal range and prevent recurrent infections, including serious bacterial infections in patients, 2 years or older, with Primary Humoral Immunodeficiency(PI). XEMBIFY provides a broad spectrum of IgG antibodies against bacterial, viral and other infections. XEMBIFY also contains a spectrum of antibodies capable of interacting with and altering the activity of cells of the immune system. The dosage is individualized amount based on patient's serum IgG trough level and pharmacokinetic and clinical response, administered 1-7 times/week as a subcutaneous infusion. It is packaged as a single use vials containing 1, 2, 4 and 10 grams of protein in 5, 10, 20 and 50 mL, respectively (200 mg protein/mL).

According to the applicant, no existing codes adequately describe XEMBIFY because it has a unique manufacturing process and additional characteristics that significantly distinguish it from all other IG products. Additionally, XEMBIFY was approved under a new, unique BLA.

CMS Decision

Establish a new Level II HCPCS code J1558 "Injection, immune globulin (Xembify), 100 mg."

Effective: 07/01/2020

Request# 20.035

Topic/Issue:

Request to establish a new Level II HCPCS code to identify an amniotic suspension allograft derived from human amnion and amniotic fluid cells.

Trade name: ReNu

Applicant's suggested language: JXXXX, Amniotic suspension allograft, Renu, 0.5 cc

Applicant's Summary

Organogenesis requests a new Level II HCPCS code to identify ReNu.

ReNu is a cryopreserved, amniotic suspension allograft and is derived from human amnion and amniotic fluid cells. It is used to treat degenerative conditions such as osteoarthritis. ReNu is used to treat osteoarthritis pain. It is composed of amniotic membrane tissue and amniotic fluids cells which are the source of its method of action. Gene expression analysis suggests that amniotic membranes may promote an anti-inflammatory environment in the surrounding tissue by suppressing interleukin-1 alpha and interleukin- 1 beta and inhibiting the activity of matrix metalloproteases. Additionally, the presence of growth factors such as insulin-like growth factor, platelet-derived growth factor and vascular endothelial growth factor in placental membranes may support tendon repair. The recommended dose is 2.0 mL but it may also be administered in 0.5 ml and 1.0 mL doses. It is administered through intra-articular injection and is packaged in single-use vials available in three sizes: 0.5 cc, 1 cc and 2 cc.

According to the applicant, there is no existing code that specifically describes amniotic suspension allografts or ReNu. Recent publication of results of a randomized controlled trial comparing outcomes from a single injection of ReNu with outcomes from injection with hyaluronic acid or saline demonstrate that ReNu provides significantly improved therapeutic outcomes relative to hyaluronan products. Therefore, as per applicant, a specific code is needed to allow payers to identify and appropriately reimburse ReNu.

CMS Decision

After review of FDA's guidance, it does not appear to CMS that the product that is the subject of this application, is appropriate for regulation solely under section 361 of the Public Health Service Act. 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. CMS recognizes the request to withdraw pending follow-up with the FDA Tissue Reference Group and the Office of Combination Products for guidance. After obtaining this 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

Information regarding the RFD Process is located at
https://www.fda.gov/combinationproducts/rfdprocess/default.htm.

Request# 20.036

Topic/Issue:

Request to establish a new Level II HCPCS code to identify an antihemophilic Factor VIII (Recombinant). Trade name: ESPEROCT

Applicant's suggested language: JXXXX, Injection, Factor VIII, ESPEROCT antihemophilic factor (recombinant), glycopegylated-exei per iu.

Applicant's Summary

Novo Nordisk requests a new Level II HCPCS code to identify ESPEROCT (antihemophilic factor (recombinant), glycopegylated-exei).

ESPEROCT is a recombinant human Factor VIII and is produced in Chinese Hamster Ovary cells and contains 21 amino acids of the endogenous B-domain. ESPEROCT has a 40 kDa polyethylene-glycol conjugated to the O-linked glycan in the truncated B-domain. When ESPEROCT is activated by thrombin at the site of injury, the B-domain containing the PEG moiety and the a3-region are cleaved off, thus generating activated Factor VIII (FVIIIa) which is similar in structure to native Factor VIIIa. The protein part of ESPEROCT is a polypeptide with a molecular mass of 166 kDa, calculated excluding post-translational modifications and the PEG moiety; it contains a heavy chain of 87 kDa and a light chain of 79 kDa held together by non-covalent interactions. ESPEROCT is indicated for use in adults and children with hemophilia A for on demand treatment and control of bleeding episodes, peri-operative management of bleeding and routine prophylaxis to reduce the frequency of bleeding episodes. It temporarily replaces the missing coagulation Factor VIII needed for effective hemostasis in congenital hemophilia A patients. The recommended dose for routine prophylaxis is 50 IU per kilogram body weight every 4 days for adolescents/adults and 65 IU per kilogram body weight twice weekly for children (0-12 years old). For bleeding in adolescents/adults, the recommended dose is 40 IU/kg body weight for minor/moderate bleeds and 50 IU/kg body weight in children (<12 years). For peri-operative management, 50 IU/kg for adults and 65 IU/kg for children with additional doses approximately every 24 hours for the first week and approximately 48 hours for the 2nd week. ESPEROCT is available as white to off white lyophilized powder in single use vials containing 500, 1000, 1500, 2000 or 3000 IU of Factor VIII activity. It is reconstituted with 4 mL of 0.9% saline diluent provided in a prefilled glass syringe in the package.

According to the applicant, there is currently no HCPCS code associated with the product.

CMS Decision

Establish a new Level II HCPCS code J7204 "Injection, factor VIII, antihemophilic factor (recombinant), (esperoct), glycopegylated-exei, per iu."

Effective: 07/01/2020

Request# 20.037

Topic/Issue:

Request to establish a new Level II HCPCS code to identify coagulation Factor Xa (recombinant), inactivated-zhzo

Trade name: Andexxa

Applicant's suggested language: JXXXX, Injection, coagulation Factor Xa (recombinant), inactivated-zhzo (andexxa), 100 mg.

Applicant's Summary

Protola requests to establish a new Level II HCPCS code to identify ANDEXXA, a coagulation factor Xa protein.

ANDEXXA is a recombinant modified human factor Xa (FXa) protein. The function of the product is factor Xa decoy molecule that sequesters the inhibitors to rapidly reduce the free plasma concentrations and neutralize the anticoagulant effects of these inhibitors, allowing for restoration of normal hemostasis. It is indicated for patients treated with rivaroxaban and apixaban, when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding. It acts as an FXa decoy molecule that sequesters rivaroxaban and apixaban, rapidly reducing free plasma concentrations and neutralizing the anticoagulant effect of these FXa inhibitors. The dose for ANDEXXA is based on specific FXa inhibitor, dose of the FXa inhibitor and the time since the patient's last dose of the FXa inhibitor. ANDEXXA is intravenously administered, with a target rate of 30 mg/min, followed by continuous infusion for up to 120 minutes. It is available in 4 single- use vials, with a blue flip off cap, each containing 100 mg of factor Xa (recombinant), inactivated-zhzo as a white to off-white lyophilized cake or powder as well as in cartons of 4 single use vials, with red flip-off cap, each containing 200 mg of factor Xa (recombinant), inactivated-zhzo as a white to off white lyophilized cake or powder.

According to the applicant, there is no permanent, national HCPCS code that describes coagulation factor Xa (recombinant), inactivated-zhzo.

CMS Decision

Establish a new Level II HCPCS code J7169 "Injection, coagulation factor Xa (recombinant), inactivated-zhzo (Andexxa), 10 mg."

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

Effective: 07/01/2020

Request# 20.038

Topic/Issue:

Request to establish a new Level II HCPCS code to identify sterile human placental allograft

Trade name: Procenta

Applicant's suggested language: QXXXX, Procenta 200 mg, 1-6 square centimeter

Applicant's Summary

Lucina BioSciences LLC requests a new Level II HCPCS code for Procenta.

Procenta is an acellular, sterile, human placental-derived allograft. It is indicated to treat chronic non-healing wounds, such as venous stasis and diabetic foot ulcers for the purpose of providing an extracellular matrix (ECM) scaffold and soluble proteins to assist in the wound healing process. It is intended for homologous use only. When Procenta is placed in the wound bed, it acts as a hydrophilic extracellular matrix scaffold and provides a rich source of collagens, glycosaminoglycans (GAG), including hyaluronic acid and soluble growth factors directly to the site of the wound. The ECM is acellular and provides 3-dimensional structural support for healing. The bioactive nature of the scaffold and soluble factors stimulate the recipient's native dermal progenitor cells, resulting in resolution of the wound. Procenta is supplied in a single use vial containing one 200 mg placental allograft, providing coverage for up to a 6 cm^2 wound surface area. Once removed from the vial, it is applied into the wound bed by a physician. It is packaged as a 200 mg, acellular human placental-derived allograft in a vial which is contained in a peel pouch placed in an outer box. It is packaged sterile, pre-hydrated, ready to use and is shelf stable at room temperature for 2 years.

According to the applicant, currently HCPCS coding system for cellular and/or tissue-based products for skin wounds (skin substitute) is product and brand specific, therefore, no existing code currently describes Procenta.

CMS Decision

Establish a new Level II HCPCS code Q4244 "Procenta, per 200 mg."

Effective: 07/01/2020

Request# 20.039

Topic/Issue:

Request to establish a new Level II HCPCS code to identify amniotic membrane allograft.

Trade name: XCellerate

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

Applicant's Summary

Precise Bioscience requests to establish a new Level II HCPCS code to identify XCellerate, a skin substitute.

XCellerate is a lyophilized amniotic membrane allograft that is aseptically processed to preserve the native extracellular matrix and endogenous proteins that can be used as a biological barrier or wound cover. XCellerate is a human cellular and tissue-based product. Each allograft is restricted to homologous use in procedures on a single occasion by a licensed physician or surgeon. It is used for the treatment of non-healing wounds and burn injuries. XCellerate Amniotic Membrane Allograft delivers cytokines, proteins and growth factors to help regenerate soft tissue. The amniotic membrane allograft is immune-privileged and possesses little or no risk of foreign body reaction, which can lead to fibrosis and graft failure. XCellerate Amniotic Membrane Allograft is available in the following size: 2 x 2 cm, 2 x 4 cm, 4 x 4 cm, 4 x 7 cm and 6 mm, 9 mm, 12 mm discs. It is applied over a wound or burn site following wound preparation in multiple sites of care. XCellerate is provided in a sterile sealed package and is intended for single use.

According to the applicant, current HCPCS codes for synthetic and biologic wound healing technologies are product and brand specific and the available code "Q4100, Skin substitute, not otherwise specified" does not accurately describe XCellerate.

CMS Decision

Establish a new Level II HCPCS code Q4234 "Xcellerate, per square centimeter."

Effective: 07/01/2020

Request# 20.040

Topic/Issue:

Request to establish a new Level II HCPCS code to identify an intrauterine foam, a drug used to assess fallopian tube patency (openness).

Trade name: ExEm Foam

Applicant's suggested language: air polymer-type A intrauterine foam, for use in imaging, per dose.

Applicant's Summary

Request to establish a new Level II HCPCS code for ExEm Foam (air polymer-type A) intrauterine foam, a drug product used to assess fallopian tube patency. Assessment of fallopian tube patency is a fundamental test in a fertility work-up; occluded 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 as a contrast agent with Sonohysterosalpingography, a transvaginal ultrasound imaging procedure, 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 setting. It 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 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. It is packaged in a single dose kit, including prefilled syringes of gel (ExEm gel) and diluent (ExEm water) and one Combifix Adapter (coupling device).

According to the applicant, there are no existing HCPCS code that adequately describe ExEm Foam. As per applicant, there are HCPCS Level I codes that are used to bill Sonohysterosalpingography procedures (CPT Codes 74740 and 58340) but these do not include any practice expense supplies for contrast material used when performing imaging procedure.

CMS Decision

It is our understanding that the item that is the subject of this application is factored into the practice expense. For additional details and for coding guidance, CMS refers the applicant to the American Medical Association (AMA).

Request# 20.041

Topic/Issue:

Request to establish a new Level II HCPCS code to identify Deoxycholic acid injection, for subcutaneous use.

Trade name: Kybella

Applicant's suggested language: JXXXX, Injection, deoxycholic acid injection, 2.0 mg.

Applicant's Summary

Allergan requests to establish a new Level II HCPCS code for KYBELLA. KYBELLA is a single source drug product indicated for improvement in the appearance of moderate to severe convexity or fullness associated with submental fat in adults. The active ingredient in KYBELLA is deoxycholic acid, a cytolytic drug that physically destroys the cell membrane causing lysis when injected into tissue. It is injected in the subcutaneous fat tissue in the submental area using an area adjusted dose of 2 mg/cm^2. A single treatment consists of a maximum of 50 injections, 0.2 mL each (up to a total of 10 mL), and spaced 1 cm apart. Up to 6 single treatments maybe administered at intervals no less than 1 month apart. KYBELLA is a 10 mg/mL injection is a clear, colorless, sterile solution supplied in 2 mL, single patient use vials in a four vial dispensing pack.

As per the applicant, no other deoxycholic acid product has been assigned a code (or approved by the FDA).

CMS Decision

Establish a new Level II HCPCS code J0591 "Injection, deoxycholic acid, 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 variety of doses, making coding more robust, facilitate accurate payment and reporting of exact dose administered.

Effective: 07/01/2020

Request# 20.042

Topic/Issue:

Request to revise the current Level II HCPCS code J9199 which currently reads “Injection, gemcitabine, 200 mg” to read “Injection, gemcitabine, 100 mg

Trade name: Infugem

Applicant’s Summary

Sun Pharmaceuticals, Inc. requests to modify the current descriptor of J9199 from 200 mg to 100 mg.

Infugem (gemcitabine in sodium chloride injection), for intravenous use, is a single source product that maintains efficacy while improving handling and safety of a cytotoxic agent. Gemcitabine is a nucleoside metabolic inhibitor indicated for treatment of ovarian, breast, non-small cell lung and pancreatic cancers. INFUGEM is supplied in 10, pre-mixed, pre-filled, and ready to administer (RTA) bags. Data confirms that 8.8% of compounded cytotoxic deliver +/- 20% of the target dose. Infugem increases safety for providers and patients through decreased cytotoxic exposure and improved dosing accuracy. Infugem injections are mixed with 0.9% sodium chloride and transferred to an IV for infusion. According to the applicant, billing units of 100 mg allow use of the current 1500 billing form for FDA-approved dosing options. Infugem is manufactured and distributed in 100 mg increments. Specifically, infugem is available in 10 different size bags, the smallest starting at 1200 mg then increasing at increments of 100 mg up to 2200 mg. In other words, Sun manufactures bags with an odd amount of liquid to be administered to the beneficiary- 1300, 1500, 1700 and 1900. As per the applicant, this presents a billing challenge if the descriptor remains at 200 mg. The 100 mg increments serve significant clinical value because it allows for the most accurate amount of active ingredient to be administered. The many manufactured NDCs will significantly reduce wastage and improve safety for the provider when administering the bag's contents.

For these reasons, all of Sun's communications to the agency regarding the billing units for Infugem specifically requested that the descriptor be 100 mg. Sun believes that Infugem was initially assigned to J9201 that has 200 mg in its descriptor but when CMS changed its position and assigned Infugem a unique J code it kept the 200 mg descriptor in error.

CMS Decision

1. Discontinue existing code J9199 “Gemcitabine hydrochloride, (Infugem), 200 mg."

Effective: 07/01/2020

2. Establish new Level II HCPCS code J9198 "Gemcitabine hydrochloride, (Infugem), 100 mg." CMS routinely issues new codes when dosages change.

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Effective: 07/01/2020

Request# 20.043

Topic/Issue:

Request to establish a new Level II HCPCS code to identify melphalan injection, powder, lyophilized, for solution. Trade name: Evomela

Applicant's suggested language: JXXXX Injection, melphalan powder lyophilized, for solution (evomela), 50 mg

Applicant's Summary

Acrotech requests to establish a new Level II HCPCS code for EVOMELA. EVOMELA (melphalan injection, powder, lyophilized, for solution) is a single-source drug product indicated (i) for use as a high-dose conditioning treatment prior to hematopoietic progenitor (stem) cell transplantation in patients with multiple myeloma and (ii) for the palliative treatment of patients with multiple myeloma for whom oral therapy is not appropriate. The active ingredient in EVOMELA is melaphanhydrochloride, an alkylating agent of the bischloroethylamine type. Like other bifunctional alkylating agents, it is active against both resting and rapidly dividing tumor cells. EVOMELA's cytotoxicity appears to be related to the extent of its interstrand cross linking with DNA, probably by binding at the N^7 position of guanine. The recommended dose for conditioning treatment is 100 mg/m^2 administered over 30 minutes by intravenous infusion for two consecutive days prior to autologous stem cell transplantation. For palliative treatment, 16 mg/m^2 administered as a single intravenous infusion over 15-20 minutes at 2 week intervals for four doses, then after adequate recovery from toxicity, at four week intervals. EVOMELA is supplied in a single carton containing 1 vial. Each vial contains 50 mg melphalan free base equivalent to 56 mg melphalan hydrochloride.

According to the applicant, although other melphalan products have been assigned HCPCS codes, EVOMELA is a single source drug and as such no other melphalan product is therapeutically equivalent to it.

CMS Decision

1. Establish new Level II HCPCS code J9246 "Injection, melphalan (evomela), 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 variety of doses, making coding more robust, facilitate accurate reporting and payment of exact dose administered.

2. Revise existing code J9245 which currently reads: "Injection, melphalan hydrochloride, 50 mg." to instead read: "Injection, melphalan hydrochloride, Not Otherwise Specified, 50 mg"

Effective: 07/01/2020

Request# 20.044

Topic/Issue:

Request to establish a new Level II HCPCS code to identify cryopreserved, injectable human amniotic flowable allograft.

Trade Name: FloGraft

No suggested language.

Applicant's Summary

Applied Biologics, LLC requests to establish a new Level II HCPCS code to identify FloGraft, a cryopreserved, injectable Human amniotic flowable allograft.

FloGraft is intended for homologous use and supports the repair of soft tissue injury by providing natural growth factors and other extracellular components to the injured area to promote healing, reduce inflammation and reduce healing time. FloGraft is implanted at the injured site to drive native tissue regeneration and minimize scar formation. The patient population indicated for use of FloGraft include those with acute and chronic wounds and soft tissue injury, muscle and meniscus tears, ligament and tendon sprains, degenerative tissue disorders and inflammatory conditions. The products are available in 0.25 cc, 0.5 cc, 1 cc, 2 cc, 4 cc, 6 cc, 12 cc and 18 cc sizes. There is not an available generic name or general product name for FloGraft. FloGraft is regulated by FDA CBER which regulates HCT/Ps as a minimally manipulated human tissue. All the allografts are processed aseptically and packaged from a quality controlled source at an FDA registered procurement and processing facility.

According to the applicant, existing coding available for injectable amniotic fluid allografts are brand name specific, as such, Applied Biologics does not currently have a HCPCS code to identify their injectable products.

CMS Decision

After review of FDA's guidance, it does not appear to CMS that the product that is the subject of this application is 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 this 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. Information regarding the RFD Process is located at https://www.fda.gov/combinationproducts/rfdprocess/default.htm.

Request# 20.045

Topic/Issue:

Request to establish a new Level II HCPCS code to identify a lyophilized placenta membrane allografts.

Trade Name: Amniorepair and Altiply

Applicant's suggested language: QXXXX Amniorepair, altiply, per square centimeter

Applicant's Summary

Zimmer Biomet, on behalf of Aziyo Biologics requests to establish a new Level II HCPCS code for AMNIOREPAIR and AltiPly.

AMNIOREPAIR and AltiPly are human cellular and tissue based products per 21 CFR Part 1271. Each allograft is restricted to homologous use for use in procedures on a single occasion by a licensed physician. The products are lyophilized placental membrane allografts that are aseptically processed to preserve the native extracellular matrix and endogenous proteins of the tissue. They are indicated for homologous use as a biological barrier or wound cover, forming a protective cover for a variety of acute and chronic wounds. The products are enclosed in a sterile wrap then sealed in a sterile inner and secondary outer pouch. The outer pouch is contained in a labeled box. Allograft size is indicated on the package label. Using sterile forceps, the physician applies the graft directly onto the prepared wound bed with the stromal side directly against the wound bed. The graft absorbs the moisture directly from the wound be; however a few drops of sterile saline may be added to the graft after it has been applied to the wound if all areas are not rehydrated. The treated wound is covered with a non-adherent dressing followed by saline moistened gauze to fill but not pack the wound.

According to the applicant, there is currently a generic, nonspecific HCPCS Level II code (Q4100) that is reported for the use of these products, however, it is not specific to these products and does not uniquely describe the product like other codes for skin substitutes.

CMS Decision

Establish a new Level II HCPCS Code Q4235 "Amniorepair or altiply, per square centimeter."

Effective: 07/01/2020

Request# 20.046

Topic/Issue:

Request to establish a new Level II HCPCS code to identify buprenorphine and naloxone.

Applicant's suggested language: J057X, Buprenorphine and naloxone, oral, 16mg/4mg or greater, or ZUBSOLV, 11.4mg/2.9 mg sublingual tablet

Applicant's Summary

Connect 4 Strategies, LLC (on behalf of Orexo US, Inc.) submitted a request to establish a new HCPCS Level II code to accommodate and reflect the dosing distinctions FDA emphasized between ZUBSOLV and other oral buprenorphine/naloxone products and to enable appropriate billing and payment for an 11.4 mg/2.9 unit dose of ZUBSOLV or 16 mg buprenorphine dose strength of buprenorphine/naloxone. The current descriptor for J0575 is "Buprenorphine/naloxone, oral, greater than 10 mg."

J0575 is primarily used to report buprenorphine/naloxone formulations containing 12 mg buprenorphine, including Suboxone film and tablets and their generic equivalents. Although a 16 mg buprenorphine daily dose is a common target dose for patients in maintenance therapy for opioid use disorder, there is no HCPCS code to accurately report that a patient receives a 16 mg buprenorphine dose or corresponding dose strength of ZUBSOLV. The FDA-approved package insert for ZUBSOLV emphasizes that: the differences in bioavailability of ZUBSOLV compared to Suboxone tablet require that different tablet strengths be given to the patient. One ZUBSOLV 11.4 mg/2.9 mg sublingual tablet corresponds to a 16 mg/4 mg buprenorphine/naloxone dose, taken as two 8 mg/2 mg sublingual buprenorphine/naloxone tablets, a combination of dose strengths of Suboxone (or its generics) sublingual/buccal film, or a single 16 mg/4 mg buprenorphine/naloxone tablet (when approved and marketed).

The new HCPCS code being requested is: J0575X – Buprenorphine/naloxone, oral, 16 mg/4 mg or greater, or ZUBSOLV, 11.4 mg/2.9 mg sublingual tablet. ZUBSOLV contains buprenorphine and naloxone, and is indicated for treatment of opioid dependence as part of a complete treatment plan. Buprenorphine is a partial agonist at the mu-opioid receptor and an antagonist at the kappa-opioid receptor. Naloxone is a potent antagonist at mu-opioid receptors and produces opioid withdrawal signs and symptoms, if administered parentally, in individuals physically dependent on full opioid agonists. ZUBSOLV sublingual tablets are menthol-flavored white tablets supplied in aluminum/aluminum child resistant unit dose blister packages and available in six dosage strengths to facilitate induction, titration, maintenance and tapering.

CMS Decision

CMS is continuing to consider this request. In the meantime, existing codes J0572 "Buprenorphine/naloxone, oral, less than or equal to 3 mg buprenorphine", J0573 "Buprenorphine/naloxone, oral, greater than 3 mg, but less than or equal to 6 mg buprenorphine" and J0574 "Buprenorphine/naloxone, oral, greater than 6 mg, but less than or equal to 10 mg

buprenorphine" and J0575 "Buprenorphine/naloxone, oral, greater than 10 mg buprenorphine", as well as other codes, are available for assignment by insurers to identify Zubsolv products as they deem appropriate.

Request# 20.047

Topic/Issue:

Request to revise current Level II HCPCS code J0573, Buprenorphine/naloxone, oral, greater than 3 mg, but less than or equal to 6 mg buprenorphine.

Applicant's suggested language: J0573, Buprenorphine/Naloxone, oral, greater than 3 mg, but less than or equal to 6 mg, or ZUBSOLV, 2.9 mg/0.71 mg sublingual tablet

Applicant's Summary

Connect 4 Strategies, LLC (on behalf of Orexo US, Inc.) submitted a code modification request to revise the descriptive language for HCPCS Level II code J0573 to reflect differences in bioavailability between ZUBSOLV and other buprenorphine/naloxone products. The current descriptor for J0573 is "Buprenorphine/naloxone, oral, greater than 3 mg, but less than or equal to 6 mg."

J0573 is primarily used to report buprenorphine/naloxone formulations containing 4 mg buprenorphine, including Suboxone film and tablets and their generic equivalents. The FDA-approved package insert for ZUBSOLV emphasizes that: [t]he differences in bioavailability of ZUBSOLV compared to Suboxone tablet require that different tablet strengths be given to the patient. One ZUBSOLV 2.9 mg/0.71 mg sublingual tablet corresponds to a 4 mg buprenorphine dose administered as two 2 mg buprenorphine tablets of Suboxone tablet or its generics. A 4mg buprenorphine dosage strength is also available in a single 4 mg Suboxone (or its generics) buccal film. The applicant requests the descriptor be revised to accommodate and reflect the dosing distinctions FDA emphasized between ZUBSOLV and other oral buprenorphine/naloxone products as follows: J0573 – Buprenorphine/naloxone, oral, greater than 3 mg, but less than or equal to 6 mg., or ZUBSOLV, 2.9 mg/0.71 mg sublingual tablet. ZUBSOLV contains buprenorphine and naloxone, and is indicated for treatment of opioid dependence as part of a complete treatment plan. Buprenorphine is a partial agonist at the mu-opioid receptor and an antagonist at the kappa-opioid receptor. Naloxone is a potent antagonist at mu-opioid receptors and produces opioid withdrawal signs and symptoms, if administered parentally, in individuals physically dependent on full opioid agonists. ZUBSOLV sublingual tablets are menthol-flavored white tablets supplied in aluminum/aluminum child resistant unit dose blister packages and available in six dosage strengths to facilitate induction, titration, maintenance and tapering.

CMS Decision

CMS is continuing to consider this request. In the meantime, existing codes J0572 "Buprenorphine/naloxone, oral, less than or equal to 3 mg buprenorphine", J0573 "Buprenorphine/naloxone, oral, greater than 3 mg, but less than or equal to 6 mg buprenorphine" and J0574 "Buprenorphine/naloxone, oral, greater than 6 mg, but less than or equal to 10 mg buprenorphine" and J0575 "Buprenorphine/naloxone, oral, greater than 10 mg buprenorphine",

as well as other codes, are available for assignment by insurers to identify Zubsolv products as they deem appropriate.

Request# 20.048

Topic/Issue:

Request to revise current Level II HCPCS code J0574 Buprenorphine/naloxone, oral, greater than 6 mg, but less than or equal to 10 mg buprenorphine

Applicant's suggested language: J0574, Buprenorphine and naloxone, oral, greater than 6 mg, but less than or equal to 10 mg, or Zubsolv, 5.7mg/1.4 mg sublingual tablet

Applicant's Summary

Connect 4 Strategies, LLC (on behalf of Orexo US, Inc.) submitted a code modification request to revise the descriptive language for HCPCS Level II code J0574 to reflect differences in bioavailability between ZUBSOLV and other buprenorphine/naloxone products. The current descriptor for J0574 is "Buprenorphine/naloxone, oral, greater than 6 mg, but less than or equal to 10 mg."

J0574 is primarily used to report buprenorphine/naloxone formulations containing 8 mg buprenorphine and 2 mg naloxone, including Suboxone film and tablets and their generic equivalents. The FDA-approved package insert for ZUBSOLV emphasizes that: [t]he differences in bioavailability of ZUBSOLV compared to Suboxone tablet require that different tablet strengths be given to the patient. One ZUBSOLV 5.7 mg/1.4 mg sublingual tablet provides equivalent buprenorphine exposure to one Suboxone 8 mg/2 mg sublingual tablet.

The applicant requests the descriptor be revised to accommodate and reflect the dosing distinctions FDA emphasized between ZUBSOLV and other oral buprenorphine/naloxone products as follows: J0574 – Buprenorphine/naloxone, oral, greater than 6 mg, but less than or equal to 10 mg., or ZUBSOLV, 5.7 mg/1.4 mg sublingual tablet. ZUBSOLV contains buprenorphine and naloxone, and is indicated for treatment of opioid dependence as part of a complete treatment plan. Buprenorphine is a partial agonist at the mu-opioid receptor and an antagonist at the kappa-opioid receptor. Naloxone is a potent antagonist at mu-opioid receptors and produces opioid withdrawal signs and symptoms, if administered parentally, in individuals physically dependent on full opioid agonists. ZUBSOLV sublingual tablets are menthol-flavored white tablets supplied in aluminum/aluminum child resistant unit dose blister packages and available in six dosage strengths to facilitate induction, titration, maintenance and tapering.

CMS Decision

CMS is continuing to consider this request. In the meantime, existing codes J0572 "Buprenorphine/naloxone, oral, less than or equal to 3 mg buprenorphine", J0573 "Buprenorphine/naloxone, oral, greater than 3 mg, but less than or equal to 6 mg buprenorphine" and J0574 "Buprenorphine/naloxone, oral, greater than 6 mg, but less than or equal to 10 mg buprenorphine" and J0575 "Buprenorphine/naloxone, oral, greater than 10 mg buprenorphine", as well as other codes, are available for assignment by insurers to identify Zubsolv products as they deem appropriate.

Request# 20.049

Topic/Issue:

Request to revise current Level II HCPCS code J0575 Buprenorphine/naloxone, oral, greater than 10 mg buprenorphine

Applicant's suggested language: J0575, Buprenorphine/Naloxone, oral, greater than 10 mg, but less than16 mg, or Zubsolv, 8.6 mg/2.1 mg sublingual tablet

Applicant's Summary

Connect 4 Strategies, LLC (on behalf of Orexo US, Inc.) submitted a code modification request to revise the descriptive language for HCPCS Level II code J0575 to reflect differences in bioavailability between ZUBSOLV and other buprenorphine/naloxone products. The current descriptor for J0575 is "Buprenorphine/naloxone, oral, greater than 10 mg."

J0575 is primarily used to report buprenorphine/naloxone formulations containing 12 mg buprenorphine, including Suboxone film and tablets and their generic equivalents. The FDA-approved package insert for ZUBSOLV emphasizes that: [t]he differences in bioavailability of ZUBSOLV compared to Suboxone tablet require that different tablet strengths be given to the patient. One ZUBSOLV 8.6 mg/2.1 mg sublingual tablet corresponds to a 12 mg/3mg buprenorphine/naloxone dose, taken as one 8 mg/2 mg sublingual buprenorphine/naloxone tablet AND two 2 mg/0.5mg sublingual buprenorphine/naloxone tablets. A 12 mg buprenorphine dosage strength is also available in a single 12 mg Suboxone (or its generics) buccal film. NOTE: The applicant has submitted a separate application to request a new HCPCS Level II Code [J0575X] to reflect details for a higher dosage strength of 11.4 mg/2.9mg corresponding to a 16 mg/4mg buprenorphine/naloxone dose.

The applicant requests the descriptor be revised to accommodate and reflect the dosing distinctions FDA emphasized between ZUBSOLV and other oral buprenorphine/naloxone products as follows: J0575 – Buprenorphine/naloxone, oral, greater than 10 mg, but less than 16 mg, or ZUBSOLV, 8.6 mg/2.1 mg sublingual tablet. ZUBSOLV contains buprenorphine and naloxone, and is indicated for treatment of opioid dependence as part of a complete treatment plan. Buprenorphine is a partial agonist at the mu-opioid receptor and an antagonist at the kappa-opioid receptor. Naloxone is a potent antagonist at mu-opioid receptors and produces opioid withdrawal signs and symptoms, if administered parentally, in individuals physically dependent on full opioid agonists. ZUBSOLV sublingual tablets are menthol-flavored white tablets supplied in aluminum/ aluminum child resistant unit dose blister packages and available in six dosage strengths to facilitate induction, titration, maintenance and tapering.

CMS Decision

CMS is continuing to consider this request pending further consideration. In the meantime, existing codes J0572 "Buprenorphine/naloxone, oral, less than or equal to 3 mg buprenorphine", J0573 "Buprenorphine/naloxone, oral, greater than 3 mg, but less than or equal to 6 mg

buprenorphine" and J0574 "Buprenorphine/naloxone, oral, greater than 6 mg, but less than or equal to 10 mg buprenorphine" and J0575 "Buprenorphine/naloxone, oral, greater than 10 mg buprenorphine", as well as other codes, are available for assignment by insurers to identify Zubsolv products as they deem appropriate.

Request# 20.050

Topic/Issue:

Request to establish a new Level II HCPCS code to identify Wharton's jelly-derived human cell and tissue product.

Trade name: PolyCyte

Applicant's suggested language: Q4XXX PolyCyte, per 0.5 mL

Applicant's Summary

Predictive Biotech kindly requests to establish a new Level II HCPCS code to identify a Wharton's jelly derived human cell and tissue product PolyCyte.

PolyCyte is a minimally manipulated human tissue allograft derived from the Wharton's jelly of the umbilical cord. It is processed to preserve the cytokines, growth factors and proteins of Wharton's jelly for homologous use. PolyCyte is intended for use in repair, reconstruction, replacement or supplementation of a recipient's cells or tissue by performing the same basic functions of Wharton's jelly in the recipient as it would in the donor. The amount and administration (injected or topical) of the allograft is determined by the clinician based on the intended use in each patient. The product is distributed as a liquid allograft contained in a vial that is shipped frozen for preservation (-80C on dry ice) and is intended to be stored in that frozen state (-60C to -80C or colder) until used or expiration date is reached. It can be ordered in 3 vial sizes: 0.5 mL, 1 mL or 2 mL. The product is simply drawn up after proper thawing using a 21G-23G needle to syringe and then prepared and applied. According to the applicant, existing categories for products similar to PolyCyte are inadequate due to variances in the way these products are received, processed and preserved, therefore, each product yields a potentially different consistency and activity of active components that may or may not best represent the donor source. As per the applicant, the payers are carefully reviewing each product and being highly selective of those that they are willing to cover as medically necessary.

CMS Decision

Establish new level II HCPCS code Q4241 "Polycyte, for topical use only, per 0.5 cc."

Effective: 07/01/2020

After review of FDA's guidance, it does not appear to CMS that the non-topical uses such as injection for cartilage repair that are also the subject of this application are appropriate for regulation solely under section 361 of the Public Health Service Act. 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 this 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.

Information regarding the RFD Process is located at
https://www.fda.gov/combinationproducts/rfdprocess/default.htm.

Request# 20.051

Topic/Issue:

Request to establish a new Level II HCPCS code to identify an amniotic matrix-derived human cell and tissue product.

Trade name: AmnioCyte Plus

Applicant's suggested language: Q4XXX AmnioCyte Plus, per 0.5 mL

Applicant's Summary

Predictive Biotech kindly requests to establish a new Level II HCPCS code to identify an amniotic matrix derived human cell and tissue product AmnioCyte Plus.

AmnioCyte Plus is a minimally manipulated human tissue allograft derived from the extracellular matrix of the amniotic membrane. It is processed to preserve the cytokines, growth factors and scaffolding proteins from within the amniotic membrane matrix for homologous use. AmnioCyte Plus is intended for use in repair, reconstruction, replacement or supplementation of a recipient's cells or tissue by performing the same basic functions of amniotic membrane matrix in the recipient as it would in the donor. The amount and administration (injected or topical) of the allograft is determined by the clinician based on the intended use in each patient. The product is distributed as a liquid allograft contained in a vial that is shipped frozen for preservation (-80C on dry ice) and is intended to be stored in that frozen state (-60C to -80C or colder) until used or expiration date is reached. It can be ordered in 3 vial sizes: 0.5 mL, 1 mL or 2 mL. The product is simply drawn up after proper thawing using a 21G-23G needle to syringe and then prepared and applied.

According to the applicant, existing categories for products similar to AmnioCyte Plus are inadequate due to variances in the way these products are received, processed and preserved, therefore, each product yields a potentially different consistency and activity of active components that may or may not best represent the donor source. As per the applicant, the payers are carefully reviewing each product and being highly selective of those that they are willing to cover as medically necessary.

CMS Decision

Establish a new Level II HCPCS code Q4242 "Amniocyte plus, per 0.5 cc."

Effective: 07/01/2020

Request# 20.052

Topic/Issue:

Request to establish a new Level II HCPCS code to identify an amniotic matrix-derived human cell and tissue product.

Trade name: AmnioCyte

Applicant's suggested language: Q4XXX AmnioCyte, per 0.5 mL

Applicant's Summary

Predictive Biotech kindly requests to establish a new Level II HCPCS code to identify an amniotic fluid derived human cell and tissue product AmnioCyte.

AmnioCyte is a minimally manipulated human tissue allograft derived from the amniotic fluid that is processed to preserve the cytokines, growth factors and proteins in the amniotic fluid. AmnioCyte is intended for use in repair, reconstruction, replacement or supplementation of a recipient's cells or tissue by performing the same basic functions of amniotic fluid in the recipient as it would in the donor. The amount and administration (injected or topical) of the allograft is determined by the clinician based on the intended use in each patient. The product is distributed as a liquid allograft contained in a vial that is shipped frozen for preservation (-80C on dry ice) and is intended to be stored in that frozen state (-60C to -80C or colder) until used or expiration date is reached. It can be ordered in 3 vial sizes: 0.5 mL, 1 mL or 2 mL. The product is simply drawn up after proper thawing using a 21G-23G needle to syringe and then prepared and applied.

According to the applicant, existing categories for products similar to AmnioCyte are inadequate due to variances in the way these products are received, processed and preserved, therefore, each product yields a potentially different consistency and activity of active components that may or may not best represent the donor source. As per the applicant, the payers are carefully reviewing each product and being highly selective of those that they are willing to cover as medically necessary.

CMS Decision

After review of FDA's guidance, it does not appear to CMS that the product that is the subject of this application, is appropriate for regulation solely under section 361 of the Public Health Service Act. 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 this 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. Information regarding the RFD Process is located at https://www.fda.gov/combinationproducts/rfdprocess/default.htm.

Request# 20.053

Topic/Issue:

Request to establish a new Level II HCPCS code to identify an amniotic membrane-derived human tissue allograft suspension product.

Trade name: AmnioText

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

Applicant's Summary

Regenative Labs requests to establish a new Level II HCPCS code for Amniotext.

Amniotext is a minimally manipulated, amniotic membrane derived, human tissue allograft suspension product. The product serves to provide a barrier/support function and to aid in healing of defect. It is intended to provide the extracellular matrix needed for the infiltration, attachment and proliferation of cells required for the repair of damaged tissue. Amniotic membrane human tissue based products have shown to reduce scarring, fibrosis and adhesions in surgical and wound sites. It is administered through a syringe to the defect and the amount is determined by the clinician based on the size of the defect. As per applicant, each human tissue based product distributed by Regenative Labs is identified by its own unique serial number. The product is packaged in a transport protective pouch. The product is contained in a cryogenic primary tissue container, which contains a product label that includes the product details such as unique product number, storage requirements and volumes. Contents are aseptically processed and are not considered sterile.

According to the applicant, currently available HCPCS codes for skin substitutes are product and brand specific, therefore there is no code that can presently be used to identify the product.

CMS Decision

Establish a new Level II HCPCS code Q4245 "Amniotext, per cc"

Effective: 07/01/2020

Request# 20.054

Topic/Issue:

Request to establish a new Level II HCPCS code to identify a Wharton's jelly-derived human tissue allograft.

Trade name: CoreText/ProText

Applicant's suggested language: CoreText, ProText, per cc

Applicant's Summary

Regenative Labs requests a new Level II HCPCS code for CoreText/ProText.

CoreText and ProText are regulated by the FDA as a human tissue product subject to Section 361 of the Public Service Act and 21 CFR 1271. The products are very similar. Wharton's jelly products have been shown to reduce scarring, fibrosis and adhesions in surgical and wound sites. The difference between ProText and CoreText is that the cell sorter used in the preparation of Protext is 300 um mesh and for CoreText is 200um. Thus the particle fiber size is larger for ProText. Both the products are intended to provide the extracellular matrix needed for the infiltration, attachment and proliferation of cells required for the repair of damaged tissue. They are typically used for muscle and cartilage tears and help to repair damaged tissue. The products are used for wounds and tissue defects and is applied directly to the defect using a syringe. The amount used depends on the size of the defect and the clinicians' discretion. As per applicant, each human tissue based product distributed by Regenative Labs is identified by its own unique serial number. The product is packaged in a transport protective pouch. The product is contained in a cryogenic primary tissue container, which contains a product label that includes the product details such as unique product number, storage requirements and volumes. Contents are aseptically processed and are not considered sterile.

According to the applicant, currently available HCPCS codes for skin substitutes are product and brand specific, therefore there isn't a code that can presently be used to identify the products.

CMS Decision

Establish a new Level II HCPCS code Q4246 "Coretext or Protext, per cc."

Effective: 07/01/2020

Request# 20.055

Topic/Issue:

Request to establish a new Level II HCPCS code for Amniotext patch.

Applicant's suggested language: Amniotext patch, per square centimeter.

Applicant's Summary

Regenative Labs requests a new Level II HCPCS code for Amniotext patch.

Amniotext patches are minimally manipulated, amniotic membrane-derived, human tissue allografts. The product serves as wound covering. It is typically used for chronic non-healing wounds such as diabetic foot ulcers and venous leg ulcers. It provides the extracellular matrix needed for the infiltration, attachment and proliferation of cells required for repair of damaged tissue. The graft is applied directly to the wound bed and is available in various sizes, the size used matches the wound defect. As per applicant, each human tissue based product distributed by Regenative Labs is identified by its own unique serial number. The product is packaged in a transport protective pouch. The product is contained in a dual package tissue container system, in which the outermost ploy-foil pouch contains a product label that includes the product details such as unique product number, storage requirements and size. Contents are aseptically processed and sterilized, and are considered sterile.

According to the applicant, currently available HCPCS codes for skin substitutes are product and brand specific, therefore, there is no code that can presently be used to identify the product.

CMS Decision

Establish a new Level II HCPCS code Q4247 "Amniotext patch, per square centimeter."

Effective: 07/01/2020

Request# 20.056

Topic/Issue:

Request to establish a new Level II HCPCS code for Dermacyte Liquid.

Applicant's suggested language: QXXXX, Dermacyte Liquid, per mL.

Applicant's Summary

Merakris requests to establish a new Level II HCPCS code for Dermacyte Liquid.

Dermacyte Amniotic Wound Care Liquid is an amniotic fluid allograft. The function of the product is to treat non-infected partial-thickness skin ulcers (Diabetic Foot Ulcer, Venous Stasis Ulcer, and Decubitus Ulcer) greater than 6 week duration that have not adequately responded to conventional therapy or as clinically indicated. Dermacyte Liquid is a non-structural acellular human amniotic fluid allograft with preserved cytokines, micro vesicles and hyaluronic acid. It provides a natural hypotonic solution for use in lubricating, protecting and allowing for nutrient exchange in and around damaged tissue during healing. Following preparation of the wound bed to ensure it is free of necrotic tissue, the clinician selects a volume of Dermacyte Liquid based on the size of the wound. The clinician thaws the cryovial containing Dermacyte for 5 to 10 minutes, and then aspirates the product from the vial into a syringe. It may then be sprayed onto or injected around and/or into the wound bed. Dermacyte Liquid is used across a range of ages in male and female patients who have chronic wounds refractory to conventional therapy.

According to the applicant, no existing code specifically identifies this product's unique properties of sterile filtered amniotic fluid processed to remove all debris and/ or particulate.

CMS Decision

After review of FDA's guidance, it does not appear to CMS that the product that is the subject of this application is 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 this 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. Information regarding the RFD Process is located at https://www.fda.gov/combinationproducts/rfdprocess/default.htm.

Request# 20.057

Topic/Issue:

Request to establish a new Level II HCPCS code to identify esketamine nasal spray. Trade Name: Spravato

Applicants suggested language: JXXXX "Nasal spray, esketamine, 28mg."

Applicant Summary

Johnson & Johnson Health Care Systems Inc. submitted a request to establish a new Level II HCPCS code to identify Spravato (Esketamine). Spravato is a non-competitive NMDA receptor antagonist indicated, in conjunction with an oral antidepressant, for treatment-resistant depression in adults. According to the applicant, the nasal spray device is a single-use device that delivers a total of 28 mg of esketamine in two sprays (one spray per nostril). To prevent loss of medication, the device should not be primed before use. The approved doses are 56 mg or 84 mg. It is intended for administration by the patient under the direct supervision of a healthcare provider, using 2 devices (for a 56 mg dose) or 3 devices (for an 84 mg dose), with a 5-minute rest between use of each device. The treatment session consists of healthcare provider supervision of the patient's administration of Spravato and post-administration observation of the patient for at least 2 hours. Direct supervision by a healthcare provider is necessary to ensure the dose is administered properly. In addition, clinicians need to monitor blood pressure pre- and post-administration. During and after esketamine nasal spray administration at each treatment session, a healthcare provider is required to observe the patient until the patient is considered clinically stable and safe to leave, based on clinical judgment. Due to the risk of serious side effects of sedation; dissociation; abuse and misuse, clinicians are required to monitor patients for at least 2 hours following administration at every treatment session, per the Spravato Risk Evaluation and Mitigation Strategy (REMS).

CMS Decision

Existing codes 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", adequately describe esketamine. These codes include administrative service and the drug. CMS does not have confirmation of a claims processing need on the part of another insurance payer or sector for a code to separately identify the drug without service. We would welcome an application in subsequent coding cycle if the situation changes.

Request# 20.058

Topic/Issue:

Request to establish a new Level II HCPCS code to identify a cryopreserved semi-transparent, collagenous membrane allograft, Trade Name: Cryo-Cord.

Applicant's suggested language: "Cryo-Cord, per square centimeter." Pending completeness

Applicant's Summary

Royal Biologics submitted a request to establish a new Level II HCPCS code to identify Cryo-Cord. Cryo-Cord is an umbilical cord product that is applied directly to a non-healing wound. It is a cryopreserved product that serves as wound covering. Cryo-cord is minimally manipulated, semi-transparent, collagenous membrane allograft obtained with consent from healthy mothers during cesarean section delivery. Cryo-cord is derived from the umbilical cord. It is typically used for chronic non-healing wounds or affected area. There are multiple product sizes; the provider uses the size that most closely matches the wound. It comes in a pouch.

As per the applicant, HCPCS code Q4100 is a generic code and is not meant to be used long term. Applicant also stated that all cellular and tissue based products are reimbursed using a product specific HCPCS (Q-code) and that not all MACs reimburse for Q4100 and none of the commercial payers do, hence, in order to secure long term coverage, a product/brand specific HCPCS code is necessary.

CMS Decision

Establish a new Level II HCPCS code Q4237 "Cryo-cord, per square centimeter."

Effective: 07/01/2020

Request# 20.059

Topic/Issue:

Request to establish a new Level II HCPCS code to identify a freeze dried decellularized dermal matrix allograft, Trade Name: Derm-Maxx.

Applicant's suggested language: "Derm-Maxx, per square centimeter."

Applicant's Summary

Royal Biologics submitted a request to establish a new Level II HCPCS code to identify Derm-Maxx. Derm-Maxx is a freeze-dried decellularized dermal matrix allograft that is provided from consenting donors. It is used for integumentary augmentation and serve as a covering for wounds and skin defects. The Derm-Maxx Allograft is produced using a process that reduces native nucleic acids, cells and other antigenic material while preserving the collagen matrix with vascular channels. The extracellular matrix supports cellular infiltration, attachment, and proliferation. The unique processing technique preserves the collagen and elastic tissue fibers while maintaining the open channels through which cells can migrate, proliferate and form new blood vessels. This biologic process is crucial to the integration and remodeling of the allograft by host cells. Derm-Maxx comes in various sizes; the provider uses the size that most closely matches the skin defect or the wound area. It is applied directly to the affected area. It comes in sterile pouches.

As per the applicant, HCPCS code Q4100 is a generic code and is not meant to be used long term. Applicant also stated that all cellular and tissue based products are reimbursed using a product specific HCPCS (Q-code) and that not all MACs reimburse for Q4100 and none of the commercial payers do, hence, in order to secure long term coverage, a product/brand specific HCPCS code is necessary.

CMS Decision

Establish a new level II HCPCS code Q4238 "Derm-maxx, per square centimeter."

Effective: 07/01/2020.

Request# 20.060

Topic/Issue:

Request to establish a new Level II HCPCS code to identify dehydrated amniotic tissue membrane graft. Trade Name: Amnio-Maxx and Amnio-Maxx Lite.

Applicant's suggested language: "Amnio-Maxx, Amnio-Maxx Lite, per square centimeter."

Applicant's Summary

Royal Biologics submitted a request to establish a new Level II HCPCS code to identify Amnio-Maxx and Amnio-Maxx Lite. Amnio-Maxx is a dual layered, dehydrated, amniotic tissue membrane graft derived from Cesarean Section donors. The Amnio-Maxx Lite version is a single layer. The product is for wound covering, applied directly to the wound bed. Both products are used for chronic, non-healing wounds such as diabetic foot ulcers and venous leg ulcers or soft tissue defects. Amniotic tissue consists primarily of fibrillary and membranous collagens, elastin, and a mix cytokines and growth factors that provide the properties unique to placental tissues. There are various sizes of each product; the provider uses the size that most closely matches the wound size. Once the graft has been applied, it is covered with a bandage. Amnio-Maxx and Amnio-Maxx-Lite both come in sterile pouches.

As per the applicant, HCPCS code Q4100 is a generic code and is not meant to be used long term. Applicant also stated that all cellular and tissue based products are reimbursed using a product specific HCPCS (Q-code) and that not all MACs reimburse for Q4100 and none of the commercial payers do, hence, in order to secure long term coverage, a product/brand specific HCPCS code is necessary.

CMS Decision

Establish a new Level II HCPCS code Q4239 "Amnio-maxx or Amnio-maxx lite, per square centimeter."

Effective: 07/01/2020

Request# 20.061

Topic/Issue:

Request to establish a new Level II HCPCS code to identify a semi-transparent collagenous membrane allograft. Trade Name: Amnio Maxx UC.

Applicant's suggested language: "Amnio Maxx UC, per square centimeter."

Applicant's Summary

Royal Biologics submitted a request to establish a new Level II HCPCS code to identify Amnio Maxx UC. Amnio Maxx UC is a semi-transparent, collagenous membrane allograft. It is derived from umbilical cord. The product serves as a wound cover or a soft tissue barrier. It 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. Amnio Maxx UC comes in a sterile pouch.

As per the applicant, HCPCS code Q4100 is a generic code and is not meant to be used long term. Applicant also stated that all cellular and tissue based products are reimbursed using a product specific HCPCS (Q-code) and that not all MACs reimburse for Q4100 and none of the commercial payers do, hence, in order to secure long term coverage, a product/brand specific HCPCS code is necessary.

CMS Decision

The product's literature and application specifies Amnio Maxx UC. This Brand (Amnio Maxx UC) does not appear on HCT/P, and as such, CMS is not able to process this application. Applicant is welcome to submit a complete application in a subsequent coding cycle.

Request# 20.062

Topic/Issue:

Request to modify an existing Level II HCPCS code Q4176 "NeoPatch per sq. cm", to include the new brand name Therion.

Applicant's suggested code language: Q4176 "NeoPatch or Therion per sq. cm".

Applicant's Summary

Therion choriamniotic membrane allograft is a minimally-processed human tissue allograft that is intended for homologous use. Therion will be used to treat patients with chronic wounds, including but not limited to diabetic foot ulcers and venous leg ulcers, in hospital outpatient wound care clinics and physician offices sites of service. Therion is a single-use, resorbable human choriamniotic membrane allograft that is administered by a physician as a wound covering to aid in the repair or replacement of lost or damaged tissue. Therion and NeoPatch are equivalent in their composition and manufacture.

According to the applicant, the existing HCPCS Level II code categories for biologic skin substitutes are based on the composition of the product and are brand-specific. While the Therion product is identical to NeoPatch, the current code to describe Therion is Q4100 'skin substitute not otherwise classified per sq. cm'. The use of code Q4100 is inadequate because it does not facilitate differentiation based on low/high cost in hospital outpatient reimbursement, does not allow for coverage and payment from private payers, and does not allow for tracking and operational uses that will inform future coverage and payment. This request seeks to add the Therion trade name to the description for HCPCS Level II Q4176 'NeoPatch per sq. cm'. The HCPCS Level II code for NeoPatch is Q4176 'NeoPatch per sq. cm'. Numerous third-party payer medical policies list the code Q4176 to report NeoPatch per sq. cm.

CMS Decision

Revise existing code Q4176 which currently reads: "Neopatch, per square centimeter" to instead read: "Neopatch or Therion, per square centimeter."

Effective: 07/01/2020

Request# 20.091

Topic/Issue:

Request to establish a new Level II HCPCS code for Dermacyte Amniotic Wound Care Matrix.

Applicant's suggested language: QXXXX, "Dermacyte Matrix, per sq cm."

Applicant's Summary

Applicant requested to establish a new Level II HCPCS code for Dermacyte Amniotic Wound Care Matrix.

Dermacyte is an amniotic membrane allograft. The function of the product, according to its indicated use, is to treat non-infected partial thickness skin ulcers (Diabetic foot Ulcer, Venous Stasis Ulcer, Decubitus Ulcer) greater than 1-month duration and which have not adequately responded to conventional therapy, or as clinically indicated. It provides a protective extracellular matrix to cover wounds and support cell attachment and ingrowth during healing of chronic non-healing wounds. Following the preparation of the wound bed to ensure it is free from necrotic tissue, a clinician selects Dermacyte Matrix according to the wound size and applies the product to the wound using aseptic technique followed by compression wraps to secure the product in place. It may be used across a range of ages in male and female patient populations with chronic wounds refractory to conventional therapy or as clinically indicated. The mean patient age is approximately 60 years of age based on existing literature, and a range between 18 and 80 years of age.

According to the applicant, no existing code specifically identifies this product, which has the unique properties of a human amniotic membrane allograft that is cross-linked to provide an extended rate of bio resorption to protect the wound bed as it heals.

CMS Decision

Establish a new HCPCS Level II code Q4248 "Dermacyte Amniotic Membrane Allograft, per square centimeter"

Effective: 07/01/2020