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

Second 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' Second Quarter 2020 Drug and Biological HCPCS code application review cycle. Each individual summary includes: the application number; topic; summary of the applicant's request as written by the applicant with occasional minor, non-substantive editorial changes made by CMS; CMS' HCPCS coding decision; and the effective date of any coding action which, for the purpose of this publication, refers to the date the code is first available to be billed on claims.

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

Request# 20.093

Topic/Issue

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

Applicant's suggested language: Injection, bimatoprost, intracameral implant, 10 mcg.

Applicant's Summary

Allergan submitted a request to establish a new Level II HCPCS code to identify DURYSTA.

DURYSTA (bimatoprost implant) is a single-source drug product indicated for the reduction of intraocular pressure (IOP) in patients with open angle glaucoma (OAG) or ocular hypertension (OHT). The active ingredient in DURYSTA is bimatoprost, a synthetic structural analog of prostaglandin with ocular hypotensive activity. No other bimatoprost drug product has been assigned a HCPCS code. Moreover, no other bimatoprost drug product comprises an implant for intracameral administration, nor is any other formulation of bimatoprost therapeutically equivalent to DURYSTA. DURYSTA is believed to lower IOP by increasing outflow of aqueous humor through both the trabecular meshwork (conventional) and uveoscleral routes (unconventional). Bimatoprost intracameral implant will sustain drug levels in target tissues and maintain IOP-lowering efficacy in patients with open angle glaucoma (OAG) or ocular hypertension (OHT). It is an intracameral implant containing l0 mcg of bimatoprost in a drug delivery system. DURYSTA is administered via intracameral injection and is supplied as a 10 mcg implant in a single-use applicator that is packaged in a sealed foil pouch containing desiccant.

As per the applicant, there are no HCPCS codes for any bimatoprost products.

Final Decision

Establish new Level II HCPCS code J7351 "Injection, bimatoprost, intracameral implant, 1 microgram".

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: 10/01/2020

Request# 20.094

Topic/Issue

Request to establish a new Level II HCPCS code to identify MONOFERRIC (ferric derisomaltose) injection.

Applicant's suggested language: JXXXX - injection, ferric derisomaltose, 100 mg.

Applicant's Summary

Pharmacosmos Therapeutics, Inc. submitted a request to establish a new Level II HCPCS code to identify MONOFERRIC (ferric derisomaltose) injection.

Monoferric is an iron replacement product indicated for the treatment of iron deficiency anemia (lDA) in adult patients who have intolerance to oral iron or have had unsatisfactory response to oral iron or for those adult patients who have non-hemodialysis dependent chronic kidney disease (NDD CKD). Monoferric is an iron carbohydrate complex with a matrix structure composed of interchanging layers of ferric hydroxide and the carbohydrate derisomaltose. Derisomaltose consists of linear, hydrogenated isomaltooligosaccharides with an average molecular weight of 1000 Da and a narrow molecular weight distribution that is almost devoid of mono- and disaccharides. Monoferric is a complex of iron (lll) hydroxide and derisomaltose 1000, an iron carbohydrate oligosaccharide that releases iron. Iron binds to transferrin for transport to erythroid precursor cells to be incorporated into hemoglobin. The recommended dose of Monoferric depends on a patient's weight. For patients weighing 50 kg or more, the recommended dose is one dose as 1,000 mg of iron per course; for patients weighing less than 50 kg, Monoferric should be given in one dose as 20 mg/kg body weight per course. The dosage of Monoferric is expressed in milligram of elemental iron. Each mL of Monoferric contains 100 mg of elemental iron. Monoferric treatment may be repeated if iron deficiency anemia reoccurs. Monoferric is administered intravenously via infusion over at least 20 minutes. lt is provided as a sterile, dark brown, non-transparent aqueous solution with pH 5.0-7.0, containing ferric derisomaltose dissolved in water for injections and filled into Type I glass vials. Monoferric vials are intended for single use.

As per the applicant, Monoferric is a unique molecule and no current HCPCS code adequately describes this product.

Final Decision

Establish new Level II HCPCS code J1437 "Injection, ferric derisomaltose, 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: 10/01/2020

Request# 20.095

Topic/Issue

Request to establish a new Level II HCPCS code for TEPEZZA (teprotumumab-trbw) injection, for intravenous use.

Applicant's suggested language: JXXXX- Injection, teprotumumab-trbw, l0 mg.

Applicant's Summary

Horizon Therapeutics USA, Inc. (Horizon) submitted a request to establish a new Level II HCPCS code to identify TEPEZZA (teprotumumab-trbw) injection, for intravenous use.

TEPEZZA is an insulin-like growth factor-1 receptor inhibitor (IGF-1R) indicated for the treatment of thyroid eye disease (TED). TEPEZZA is a fully human IgG1 monoclonal antibody produced in Chinese hamster ovary (CHO-DG44) cells. TEPEZZA binds to IGF-1R and blocks its activation and signaling. The recommended dose of TEPEZZA is an initial dose of 10 mg/kg administered as a 90-minute intravenous infusion, followed by a 20 mg/kg dose administered as a 90-minute intravenous infusion, followed by a 20mg/kg dose administered as a 60 to 90-minute intravenous infusion provided every 3 weeks. The recommended course of therapy is 8 infusions. TEPEZZA is administered as an intravenous infusion and should only be prepared and administered by a healthcare provider. TEPEZZA is supplied as a sterile, preservative-free, white to off-white, lyophilized powder for intravenous infusion in a single-use vial delivering 500mg of teprotumumab-trbw, L- histidine, L-histidine hydrochloride monohydrate, polysorbate 20, and trehalose dihydrate (NDC 75987-0130- 1s).

As per the applicant, TEPEZZA is a biological that was approved under a unique biologics license application (BLA). There is no existing HCPCS code that adequately describes TEPEZZA.

Final Decision

Establish new Level II HCPCS code J3241 "Injection, teprotumumab-trbw, 10 mg"

Effective: 10/01/2020

Request# 20.097

Topic/Issue

Request to establish a new Level II HCPCS code to identify VYEPTI (eptinezumab-jjmr)

Applicant's suggested language: JXXXX: Injection, eptinezumab-jjmr, 100 mg.

Applicant's Summary

Lundbeck LLC submitted a request to establish a new Level II HCPCS code to identify VYEPTI (eptinezumab-jjmr).

VYEPTI (eptinezumab-jjmr) is a humanized immunoglobulin G1 (lgG1) monoclonal antibody specific for calcitonin gene-related peptide (CGRP) ligand. It binds to calcitonin gene-related peptide (CGRP) ligand and blocks its binding to the receptor. VYEPTI (eptinezumab-jjmr) was approved by the FDA under a Biologics License Application (BLA) on February 21, 2020 and is indicated for the preventive treatment of migraine in adults. VYEPTI (eptinezumab-jjmr) inhibits the activity of calcitonin gene-related peptide (CGRP), a neuropeptide known to play a key role in initiating and mediating migraine. The recommended dosage is 100 mg administered by intravenous infusion every 3 months. Some patients may benefit from a dosage of 300 mg administered by intravenous infusion every 3 months. VYEPTI (eptinezumab-jjmr) is a clear to slightly opalescent, colorless to brownish-yellow solution supplied in a carton containing one 100 mg/ml single-dose vial.

According to the applicant, there are currently no other drugs or biologicals with the same active ingredient category/generic name as VYEPTI™ (eptinezumab-jjmr) and therefore, no existing HCPCS codes adequately describe this product.

Final Decision

Establish new Level II HCPCS code J3032 "Injection, eptinezumab-jjmr, 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: 10/01/2020

Request# 20.098

Topic/Issue

Request to establish a new Level II HCPCS code to identify isatuximab-irfc.

Trade Name: SARCLISA

Applicant's suggested language: J9XXX- Injection, isatuximab-irfc, 10 mg.

Applicant's Summary

Sanofi submitted a request to establish a new Level II HCPCS code to identify its new anticancer monoclonal antibody isatuximab-irfc.

Isatuximab-irfc is an IgG1-derived monoclonal antibody that binds to CD38 expressed on the surface of hematopoietic and tumor cells, including multiple myeloma cells. Isatuximab-irfc induces apoptosis of tumor cells and activation of immune effector mechanisms including antibody-dependent cell mediated cytotoxicity (ADCC), antibody-dependent cellular phagocytosis (ADCP), and complement dependent cytotoxicity (CDC). Isatuximab-irfc is indicated, in combination with pomalidomide and dexamethasone, for the treatment of adult patients with multiple myeloma who have received at least two prior therapies including lenalidomide and a proteasome inhibitor. The product is dosed at 10mg/kg. Patients weighing more than 220 lbs will require doses in excess of 1,000 mg. The product is administered by intravenous infusion following a schedule of controlled infusion rates published in the package insert. The product is provided in 100 mg and 500 mg single use vials.

According to the applicant, there are no current HCPCS Level II code that currently describe isatuximab-irfc and a new single unique and permanent HCPCS level II J9XXX code is required. As patients over 220 lbs will be dosed at more than 1,000 mg, Sanofi requests that the units in the dose descriptor be 10 mg. This will ensure that a dose of isatuximab-irfc can be recorded on one line on either the CMS 1450 or CMS 1500 claim forms.

Final Decision

Establish new Level II HCPCS code J9227 "Injection, isatuximab-irfc, 10 mg"

Effective: 10/01/2020

Request# 20.099

Topic/Issue:

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

Trade name: Macrilen

Applicant suggested language: JXXXX macimorelin 60 mg, oral solution.

Applicant's Summary

Novo Nordisk submitted a request to establish a new Level II HCPCS code to identify MACRILEN (macimorelin). MACRILEN is a drug product (ghrelin analogue) that stimulates the release of growth hormone from the pituitary gland and is used to aid in the diagnosis of adult growth hormone deficiency (AGHD). It is the only FDA approved oral drug stimulant used in the process of the diagnosis of adult growth hormone deficiency. Following administration of MACRILEN the patient has four serial blood draws at 30, 45, 60, and 90 minutes; these blood samples are tested for human growth hormone levels in a clinical laboratory. MACRILEN is indicated for the diagnosis of adult growth hormone deficiency (AGHD). It stimulates GH release by activating growth hormone secretagogue receptors (GHSR) mainly present in the pituitary and hypothalamus. MACRILEN is prescribed by a healthcare professional. MACRILEN solution should be prepared and administered by a health care professional. MACRILEN dose must be calculated based on each patient's body weight. The recommended single oral dose is defined as 0.5 mg MACRILEN per kg body weight. The dose is administered as a reconstituted MACRILEN oral solution, after the patient has fasted for a minimum of 8 hours. The solution must be used within 30 minutes after preparation. Discard unused portion. MACRILEN is supplied as 60 mg granules in a single dose pack, it requires a health care professional to prepare and administer as an oral solution, under physician supervision. When reconstituted with 120 mL of water provides a 60 mg/120 mL (0.5 mg/mL) macimorelin solution.

According to the applicant, there is no Level II HCPCS code(s) that describes MACRILEN.

Final Decision

This request to establish a new Level II HCPCS code to identify MACRILEN has not been approved. MACRILEN is not suitable for coding in Level II HCPCS. CMS refers the applicant to the AMA for consideration of the appropriateness of CPT coding, as with other lab tests that include oral administration of drugs followed by serial blood draws.

Request# 20.100

Topic/Issue

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

Applicant's suggested language: JXXXX- injection, pemetrexed (PEMFEXY), per 10 mg

Applicant's Summary

Eagle Pharmaceuticals, Inc. submitted a request to establish a new Level II HCPCS code to identify PEMFEXY (pemetrexed injection) for intravenous use.

PEMFEXY for intravenous use is a newly FDA-approved product indicated for the treatment of certain patients with non-squamous non-small cell lung cancer (NSCLC) OR Mesothelioma. It is a unique single source drug (NDA#209472). PEMFEXY is a novel liquid formulation of pemetrexed diacid, a folate analog metabolic inhibitor that disrupts folate dependent metabolic processes essential for cell replication. For all indicated uses, PEMFEXY is administered by intravenous infusion over 10 minutes on Day 1 of a 21-day treatment cycle at a recommended dose of 500 mg/m2 for patients with a creatinine clearance rate greater than or equal to 45ml/min. PEMFEXY is a clear, colorless to yellow or green-yellow solution supplied in a single-dose vial for intravenous use. Each ml of PEMFEXY contains 25mg pemetrexed diacid, 260 mg propylene glycol, up to 16.5-19.9mg tromethamine, and water for injection.

According to the applicant, no current, specific HCPCS code adequately describes PEMFEXY.

Final Decision

1. Establish new Level II HCPCS code J9304 "Injection, pemetrexed (PEMFEXY), 10 mg"

2. Revise long descriptor of existing code J9305 which currently reads "Injection, pemetrexed, 10 mg " to instead read "injection, pemetrexed, not otherwise specified, 10 mg"

Effective: 10/01/2020

Request# 20.101

Topic/Issue

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

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

Applicant's Summary

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

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

Final Decision

For the purpose of reporting to Medicare, SPRAVATO is bundled. We have not heard from non-Medicare insurers that a separate code to identify SPRAVATO is necessary for their claims processing. We seek to better understand whether a separate code (outside of a bundled payment) is needed, and by whom. As such, we are deferring this application for processing in a subsequent coding cycle as we anticipate further dialogue with Janssen Pharmaceutical Companies of Johnson & Johnson and others to obtain more specific policy information particularly in regard to private insurer policy for SPRAVATO.

Request# 20.102

Topic/Issue

Request to establish a new Level II HCPCS code to identify ZULRESSO (brexanolone) injection.

Applicant's suggested language: JXXXX - Injection, brexanolone, 1mg

Applicant's Summary

Sage Therapeutics, Inc. submitted a request to establish a new Level II HCPCS code to identify ZULRESSO (brexanolone) injection for IV infusion for the treatment of postpartum depression (PPD) in adults.

ZULRESSO was approved by the US Food & Drug Administration (FDA) on March 19, 2019. On June 17, 2019, the Drug Enforcement Administration (DEA) placed ZULRESSO into Schedule IV of the Controlled Substances Act. ZULRESSO is a neuroactive steroid gamma-aminobutyric acid (GABA) A receptor positive modulator indicated for the treatment of PPD in adults. ZULRESSO is the only pharmacologic therapy specifically indicated to treat PPD. ZULRESSO was granted transitional pass-through status as well as a new C-code which became effective January I, 2020. However, many hospitals have reported that they are unable to bill C-codes, to certain Medicaid and commercial health plans. Additionally, non-hospital providers, which serve 41 % of ZULRESSO patients to date, cannot bill C-codes. ZULRESSO injection is supplied as 100 mg brexanolone in 20 mL (5 mg/mL) single-dose vials containing a sterile, preservative-free, clear, colorless solution intended for dilution prior to administration. ZULRESSO is administered as a continuous intravenous (IV) infusion over a total of 60- hours requiring titration: 0 to 4 hours: Initiate with a dosage of 30 mcg/kg/hour ; 4 to 24 hours: Increase dosage to 60 mcg/kg/hour; 24 to 52 hours: Increase dosage to 90 mcg/kg/hour (a reduction in dosage to 60 mcg/kg/hour may be considered during this time period for patients who do not tolerate 90 mcg/kg/hour); 52 to 56 hours: Decrease dosage to 60 mcg/kg/hour; 56 to 60 hours: Decrease dosage to 30 mcg/kg/hour.

Final Decision

Establish new Level II HCPCS code J1632 "Injection, brexanolone, 1 mg"

Effective: 10/01/2020

Request# 20.103

Topic/Issue

Request to establish a new Level II HCPCS code to identify a bevacizumab pre-filled syringe.

Applicant's suggested language: J90XX - lntravitreal bevacizumab with Crystal Zenith Syringe, 25mg/ml.

Applicant's Summary

Fagron submitted a request to establish a new Level II HCPCS code to identify the Crystal Zenith (CZ COP) Syringe with a descriptor that provides for utilization with either bevacizumab or its biosimilar therapy MVASI (bevacizumab-awwb) Q5107. A unique J code and increased reimbursement for the CZ COP syringe will increase the safety profile of these intravitreal injections.

The bevacizumab prefilled CZ COP Crystal Zenith Syringe is used off label for multiple ophthalmic indications. Fagron seeks a J code for bevacizumab and MVASI (and potentially other biosimilars to Avastin) to treat neovascular (wet) age-related macular degeneration (nAMD), macular edema following retinal vein occlusion (RVO), diabetic macular edema (DME) and diabetic retinopathy (DR). The bevacizumab prefilled Crystal Zenith Syringe, is intended for the long-term storage of a biologic and administration of intravitreal injections. The current containers used for prefilled bevacizumab syringes can lead to wide scale contamination of the sterile repackaging process because they were never intended for the long-term storage of any sterile solution let alone a complex protein drug product, such as bevacizumab. Issues with current syringes include, barrel lubricants mixing with the bevacizumab solution, stuck plungers (difficult to express solution) and rising particulate levels in the syringes, and container closure issues leading to significant adverse beneficiary outcomes and multiple FDA recalls. As more care moves to the home, a safer pre-filled syringe should accompany this care. The administration dose is-1.25mg I 0.05ml -50 µL. This is an intravitreal injection. The CZ COP syringe is packaged in a protective plastic sleeve, shipped five to a carton with a user information sheet to ensure proper administration of an intravitreal injection. The safety shell in which the syringes nest protects the plunger from movement and the tip cap from being damaged in transit protecting against displacement of the tip cap which could lead to microbial ingress. Current bevacizumab syringes are shipped in a bag without regard to damage to the syringe during transit. The protective plastic shell is placed inside of a cardboard sleeve further protecting the pre-filled syringes and allowing appropriate labeling of the closure and container.

According to the applicant, current reimbursements are inadequate to support the quality of this syringe. The additional expense of automated fill/finish machine, superior commodities and storage containers require a higher level of reimbursement to ensure a continuous supply of this vision and cost savings product. There are different levels of reimbursement and reimbursement varies depending on the company and the region. Through a unique HCPCS code and differentiated reimbursement rate, a standardized reimbursement rate can be established to cover

the additional expenses of preparing a pharmaceutical manufacturer equivalent bevacizumab syringe.

Final Decision

There is no FDA approval for the compounded biological and CMS does not provide unique codes for compounded biologics. We note that in the absence of a unique code for a compounded product, there is sufficient flexibility within the existing code set for insurers to assign other codes for use for reporting compounded products, if deemed appropriate. For instance, insurers that would pay for compounded biologics could assign miscellaneous biological code for use to identify the product that is the subject of this request on the claim if they deem appropriate.

Request# 20.104

Topic/Issue

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

Applicant's suggested language: QXXXX- Novafix DL, per sq. cm.

Applicant's Summary

Triad Life Sciences, Inc. submitted a request to establish a new Level II HCPCS code to identify Novafix DL. Novafix DL is a sterile, single use, dehydrated human amnion chorion membrane allograft used for safe and effective wound treatment. Novafix DL will fully resorb into the wound and provide a scaffold for cellular infiltration and vascularization. Working as a skin substitute, Novafix DL permits the ingress of cells and soft tissue formation in the defect space or wound bed. Novafix DL is intended for use in the management of wounds, including: partial and full thickness wounds, pressure sores/ulcers, venous 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, (e.g., abrasions, lacerations, partial thickness burns, skin tears), and draining wounds. It is applied on a wound after the wound bed is prepared with standard debridement methods. The product will fully resorb and does not have to be removed from the wound bed. Novafix DL is supplied terminally sterile, in a single use package in a variety of sizes. Novafix DL may be fenestrated, and/or reapplied as necessary.

According to the applicant, there are no current HCPCS codes to define a dehydrated (dry) amnion chorion membrane only extracellular matrix allograft with a known membrane nominal thickness of 50-100 microns that is sterilized through E-Beam irradiation to achieve a sterility assurance level of 10^-6. A new and unique HCPCS code is requested in order to facilitate proper billing and coding to all payers in the full range of site of care settings.

Final Decision

Establish new Level II HCPCS code Q4254 "Novafix DL, per square centimeter"

Effective: 10/01/2020

Request# 20.105

Topic/Issue

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

Applicant's suggested language: QXXXX- Innovacell, per ml.

Applicant's Summary

Triad Life Sciences, Inc. submitted a request to establish a new Level II HCPCS code for Innovacell.

Innovacell is a sterile, single use, 100% human amniotic fluid allograft used for safe and effective wound treatment. Innovacell will fully resorb into the wound and may provide a good healing environment for cellular infiltration and vascularization of the wound bed. Working as a skin substitute, Innovacell may provide the environment for the ingress of cells and soft tissue formation in the defect space or wound bed. Innovacell is intended for use in the management of wounds, including: partial and full thickness wounds, pressure sores/ulcers, venous 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, (e.g., abrasions, lacerations, partial thickness burns, skin tears), and draining wounds. It is applied on or into a wound after the wound bed is prepared with standard debridement methods. The product will fully resorb and does not have to be removed from the wound bed. Innovacell is supplied terminally sterile, in a single use package in a variety of sizes. Innovacell may be reapplied as necessary.

According to the applicant, there are no current HCPCS codes to define a 100% human amniotic fluid allograft and is recovered sterilely during scheduled C sections, visually inspected, processed in an aseptic controlled environment including filtration and terminal sterilization via lower dose gamma irradiation to achieve a sterility assurance level of 10^{-6}. A new and unique HCPCS code is requested in order to facilitate proper billing and coding to all payers in the full range of site of care settings.

Final Decision

After review of FDA's guidance, it does not appear to CMS that Innovacell is an HCT/P. CMS refers the applicant to the FDA's Tissue Reference Group (TRG) 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.

Request# 20.106

Topic/Issue

Request to establish a new Level II HCPCS code to identify Novafix PD.

Applicant's suggested language: Novafix PD, per mg.

Applicant's Summary

Triad Life Sciences, Inc. submitted a request to establish a new Level II HCPCS code to identify Novafix PD.

Novafix PD is a sterile, single use, dehydrated human amnion chorion membrane allograft morselized into a particulate based powder used for safe and effective wound treatment. Novafix PD will fully resorb into the wound and provides a scaffold for cellular infiltration and vascularization. Working as a skin substitute, Novafix PD permits the ingress of cells and soft tissue formation in the defect space or wound bed. Novafix PD is intended for use in the management of wounds, including: partial and full thickness wounds, pressure sores/ulcers, venous 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, (e.g., abrasions, lacerations, partial thickness burns, skin tears), and draining wounds. It is applied on and/or deep into a wound after the wound bed is prepared with standard debridement methods. The product will fully resorb and does not have to be removed from the wound bed. Novafix PD is supplied terminally sterile, in a single use package, in a variety of sizes, and can be applied as a particulate or hydrated with sterile water, saline or blood for precise syringe delivery. Novafix PD may be reapplied as necessary.

According to the applicant, there are no current HCPCS codes to define a dehydrated (dry) particulate based powdered amnion chorion allograft with a known particle size less than 200 microns that is sterilized through lower dose gamma irradiation to achieve a sterility assurance level of 10^{-6}. A new and unique HCPCS code is requested in order to facilitate proper billing and coding to all payers in the full range of site of care settings.

Final Decision

After review of FDA's guidance, it does not appear to CMS that Novafix PD is an HCT/P. CMS refers the applicant to the FDA's Tissue Reference Group (TRG) 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

Request# 20.107

Topic/Issue:

Request to establish a new Level II HCPCS code to identify cocaine hydrochloride nasal solution, 4% (CII)

Applicant's suggested language: JXXXX-Solution, cocaine hydrochloride, 1 mg.

Applicant's Summary

Genus Lifesciences, Inc. submitted a request to establish a new Level II HCPCS code to identify cocaine hydrochloride nasal solution, 4% (CII).

Cocaine hydrochloride nasal solution, 4% (CII) is an ester local anesthetic. Cocaine hydrochloride nasal solution, 4% (CII), is an ester local anesthetic indicated for the induction of local anesthesia of the mucous membranes when performing diagnostic procedures and surgeries on or through the nasal cavities in adults. Cocaine hydrochloride prevents conduction in nerve fibers by reversibly blocking sodium channels and preventing the transient rise in sodium conductance. The recommended dose of cocaine hydrochloride nasal solution, 4% (CII) is two soaked cottonoid pledgets placed in each nasal cavity, equivalent to 40 mg cocaine hydrochloride per pledget, for a total dose of 160 mg for four pledgets. The route of administration is intranasal. Cocaine hydrochloride nasal solution, 4% (CII), is a clear, green-colored liquid available as one dosage strength: 160 mg/4 mL (40 mg/mL or 4%) cocaine hydrochloride in a single-use bottle, equivalent to 142.4 mg/4 mL (35.6 mg/mL) cocaine free-base.

Cocaine hydrochloride nasal solution, 4% (CII) is a single-source drug required to be treated as a multiple source per subsection (c)(6)(C) of Section 1847A of the Social Security Act. A unique J-code is necessary to appropriately identify and reimburse cocaine hydrochloride nasal solution, 4% (CII) and implement current Medicare payment policy across all settings of care subject to the Outpatient Prospective Payment System (OPPS). CMS did assign a C-code to cocaine hydrochloride nasal solution, 4% (CII) (C9046); however, C-codes are used only by Medicare, and utilization is also anticipated to treat patients who are not Medicare beneficiaries. Existing HCPCS codes for other products used to induce local anesthesia of the mucous membranes do not describe cocaine hydrochloride nasal solution, 4% (CII) and cannot be used to report its use.

Final Decision

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

Request# 20.108

Topic/Issue

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

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

Applicant's Summary

International Tissue Inc. submitted a request to establish a new Level II HCPCS code to identify Amniply.

Amniply is an amniotic membrane graft. It comes in both a single and dual layer option. Amniply is a collagenous membrane derived from the submucosa of the placenta. The product serves multiple functions. It can be used in surgical procedures such as tendon repairs and spinal fusions. It can also be utilized as a wound covering for chronic, non-healing wounds such as diabetic foot ulcers, venous leg ulcer, and pressure ulcers. The graft is either placed into the wound bed or to the affected area. It is then covered using the physician's choice of a dressing to keep the graft in place. There are numerous sizes of Amniply. The provider should always use the size that most closely matches the defect or wound. Each graft is individually packaged and can be stored in ambient temperature. Refrigeration is not required.

As per the applicant, all of the current cellular and tissue based HCPCS (Q-codes) are brand/manufacturer specific and therefore unable to use any of them. Amniply is regulated under the FDA 21CFR1271 and PHSA Section 361 as a HCT/P and as noted above may be used in a variety of surgical and wound care procedures.

Final Decision

Establish new Level II HCPCS code Q4249 " Amniply, for topical use only, per square centimeter"

Effective: 10/01/2020

After review of FDA's guidance, it does not appear to CMS that the non-topical uses such as tendon repair and spinal fusion, 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 (TRG) 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.

Request# 20.109

Topic/Issue

Request to establish a new Level II HCPCS code to identify a dehydrated amniotic membrane allograft, AmnioAMP-MP

Applicant's suggested language: Q4XXX AmnioAMP-MP, per CM2 for a decellularized, dehydrated human amniotic membrane allograft.

Applicant's Summary

Stratus BioSystems submitted a request to establish a new Level II HCPCS code to identify AmnioAMP-MP, a decellularized dehydrated human amniotic membrane (DDHAM) which is derived from the placental amnion and includes epithelial and stromal components that provide a collagen-rich extracellular matrix, cytokines, and growth factors. The allograft, which is chorion free, provides a physical platform for infiltrating cells as well as extracellular proteins such as elastin, fibronectin, proteoglycans, glycosaminoglycans, and laminins, important in extracellular matrix strength, cell attraction, and migration. AmnioAMP-MP human amniotic extracellular matrix provides the scaffold for cell attachment and proliferation needed for granulation tissue development, vascularization, and epithelization for tissue repair with minimized inflammation and scarring. AmnioAMP-MP is E-Beam sterilized and provided in a dry sheet form that is ready to use and is stored at ambient temperature. Indications include, but not limited to, application to partial and full-thickness acute and chronic wound (such as burns, diabetic wounds, venous wounds, arterial wounds, pressure wounds), including wounds with exposed tendon, muscle, and bone. AmnioAMP-MP delivers a natural collagen rich (Type 1,11) extracellular matrix with extracellular proteins, including fibronectin and laminins, as well as cytokines and growth factors to damaged soft tissues. AmnioAMP-MP serves as a barrier to microbes and adhesions and as the structural platform to support appropriate cellular growth resulting in efficient healing with minimal inflammation and scarring. The AmnioAMP-MP allograft is supplied sterile as single use products available in multiple sizes. The actual size of the amniotic allograft that is applied is determined by the health care provider based on wound size. According to the applicant, Q4100 (skin substitute, NOC) is not an acceptable billable code for the hospital outpatient clinic and creates automatic rejections in many payer's billing systems. Other potential codes (C9339 or J3590- Unclassified Biologics) are not applicable as they require billing under 636 revenue code, which requires an NDC. AmnioAMP-MP is not a pharmaceutical product and therefore would not be issued an NDC. The existing codes are inadequate to describe this product.

Final Decision

Establish new Level II HCPCS code Q4250 "AmnioAMP- MP, per square centimeter"

Effective: 10/01/2020

Request# 20.110

Topic/Issue

Request to establish a new Level II HCPCS code to identify Magtrace® lymphatic tracer

Applicant's suggested language: Q99XX: injection, liquid magnetic marker, 2 ml vial

Applicant's Summary

Endomag submitted a request to establish a new Level II HCPCS code to identify Magtrace® lymphatic tracer. The Magtrace® lymphatic tracer is a unique nonradioactive liquid magnetic marker specifically designed for sentinel lymph node biopsy. It is used to map the lymphatic drainage to the axilla in patients with breast cancer. The Magtrace® lymphatic tracer is a solution of iron nanoparticles coated with a carboxydextran shell. These magnetic particles are injected into the patient's breast tissue and absorbed into the lymph nodes. The surgeon uses the Sentimag® probe to detect the magnetic particles located within the sentinel lymph node. The identified node(s) is removed and tested for the presence of cancer cells. The use of a liquid magnetic marker avoids injection of radioactive materials or blue dye which can cause severe allergic reaction in some patients. The Magtrace® lymphatic tracer is provided in a 2 ml single use vial and administered in the physician office weeks/days/hours prior to surgery via subcutaneous injection into the interstitial breast tissue. According to the applicant, current coding is limited to: 1) HCPCS Q9968 which is specific to blue dye and not applicable in the physician office setting; 2) CPT 38792 which is specific to injection of radioactive tracer (Tc99) which precludes the use of a nonradioactive liquid magnetic marker; 3) CPT code 38900 is an add-on code used intraoperatively and therefore is not applicable to the physician office setting. As per the applicant, these codes do not appropriately describe a nonradioactive liquid magnetic tracer injected in the physician office.

Final Decision

CMS reached out to the American Medical Association (AMA). The AMA recommended that CMS refer the applicant to the AMA, because the product should actually be included in a CPT code. The application refers to a highly analogous CPT code 38792 Injection procedure; radioactive tracer for sentinel node identification. Since this is a non-radioactive tracer the applicant should approach the CPT Editorial Panel to request a code similar to 38792, but specific to injection of a non-radioactive tracer.

Request# 20.112

Topic/Issue

Request to establish a new level II HCPCS code to identify a sterilized amniotic fluid flowable allograft. Trade Name: AmnioEXS-P

Applicant's suggested language: Q4XXX AmnioEXS-P, per for amniotic fluid flowable allograft

Applicant's Summary

Stratus BioSystems submitted a request to establish a new Level II HCPCS code to identify a sterilized amniotic liquid fluid allograft.

AmnioEXS-P is a cryopreserved amniotic particulate allograft suspension intended for homologous use. This amniotic flowable allograft is a concentration of trophic factors, extracellular proteins, cytokines, and exosomes that provides a physical conduit for infiltrating cells that enhances cell migration and promotes the natural cascade of healing. The proprietary process limits the denaturation of proteins and cytokines thus having a greater effect on damaged tissue. AmnioEXS-P is provided in a sterile vial and cryopreserved without DMSO, digestive enzymes, or preservative agents and does not need reconstitution. AmnioEXS-P is intended for use to aid in the regenerative healing process of damaged soft tissue. Indications include, but not limited to, application to partial and full thickness acute and chronic wounds (such as diabetic wounds, venous wounds, arterial wounds, pressure wounds, and bums), including wounds with exposed tendon, muscle, and bone. AmnioEXS-P delivers a natural collagen rich (Type I, II) chorion free allograft along with extracellular matrix proteins and exosomes, including fibronectin and laminins, cytokines, and growth factors to damaged soft tissue. The AmnioEXS-P allograft is supplied sterile in a one time, ready to use vial with different dosages and easily administered through a 25G needle for precise targeting. AmnioEXS-P has a shelf life with controlled temperature of -20 degrees C for short term storage up to 6 months, or -40 degrees C for long term storage up to 5 years.

There are no current codes to define an amniotic fluid flowable allograft used in the repair of damaged or lost soft tissue.

Final Decision:

After review of FDA guidance, it does not appear to CMS that AmnioEXS-P is an HCT/P. CMS refers the applicant to the FDA's Tissue Reference Group (TRG) 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

Request# 20.113

Topic/Issue

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

No suggested language.

Applicant's Summary

New Life Medical, LLC submitted a request to establish a new Level II HCPCS code to identify REGUaRD.

REGUaRD is an HCT/P donated allograft placental membrane tissue. New Life is requesting that the code uses the language REGUaRD. REGUaRD is a hydrated acellular (human) dermal allograft matrix used for the treatment of non-healing wounds and bum injuries. REGUaRD contains extracellular matrix (ECM) that provides a scaffold for cellular ingrowth vascularization, tissue regeneration and formation of granulation tissue. REGUaRD is supplied as a thin (0.5mm) allograft, in a variety of sizes. REGUaRD may be cut and shaped to the appropriate size. Existing codes are not applicable as they are identified by specific branding. REGUaRD is administered by a health care professional in a physician's office, outpatient surgery center, or acute care facility. The size is determined by the injury or wound. REGUaRD is packaged in the following sizes: 2cm X 2cm, 2cm X 4cm, 4cm X 4cm, 4cm X 6 and 4cm X 8cm and stored at ambient temperatures.

Final Decision

Establish new Level II HCPCS code Q4255 "Reguard, for topical use only, per square centimeter"

Effective: 10/01/2020

After review of FDA's guidance, it does not appear to CMS that the non-topical uses such as creation of nerve wrap and hernia repair, 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 (TRG) 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.

Request# 20.114

Topic/Issue

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

No suggested language.

Applicant's Summary

New Life Medical, LLC submitted a request to establish a new Level II HCPCS code to identify RELeV. RELeV is an HCT/P donated allograft placental tissue. New Life is requesting that the code uses the language RELeV. RELeV is 100% acellular liquid amniotic fluid which is intended for the help of soft tissue repair from wounds, burns or injuries causing inflammation. RELeV is comprised of cytokines, proteins, growth factors, and other components to help expedite the healing of soft tissue. Existing codes are not applicable as they are identified by specific branding. RELeV is administered by a health care professional for injections on or around site of injury. Treatment can be administered in a physician's office, outpatient surgery center, or acute care facility. The dosage is administered by milliliter and is determined by the injury or wound. RELeV is packaged in .25ml .5ml, 1ml, and Iml applications and in stored at temperatures of-80° C.

Final Decision

After review of FDA's guidance, it does not appear to CMS that RELeV is an HCT/P. CMS refers the applicant to the FDA's Tissue Reference Group (TRG) 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

Request# 20.115

Topic/Issue

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

No suggested language.

Applicant's Summary

New Life Medical, LLC submitted a request to establish a new Level II HCPCS code to identify REViV. REViV is an HCT/P donated allograft placental tissue. New Life is requesting that the code uses the language REViV. REViV is liquid amniotic fluid and extra cellular matrix which is intended for soft tissue repair as well. REViV is comprised of cytokines, growth factors, and extra cellular matrix intended to expedite the healing of soft tissue caused by wounds, bums and injuries causing inflammation. Existing codes are not applicable as they are identified by specific branding. REViV is administered by a health care professional for injections on or around site of injury. Treatment can be administered in a physician's office, outpatient surgery center, or acute care facility. The dosage is administered by milliliter and is determined by the injury or wound. REViV is packaged in .25ml .5ml, 1ml, and 2ml applications and in stored at temperatures of -80° C.

Final Decision

After review of FDA's guidance, it does not appear to CMS that REViV is an HCT/P. CMS refers the applicant to the FDA's Tissue Reference Group (TRG) 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

Request # 20.151

Topic/Issue

Request to establish new Level II HCPCS code to identify ANJESO (meloxicam) injection.

Applicant's suggested language: JXXXX, meloxicam injection, 30mg

Applicant's summary

Baudax Bio, Inc., submitted a request to establish a new Level II HCPCS code to identify meloxicam injection, 30mg, Trade Name: ANJESO. ANJESO is an aqueous dispersion containing the active pharmaceutical ingredient meloxicam for intravenous administration. Each mL of aqueous dispersion contains 30mg of meloxicam, povidone, sodium deoxycholate (deoxycholic acid), sucrose, and water for injection. ANJESO is a non-opioid, non-steroidal anti-inflammatory drug (NSAID) that has analgesic, anti-inflammatory, and antipyretic properties and is indicated for use in adults for the management of moderate to severe pain, alone or in combination with other non-NSAID analgesics. It is the first and only IV formulation of meloxicam available in the U.S for human use. There is no HCPCS Level II code for an intravenous formulation of meloxicam. Baudax Bio, Inc. requests a new HCPCS code for ANJESO "to facilitate appropriate pricing as a single source drug". The recommended dose of ANJESO is 30 mg once daily. ANJESO aqueous dispersion is administered only by intravenous administration over 15 seconds. ANJESO is supplied as a 1 mL fill (30 mg/mL) in a clear 2 mL single dose vial.

Recommended final decision:

Establish new Level II HCPCS code J1738 "Injection, meloxicam**,** 1 mg"

Effective: 10/01/2020

Note that this entry is a correction to this Application Summary to include an application that was filed timely per our application instructions but was inadvertently omitted in the previously published version. The new Level II HCPCS code J1738 that resulted from processing this application will be implemented with an October 1, 2020 effective date, consistent with other applications submitted timely to our Second Quarterly (Q2) coding cycle.