Centers for Medicare & Medicaid Services (CMS) Healthcare Common Procedure Coding System (HCPCS) Application Summaries and Coding Decisions First Quarter 2021 Coding Cycle for Drug and Biological Products

This document presents, in request number sequence, a summary of each HCPCS code application and CMS' coding decision for each application processed in CMS' First Quarter 2021 Drug and Biological HCPCS code application review cycle. Each summary includes:

- Application number;
- Topic/Issue;
- Summary of the applicant's request as written by the applicant with occasional minor, non-substantive editorial changes made by CMS;
- CMS' final or preliminary coding decision; and
- 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.

The HCPCS coding decisions below will also be included in the July 2021 HCPCS Quarterly Update, pending publication by CMS in the coming weeks at: https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Alpha-Numeric-HCPCS.

Request # 20.125

Topic/Issue

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

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

Applicant's Summary

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

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

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

Final Decision

Establish new Level II HCPCS code J1951 "Injection, leuprolide acetate for depot suspension (Fensolvi), 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 a variety of doses, making coding more robust, facilitate accurate payment and reporting of exact dose administered.

Effective: 07/01/2021

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

Request # 20.146

Topic/Issue

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

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

Applicant's Summary

The name of the product is Romidepsin Injection, liquid (Romidepsin injection) for intravenous use. Romidepsin Injection, liquid is a histone deacetylase (HDAC) inhibitor drug. Romidepsin Injection, liquid is a drug used in the treatment of certain types of lymphoma cancer. A new HCPCS code for Romidepsin Injection, non-lyophilized liquid is needed because it is a single-source drug approved under a unique NDC number, and it needs to be differentiated from the existing HCPCS code for a multi-sourced Romidepsin drug in lyophilized powder form. Romidepsin Injection, liquid is indicated treatment of cutaneous T-cell lymphoma (CTCL) in adult patients who have received at least one prior systemic therapy. Treatment of peripheral T-cell lymphoma (PTCL) in adult patients who have received at least one prior therapy. The mechanism of the antineoplastic effect of Romidepsin has not been fully characterized. Romidepsin Injection, liquid is supplied in single-dose vials in the following carton packaged 10 mg/2 mL (5 mg/mL) and 27.5 mg/5.5 mL (5 mg/mL).

Preliminary Decision

1. Establish new Level II HCPCS code JXXXX "Injection, romidepsin, non-lyophilized, 0.1 mg."

2. Establish new Level II HCPCS code JXXXX "Injection, romidepsin, lyophilized, 0.1 mg."

3. Discontinue existing Level II HCPCS code J9315 "Injection, romidepsin, 1 mg."

CMS will take this issue to the next public meeting to allow all interested stakeholders an opportunity to opine on this preliminary decision.

Request # 20.200

Topic/Issue

Request to establish a new Level II HCPCS code to identify Symphony, an extracellular matrix bioengineered skin substitute derived from ovine forestomach tissue and including hyaluronic acid.

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

Applicant's Summary

Symphony is a bioengineered skin substitute composed of extracellular matrix (ECM) and hyaluronic acid (HA). Symphony contains three layers of ovine-derived ECM, which contains more than 150 essential ECM proteins, including structural proteins, adhesion proteins, and signaling proteins—all of which aid the wound healing process. A single layer of HA has been included in the composite design to provide additional healing biology and ensure a moist wound environment that is critical to healing. The composite design scaffolds the patient's own cells to rebuild dermal tissues in acute and chronic wounds.

Preliminary Decision

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

Request # 21.001

Topic/Issue

Request to establish a new Level II HCPCS code to identify segesterone acetate and ethinyl estradiol vaginal system.

Applicant's suggested language: J7XXX "Annovera (segesterone acetate and ethinyl estradiol vaginal system), each."

Applicant's Summary

Annovera is a hormonal birth control method that is used for 3 out of 4 weeks every month. The same vaginal system is reusable for up to one full year (1 year includes 13 cycles; each cycle is 28 days). After the patient inserts Annovera for the first time, the patient will remove it at the end of week 3 and leave it out for 7 days. The patient will then reinsert Annovera at the end of week 4 of each 4-week cycle.

Preliminary Decision

1. Establish new Level II HCPCS code JXXXX "Segesterone acetate and ethinyl estradiol 0.15mg, 0.013mg per 24 hours; yearly vaginal system, each"

2. Establish new Level II HCPCS code JXXXX "Ethinyl estradiol and etonogestrel 0.015mg, 0.12mg per 24 hours; monthly vaginal ring, each"

3. Discontinue existing Level II HCPCS code J7303 "Contraceptive supply, hormone containing vaginal ring, each"

CMS will take this issue to the next public meeting to allow all interested stakeholders an opportunity to opine on this preliminary decision.

Request # 21.001i

Topic/Issue

Replace HCPCS code J2505 with a new code with a small dose descriptor similar to its biosimilar.

Suggested language: J code "Injection, pegfilgrastim, 0.5 mg"

Applicant's Summary

CMS has a long-standing convention to assign dose descriptors in the smallest amount that could be billed in multiple units to accommodate a variety of doses, making coding more robust, facilitate accurate payment and reporting of exact dose administered. According to the published prescribing information, pegfilgrastim dosing could be 1.5 mg to 6 mg depending on the patient's weight. In order to facilitate more accurate billing and to simplify the comparison of payment amounts for pegfilgrastim and biosimilar products, CMS is considering the discontinuation of J2505 and replacement with a code that utilizes a descriptor that matches the amount of drug in the pegfilgrastim biosimilar codes.

Preliminary Decision

All of the biosimilars for Neulasta, the brand name for pegfilgrastim, are 0.5 mg. CMS proposes to discontinue HCPCS code J2505 and establish a new code, which will specify 0.5 mg, for consistency.

1. Establish new Level II HCPCS code JXXXX "Injection, pegfilgrastim, excludes biosimilar, 0.5 mg."

2. Discontinue existing Level II HCPCS code J2505 "Injection, pegfilgrastim, 6 mg."

CMS will take this issue to the next public meeting to allow all interested stakeholders an opportunity to opine on this preliminary decision.

Request # 21.002

Topic/Issue

Request to establish a new Level II HCPCS code to identify Cygnus Matrix.

Applicant's Summary

Cygnus Matrix is a multilayer allograft derived from the amnion and chorion layers of the placental membrane and is manufactured using a proprietary Integrity Processing Methodology, which helps to maintain the inherent levels of key extracellular matrices, including proteins, carbohydrates, growth factors, and cytokines. Cygnus Matrix retains the structural and functional characteristics of the membrane to provide a barrier or covering, protecting injured tissue from the external environment.

Final Decision

After review of the Food and Drug Administration's (FDA's) guidance, it does not appear to CMS that Cygnus Matrix is suitable for registration as a Human Cells, Tissues, and Cellular and Tissue-Based Product (HCT/P). CMS refers the applicant to the FDA's Tissue Reference Group (TRG) to obtain written feedback regarding how the product is appropriately regulated. After obtaining the FDA's written feedback, the applicant is welcome to submit a complete HCPCS code application in a subsequent coding cycle.

Information for submitting questions to the TRG is located at:

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

Request # 21.003

Topic/Issue

Request to establish a new Level II HCPCS code to identify Danyelza (naxitamab-gqgk).

Applicant's suggested language: J9XXX "injection, naxitamab-gqgk, 1mg."

Applicant's Summary

Danyelza (naxitamab-gqgk) is a glycolipid disialoganglioside (GD2)-binding monoclonal antibody that binds to GD2, which is overexpressed on neuroblastoma cells and other tumors of neuroectodermal origin, including the central nervous system and peripheral nerves. Danyelza was approved by the FDA in November 2020, and received rare pediatric disease, orphan drug, and breakthrough therapy designations from the FDA.

Final Decision

Establish new Level II HCPCS code J9348 "Injection, naxitamab-gqgk, 1 mg"

Effective: 07/01/2021

Request # 21.004

Topic/Issue

Request to establish a new Level II HCPCS code to identify Gallium Ga 68 PSMA-11.

Applicant's Summary

Ga 68 PSMA-11 is a radiopharmaceutical that is used to localize PSMA-positive metastatic disease in patients with prostate cancer. Prostate specific membrane antigen (PSMA) is overexpressed on prostate cancer cells, and can be used to target prostate cancer for the purpose of imaging. After injection of Ga 68 PSMA-11, it is imaged using positron emission tomography (PET) to localize where the radiotracer is, allowing the localization of metastatic disease. There are two main uses of Ga 68 PSMA-11 PET in patients with prostate cancer as listed in the prescribing information. The first is in patients at initial staging prior to definitive therapy who are at risk for prostate cancer. Patients with clinically significant prostate cancer will typically be treated first using either radiation therapy (either external beam or brachytherapy) or radical prostatectomy. Both of these treatments assume that the prostate cancer is localized. Ga 68 PSMA-11 PET allows us to determine if disease is in fact localized to the prostate or has already metastasized outside of the prostate, which would have a significant impact on the treatment of the patient. The second use of PSMA PET is in prostate cancer patients with biochemical recurrence after definitive therapy. This is typically patients who have undergone either radical prostatectomy or radiation therapy, and the patient's prostate specific antigen (PSA) begins to rise. When the PSA begins to rise, the patient is known to have recurrence disease, but it is not known where that disease exists. Ga 68 PSMA-11 PET has a role in localizing metastatic disease in these men, allowing physicians to choose the appropriate treatment based on where the disease is localized.

Final Decision

Establish new Level II HCPCS code A9593 "Gallium ga-68 psma-11, diagnostic, (ucsf), 1 millicurie"

During this first quarterly HCPCS coding cycle of 2021, CMS reviewed two applications for very similar radiopharmaceutical products from different applicants. The application for this product was submitted by the University of California San Francisco. To distinguish the code we are establishing for this product from the code we are establishing for the similar product (discussed below), we are adding "(ucsf)" to the descriptor for HCPCS code A9593.

Effective: 07/01/2021

Request # 21.005

Topic/Issue

Request to establish a new Level II HCPCS code to identify Gleolan (aminolevulinic acid HCl).

Applicant's Summary

NX Development Corp is submitting a request for a new HCPCS Code for Gleolan (aminolevulinic acid HCl). Gleolan was approved in June 2017 by the FDA for use as an optical imaging agent to improve extent of resection in suspected high grade glioma patients. This is a significant therapeutic distinction for currently, there are no existing HCPCS code that describes using (Gleolan) to visualize gliomas during brain surgery. Since glioma is a rare disease affecting fewer than 200,000 people annually in the United States, Gleolan received "Orphan Drug" designation to assist surgeons in managing the tumor removal procedure in this critically ill population. Gleolan is the first fluorescent guided imaging agent approved in patients with suspected WHO Grades III or IV gliomas and there are no FDA approved comparator products.

Final Decision

Gleolan is not suitable for coding in Level II HCPCS as it is used exclusively in hospital inpatient and outpatient settings. For inpatient use, Gleolan would be bundled in hospital payment. CMS refers the applicant to CMS' pass-through coding program for consideration of pass-through coding for use in hospital outpatient settings.

Request # 21.006

Topic/Issue

Request to establish a new Level II HCPCS code to establish SkinTE.

Applicant's language: QXXXX "Autologous skin product, not otherwise specified."

Applicant's Summary

SkinTE is not a skin substitute, and has none of the characteristics of a skin substitute. It is a fully autologous (from the patient for the patient) product used for repair, replacement, reconstruction, or supplementation of skin tissue and integumentary system. SkinTE is manufactured from a harvested sample of the patient's full thickness skin and is entirely autologous, with no additional or supplementary cell or tissue source from another human being (allogeneic) or another animal (xenogeneic), as well as no additive synthetic or prosthetic components.

Final Decision

After review of the FDA's guidance, it does not appear to CMS that Skin TE is suitable for registration as a Human Cells, Tissues, and Cellular and Tissue-Based Product (HCT/P). CMS refers the applicant to the FDA's Tissue Reference Group (TRG) to obtain written feedback regarding how the product is appropriately regulated. After obtaining the FDA's written feedback, the applicant is welcome to submit a complete HCPCS code application in a subsequent coding cycle.

Information for submitting questions to the TRG is located at:

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

Request # 21.008

Topic/Issue

Request to establish a new Level II HCPCS code to establish Kcentra.

Applicant's suggested language: JXXXX "Prothrombin complex concentrate (human), kcentra, per i.u. of factor ix activity."

Applicant's Summary

Kcentra (prothrombin complex concentrate (human)) is a blood coagulation factor replacement product. The existing code (C9132) is only recognized by Medicare when furnished in a hospital setting. In some instances, Kcentra may be furnished in a nonhospital setting and would be reported under an unspecified code for Medicare patients. In addition, not all payers recognize C codes and may require that the product be reported under an unspecified code in the hospital as well as non-hospital settings. A J code is necessary to facilitate consistent reporting of Kcentra across settings and payers. We note that CMS recently established a J code for a different anticoagulation reversal product (Andexxa) and the same program operating need identified for a J code for Andexxa would also apply to Kcentra. Kcentra is indicated for the urgent reversal of acquired coagulation factor deficiency induced by Vitamin K antagonist (VKA, e.g., warfarin) therapy in adult patients with acute major bleeding or the need for an urgent surgery/invasive procedure. The recommended dose is based on the measurement of the International Normalized Ration (INR) prior to treatment and the patient's body weight. Kcentra is administered through an intravenous infusion and is supplied in a single use vial.

Final Decision

Establish new Level II HCPCS code J7168 [1]"Prothrombin complex concentrate (human), kcentra, per i.u. of factor ix activity"

Effective: 07/01/2021

Discontinue existing HCPCS code C9132 "Prothrombin complex concentrate (human), kcentra, per i.u. of factor ix activity"

Effective: 06/30/2021

[1] The final, corrected code assignment, for item 21.008, is J7168, as specified in the Final Decision in the 2021 HCPCS Application Summary for Quarter 1, 2021 Drugs and Biologics document. Code number J7168 replaces code J7169, which was previously published in error.

Request # 21.009

Topic/Issue

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

Applicant's suggested language: "Margetuximab-cmkb injection for intravenous use, 250mg/10ml."

Applicant's Summary

Margenza, a HER2/neu receptor antagonist, is a chimeric Fe-engineered IgG 1 kappa monoclonal antibody used in anticancer treatment. No HCPCS code currently identifies this unique biological product because no other drugs or biologicals with the same active ingredient (margetuximab-cmkb) exist.

The product is indicated, in combination with chemotherapy, for the treatment of adult patients with metastatic HER2-positive breast cancer who have received two or more prior anti-HER2 regimens, at least one of which was for metastatic disease.

Upon binding to the extracellular domain of HER2-expressing tumor cells, Margenza inhibits tumor cell proliferation, reduces shedding of the HER2 extracellular domain, and mediates antibody-dependent cellular cytotoxicity (ADCC). In vitro, the modified Fe region of the product increases binding to activating Fe receptor FCGR3A (CD16A) and decreases binding to inhibitory Fe receptor FCGR2B (CD32B), which leads to greater in-vitro ADCC and NK cell activation.

The recommended dose is 15 mg/kg, administered every three weeks until disease progression or unacceptable toxicity. The initial dose should be administered over 120 minutes and subsequent doses over 30 or more minutes every three weeks. Margenza is administered as an intravenous infusion.

Final Decision

Establish new Level II HCPCS code J9353 "Injection, margetuximab-cmkb, 5 mg"

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

Effective: 07/01/2021

Request # 21.011

Topic/Issue

Request to establish a new Level II HCPCS code to identify Oxlumo (lumasiran).

Applicant's suggested language: JXXXX "Injection, lumasiran, 3 mg."

Applicant's Summary

Oxlumo contains lumasiran, a double-stranded siRNA covalently linked to a ligand containing N-acetylgalactosamine (GalNAc) that reduces Levels of GO enzyme by targeting the HAO1 mRNA in hepatocytes through RNA interference.

Oxlumo reduces urinary oxalate, the cause of progressive renal failure in patients with PH1. Oxlumo's mechanism of action is to reduce Levels of GO enzyme by targeting the HAO1 mRNA in hepatocytes through RNA interference. Decreased GO enzyme Levels reduce the amount of available glyoxylate, a substrate for oxalate production.

Final Decision

Establish new Level II HCPCS code J0224 "Injection, lumasiran, 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 a variety of doses, making coding more robust, facilitate accurate payment and reporting of exact dose administered.

Effective: 07/01/2021

Request # 21.012

Topic/Issue

Request to establish a new Level II HCPCS code to identify Riabni (rituximab-arrx).

Applicant's suggested language: QXXXX "Injection, rituximab-arrx, biosimilar (Riabni), 10 mg."

Applicant's Summary

Riabni (rituximab-arrx) is a CD20-directed cytolytic antibody that is administered via intravenous (IV) infusion. Rituximab products target the CD20 antigen expressed on the surface of pre-B and mature B-lymphocytes. Upon binding to CD20, rituximab products mediate B-cell lysis. Riabni has a Boxed Warning in its product labeling regarding the potential risk of fatal infusion-related reactions, severe mucocutaneous reactions, Hepatitis B virus reactivation, and progressive multifocal leukoencephalopathy. The FDA approved the Biologics License Application (BLA) for Riabni on December 17, 2020.

Final Decision

Establish new Level II HCPCS code Q5123 "Injection, rituximab-arrx, biosimilar, (riabni), 10 mg"

Effective: 07/01/2021

Request # 21.013

Topic/Issue

Request to establish a new Level II HCPCS to identify Human Health Factor 10 Amniotic Patch [HHF10-P].

Applicant's Summary

Wolver and Poole Distribution LLC respectfully requests to establish a new Q-code for an amniotic membrane allograft, Human Health Factor 10 Amniotic Patch [HHF10-P]. HHF10-P is a semi-transparent, minimally manipulated, freeze-dried, collagenous membrane allograft derived from donated human birth tissue, specifically the immune privileged amnion layer of fetal membranes. It is composed of a single layer of epithelial cells, a basement membrane, and an avascular connective tissue matrix. It is intended for homologous use as a wound covering/cushion and protective barrier against the surrounding environment. HHF10-P is intended for homologous use to act as a wound covering/cushion and protective barrier for the treatment of non-healing, acute or chronic wounds and burn injuries.

Final Decision

After review of the FDA's guidance, it does not appear to CMS that Human Health Factor 10 Amniotic Patch is suitable for registration as a Human Cells, Tissues, and Cellular and Tissue-Based Product (HCT/P). CMS refers the applicant to the FDA's Tissue Reference Group (TRG) to obtain written feedback regarding how the product is appropriately regulated. After obtaining the FDA's written feedback, the applicant is welcome to submit a complete HCPCS code application in a subsequent coding cycle.

Information for submitting questions to the TRG is located at:

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

Request # 21.014

Topic/Issue

Request to establish a new Level II HCPCS code to identify VIA Disc.

Applicant's suggested language: QXXXX "Via Disc."

Applicant's Summary

VIA Disc is intended for use as an allograft to supplement degenerative intervertebral discs. Patients with degenerated discs lose hydration, mechanical competence, and load absorption, which leads to decreased disc height and loss of nutrient content. As these structural and functional changes in the degenerated disc strain the nerves, it can put focal pressure on the spine and ultimately cause lower back pain. Supplementing the intervertebral disc with processed allogeneic disc tissue may support biomechanical function and overcome a loading imbalance resulting from tissue loss and disruption. VIA Disc addresses the desiccation and loss of tissue and cells that is integral to the course of degeneration. A typical patient presents with discogenic lower back pain with radiographic evidence of disc degeneration and remains symptomatic despite conservative therapy, including pharmaceuticals, physical therapy, and epidural injections, while wishing to avoid opioids and/or surgical intervention.

Final Decision

After review of the FDA's guidance, it does not appear to CMS that VIA Disc is suitable for registration as a Human Cells, Tissues, and Cellular and Tissue-Based Product (HCT/P). CMS refers the applicant to the FDA's Tissue Reference Group (TRG) to obtain written feedback regarding how the product is appropriately regulated. After obtaining the FDA's written feedback, the applicant is welcome to submit a complete HCPCS code application in a subsequent coding cycle.

Information for submitting questions to the TRG is located at:

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

Request # 21.015

Topic/Issue

Request to establish a new and single Level II HCPCS code to identify WJ Flow.

Applicant's suggested language: Q4xxx "Wharton's Jelly Flow, per cc."

Applicant's Summary

Predictive Biotech requests to establish a new and single Level II HCPCS code that identifies unique, Wharton's Jelly Human Cells, Tissues, and Cellular and Tissue-Based Product (HCT/Ps). Wharton's Jelly Flow is currently regulated by the FDA as HCT/Ps subject to Section 361 of the Public Service Act and 21 CFR 1271. Products derived from the Wharton's Jelly layer of the umbilica1 cord have been shown to reduce scarring, fibrosis, and adhesions in surgical and wound sites1. WJ Flow is cryopreserved to maintain viability of the cellular fraction found within the Wharton's Jelly. This product is intended to provide extracellular matrix necessary for the infiltration, attachment, and proliferation of cells required for the repair of damaged tissue. This product is used for wounds and tissue defects and are 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 Predictive Biotech is identified by its own unique QR code. The product is packaged in a transport protective formed plastic container. The product is contained in a cryogenic vial and identified by a product label that contains the unique product code, lot number, expiry, and volume. Contents are aseptically processed and not considered sterile.

Final Decision

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

Information for submitting questions to the TRG is located at:

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

Request # 21.016

Topic/Issue

Request to establish a new and single Level II HCPCS code that identifies PolyCyte.

Applicant's language: Q4xxx "PolyCyte, per cc."

Applicant's Summary

Predictive Biotech requests to establish a new and single Level II HCPCS code that identifies unique, Wharton's Jelly Human Cells, Tissues, and Cellular and Tissue-Based Product (HCT/Ps). PolyCyte is currently regulated by the FDA as an HCT/P subject to Section 361 of the Public Health Service Act and 21 CFR 1271. Products derived from the Wharton's Jelly layer of the umbilical cord have been shown to reduce scarring, fibrosis, and adhesions in surgical and wound sites. PolyCyte is frozen to maintain viability of the matrix materials, growth factors, cytokines, and exosomes found naturally within the Wharton's Jelly. PolyCyte is intended to provide extracellular matrix necessary for the infiltration, attachment, and proliferation of cells required for the repair of damaged tissue. The products are used for wounds and tissue defects and are 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 Predictive Biotech is identified by its own unique QR code. The product is packaged in a transport protective formed plastic container. The product is contained in a cryogenic vial and identified by a product label that contains the unique product code, lot number, expiry, and volume. Contents are aseptically processed and not considered sterile.

Final Decision

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

Information for submitting questions to the TRG is located at:

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

Request # 21.017

Topic/Issue

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

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

Applicant's Summary

Signature APatch is a cryopreserved, minimally manipulated amniotic membrane allograft for homologous use as a cover or barrier for the treatment of non-healing wounds and burn injuries as a skin substitute. The hexagon shape allows for coverage over many non-healing wound shapes and multi-directional expansion to cover unique wounds sizes and morphology. Signature APatch is available in a single size: hexagon with 2.5 cm sides, measuring 5.0 cm in diameter, and a total surface area of 16 cm^2.

Final Decision

After review of the FDA's guidance, it does not appear to CMS that Signature APatch is suitable for registration as a Human Cells, Tissues, and Cellular and Tissue-Based Product (HCT/P). CMS refers the applicant to the FDA's Tissue Reference Group (TRG) to obtain written feedback regarding how the product is appropriately regulated. After obtaining the FDA's written feedback, the applicant is welcome to submit a complete HCPCS code application in a subsequent coding cycle.

Information for submitting questions to the TRG is located at:

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

Request # 21.019

Topic/Issue

Request to establish a new Level II code to identify Olinvyk.

Applicant's suggested language: JXXXX "(oliceridine) injection, for intravenous use, 1 mg."

Applicant's Summary

Olinvyk is indicated in adults for the management of acute pain severe enough to require an intravenous opioid analgesic. Oliceridine is a full opioid agonist and is relatively selective for the mu-opioid receptor. The principal therapeutic action of oliceridine is analgesia. Like all full opioid agonists, there is no ceiling effect to analgesia for oliceridine. Clinically, dosage is titrated to provide adequate analgesia and may be limited by adverse reactions, including respiratory, and CNS depression. The precise mechanism of the analgesic action is unknown. However, specific CNS opioid receptors for endogenous compounds with opioid-like activity have been identified throughout the brain and spinal cord and are thought to play a role in the analgesic effects of this drug.

Final Decision

Olinvyk is not suitable for coding in Level II HCPCS as it is used exclusively in hospital inpatient and outpatient settings. For hospital inpatient and outpatient use, Olinvyk would be bundled in hospital payment.

Request # 21.021

Topic/Issue

Request to establish a new Level II HCPCS code to identify RevoGen AmnioGraft + Patch.

Applicant's suggested language: 4XXX "RevoGen AmnioGraft + Patch, per sq cm."

Applicant's Summary

The RevoGen AmnioGraft + Patch is a minimally manipulated dual layer tissue-based product derived from the amniotic membrane of the human placenta. It is regulated by the FDA as a Human Cells, Tissues, and Cellular and Tissue-Based Product (HCT/P). Following preparation of the wound (e.g., excision and debridement), the RevoGen AmnioGraft + Patch is applied to the wound. It is used as a skin substitute to cover the wound, providing a protective barrier, and as such, is used adjunctively to aid in healing chronic wounds such as pressure ulcers, diabetic foot ulcers and venous leg ulcers. Amniotic membrane grafts contain cytokines and growth factors which have been demonstrated to enhance chronic wound healing. The RevoGen AmnioGraft + Patch is available in the following sizes: 2x3cm, 3x4cm, 4x4cm, 4x6cm and 4x8cm.

Final Decision

After review of the FDA's guidance, it does not appear to CMS that RevoGen AmnioGraft + Patch is suitable for registration as a Human Cells, Tissues, and Cellular and Tissue-Based Product (HCT/P). CMS refers the applicant to the FDA's Tissue Reference Group (TRG) to obtain written feedback regarding how the product is appropriately regulated. After obtaining the FDA's written feedback, the applicant is welcome to submit a complete HCPCS code application in a subsequent coding cycle.

Information for submitting questions to the TRG is located at:

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

Request # 21.071

Topic/Issue

Request to establish a new Level II HCPCS code for Gallium Ga 68 PSMA-11.

Applicant's Summary

Gallium Ga 68 PSMA-11 is a radioactive indicated for positron emission tomography (PET) of prostate-specific membrane antigen (PSMA) positive lesions in men with prostate cancer: with suspected metastasis who are candidates for initial definitive therapy, with suspected recurrence based on elevated serum prostate-specific antigen (PSA) Level.

Final Decision

Establish new Level II HCPCS code A9594 "Gallium ga-68 psma-11, diagnostic, (ucla), 1 millicurie."

During this first quarterly HCPCS coding cycle of 2021, CMS reviewed two applications for very similar radiopharmaceutical products from different applicants. The application for this product was submitted by the University of California, Los Angeles. To distinguish the code we are establishing for this product from the code we are establishing for the similar product (discussed above), we are adding "(ucla)" to the descriptor for HCPCS code A9594.

Effective: 07/01/2021