



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

Fourth Quarter, 2021 HCPCS Coding Cycle

This document presents a summary of each HCPCS code application and CMS' coding decision for each application processed in CMS' Fourth Quarter 2021 Drug and Biological HCPCS code application review cycle. Each individual summary includes the request number; topic/issue; summary of the applicant's request as written by the applicant with occasional non-substantive editorial changes made by CMS; and CMS' final HCPCS coding decision. All new coding actions will be effective April 1, 2022, unless otherwise indicated.

The HCPCS coding decisions below will also be included in the April 2022 HCPCS Quarterly Update, pending publication by CMS in the coming weeks at:

<https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update>

For inquiries regarding coverage, please contact to the insurer(s) in whose jurisdiction(s) claim(s) would be filed. Specifically, contact the Medicaid agency in the state in which a Medicaid claim is filed, the individual private insurance entity, the Department of Veterans Affairs, or, for local Medicare coverage determinations, contact the Medicare contractor in the jurisdiction the claim would be filed. For detailed information describing CMS' national coverage determination process, refer to information published at

<https://www.cms.gov/Medicare/Coverage/DeterminationProcess> and

<https://www.cms.gov/Center/Special-Topic/Medicare-Coverage-Center>.

Tivdak™- HCP2109287FYQ1

Topic/Issue

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

Applicant's suggested language: J9XXX "injection, tisotumab vedotin-tftv, 1 mg."

Applicant's Summary

Seagen INC. submitted a request to establish a new HCPCS Level II code to identify Tivdak™ (tisotumab vedotin-tftv), a novel, health care provider administered tissue factor (TF) directed antibody drug conjugate. The FDA approved Tivdak™ under accelerated approval on September 20, 2021 for the treatment of adult patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy. The accelerated approval is based on tumor response and durability of response. Continued approval may be contingent upon verification and description of clinical benefit in confirmatory trials. As a first-in-class anti-cancer agent, there are no similar products on the market and no drug-specific HCPCS codes that describe Tivdak™, a TF-directed antibody and microtubule-disrupting agent. Tivdak™ is administered via intravenous infusion, over 30 minutes and is dosed at 2mg/kg in a cycle every three weeks until disease progression or unacceptable toxicity. Tivdak™ is packaged as a preservative-free lyophilized cake or powder in a carton of one 40mg, single-dose vial for reconstitution.

Final Decision

Establish new HCPCS Level II code J9273 "Injection, tisotumab vedotin-tftv, 1 mg"

Under long-standing policy, CMS assigns the dose descriptor in the smallest amount that could be billed in multiple units to accommodate a variety of doses, thus making coding more robust, and facilitating accurate payment and reporting of the exact dose administered.

Effective: 4/1/2022

SAPHNELO™ - HCP2109155FKFM

Topic/Issue

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

Applicant's suggested language: JXXXX "Injection, anifrolumab-fnia, 1 mg"

Applicant's Summary

AstraZeneca, LP submitted a request to establish a new HCPCS Level II code to identify SAPHNELO™ (anifrolumab-fnia) injection. SAPHNELO™ (anifrolumab-fnia) is a type I interferon (IFN) receptor antagonist indicated for the treatment of adult patients with moderate to severe systemic lupus erythematosus, who are receiving standard therapy. SAPHNELO™ is a human IgG1κ monoclonal antibody that binds to sub-unit 1 of the type I interferon receptor (IFNAR1) with high specificity and affinity. This binding inhibits type I IFN signaling, thereby blocking the biologic activity of type I IFNs. Anifrolumab-fnia also induces the internalization of IFNAR1, thereby reducing the levels of cell surface IFNAR1 available for receptor assembly. Blockade of receptor mediated type I IFN signaling inhibits IFN responsive gene expression as well as downstream inflammatory and immunological processes. Inhibition of type I IFN blocks plasma cell differentiation and normalizes peripheral T-cell subsets. SAPHNELO™ is a unique biological and no current specific HCPCS code adequately describes this product. The recommended dosage of SAPHNELO™ is 300 mg, administered as an intravenous infusion over a 30-minute period, every 4 weeks. SAPHNELO™ is packaged in a 2 mL clear glass vial containing 300 mg/2 mL (150 mg/mL) of anifrolumab-fnia. SAPHNELO™ is available in a carton containing one single-dose vial (NDC-0310-3040-00).

Final Decision

1. Establish new HCPCS Level II code J0491 "Injection, anifrolumab-fnia, 1 mg"

Effective: 4/1/2022

Under long-standing policy, CMS assigns the dose descriptor in the smallest amount that could be billed in multiple units to accommodate a variety of doses, thus making coding more robust, and facilitating accurate payment and reporting of the exact dose administered.

2. Discontinue existing HCPCS Level II code C9086 "Injection, anifrolumab-fnia, 1 mg"

Effective: 3/31/2022

ZYNLONTA - HCP211115F103C

Topic/Issue

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

Applicant's suggested language: J9XXX, "Loncastuximab Tesirine."

Applicant's Summary

ADC Therapeutics SA submitted a request to establish a new HCPCS Level II code to identify Loncastuximab Tesirine. Loncastuximab tesirine (Lonca, formerly ADCT-402) is a next-generation antibody drug conjugate (ADC) composed of a humanized monoclonal antibody that binds to CD19, a protein that is expressed in a variety of hematological tumors including certain lymphomas and leukemias. The antibody is conjugated through a linker to a very potent and targeted pyrrolobenzodiazepine (PBD) dimer toxin. CD19 expression on healthy non-cancerous tissue is limited. The ADC binds to CD19+ cells, internalizes and is trafficked to the lysosomes where the linker is cleaved, and the PBD dimers are released. The toxin binds irreversibly to DNA to create highly potent inter-strand cross-links that block the DNA replication fork, thus disrupting essential DNA metabolic processes such as replication and ultimately resulting in cell death. Because of their novel mechanism of action, PBD-containing ADCs are active in tumors, inherently resistant to other warhead types and against multidrug-resistant cancers. A unique HCPCS code is needed to implement payment provisions of the Social Security Act. Loncastuximab Tesirine is for the treatment of diffuse large B-cell lymphoma (DLBCL) and mantle cell lymphoma (MCL). Loncastuximab tesirine is an ADC composed of a humanized monoclonal antibody that binds to human CD19 and conjugated through a linker to a PBD-dimer toxin. Once bound to a CD19-expressing cell, Lonca is internalized into the cell where enzymes release the PBD-based warhead. Lonca is dosed as a 30-min IV infusion Q3W at 0.15mg/kg on day 1 of each cycle (every 3 weeks) for the first 2 cycles and at 0.075mg/kg for the remaining cycles for up to 1 year or until disease progression, unacceptable toxicity, or other discontinuation criteria, whichever occurred first. For Injection: 10 mg of loncastuximab tesirine-lpyl as a white to off-white lyophilized powder in a single-dose vial for reconstitution and further dilution.

Final Decision

1. Establish new HCPCS Level II code J9359 "Injection, loncastuximab tesirine-lpyl, 0.075 mg"

Under long-standing policy, CMS assigns the dose descriptor in the smallest amount that could be billed in multiple units to accommodate a variety of doses, thus making coding more robust, and facilitating accurate payment and reporting of the exact dose administered.

Effective: 4/1/2022

2. Discontinue existing HCPCS Level II code C9084 "Injection, loncastuximab tesirine-lpyl, 0.1 mg"

Effective: 3/31/2022

BYOOVIZ™ – HCP211001WVPYX

Topic/Issue

Request to establish a new HCPCS Level II Code to identify BYOOVIZ™.

Applicant's suggested language: QXXXX, "Injection, ranibizumab-nuna, biosimilar (byooviz), 0.1 mg."

Applicant's Summary

Samsung Bioepis and Biogen submitted a request to establish a new HCPCS Level II code to identify BYOOVIZ™ (ranibizumab-nuna). BYOOVIZ™ is an ophthalmic injection for intravitreal use. BYOOVIZ™ is biosimilar to LUCENTIS® (ranibizumab injection) and the FDA approved to treat neovascular (wet) age-related macular degeneration (AMD), macular edema following retinal vein occlusion (RVO), and myopic choroidal neovascularization (mCNV). BYOOVIZ™ is a vascular endothelial growth factor A (VEGF-A) inhibitor. BYOOVIZ™ is a unique biosimilar biological product, and as such, a unique HCPCS code is needed for reimbursement as a "single source drug or biological" under Section 1847A of the Social Security Act. BYOOVIZ™ is a recombinant humanized immunoglobulin gamma 1 (IgG1) kappa isotype monoclonal antibody fragment designed for intraocular use. BYOOVIZ™ binds to and inhibits the biologic activity of human VEGF-A. Each BYOOVIZ™ vial provides 0.05 mL of 10 mg/mL solution (0.5 mg dose vial) for intravitreal injection. BYOOVIZ™ is an ophthalmic intravitreal injection recommended to be administered once a month (approximately 28 days). Each BYOOVIZ™ 0.5 mg carton contains a single-dose, 2-mL glass vial designed to deliver 0.05 mL of 10 mg/mL BYOOVIZ™ solution that is clear to slightly opalescent and colorless to pale yellow.

Final Decision

Establish new HCPCS Level II code Q5124 "Injection, ranibizumab-nuna, biosimilar, (byooviz), 0.1 mg"

Effective: 4/1/2022

Release™ - HCP211001CM4X1

Topic/Issue

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

Applicant's suggested language: Q42XX "Release™, per square centimeter."

Applicant's Summary

StimLabs, LLC submitted a request to establish a new HCPCS Level II code to identify Release™. Release™ is comprised of dehydrated human amniotic membrane obtained from donated placental tissue. Release™ is a sheet skin substitute product that contains non-viable cells and is intended for use as a selective barrier and to protect wounds from the surrounding environment for chronic and acute wounds including dermal ulcers and other defects. The processed membrane is dehydrated, fenestrated and cut into various sizes, and presented in a sterilized, dehydrated sheet graft form. Release™ is intended for use as a selective barrier and to protect wounds from the surrounding environment for chronic and acute wounds including dermal ulcers and other defects. The processing of Release™ preserves all layers of the placental membrane and maintains the 3D physiologic architecture of the natural barrier membrane. This triple layer barrier containing amnion, intermediate layer, and chorion provides a selective barrier and protection between wound and the surrounding environment. Release™ is for single patient use only. Release™ is offered in a variety of sizes from 2x2 cm to 6x8 cm sheets. The amount of Release™ used will be determined by the treating health care provider, based on the size of the wound. Release™ can be applied over the wound area either wet or dry. If hydration is preferred, sterile solution is used to hydrate the graft after placement on the wound site. Release™ is supplied as a terminally sterilized dehydrated human tissue allograft derived from human amnion and chorion membrane. Release™ should be maintained in its original packaging and stored at ambient temperature (0°C to 38°C) until ready to use.

Final Decision

Based on written feedback from the FDA's Tissue Reference Group (TRG), Release™, when intended to serve as a selective barrier and to protect wounds from the surrounding environment, and its use is "not intended for wound healing", it meets the criteria for regulation solely under section 361 of the Public Health Service (PHS) Act and the regulations in 21 CFR part 1271. As a result of our review of the TRG's feedback, CMS has decided to:

Establish new HCPCS Level II code Q4257 "Release, per square centimeter"

Effective: 4/1/2022

Enverse™ - HCP2110013M2DA

Topic/Issue

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

Applicant's suggested language: "Q42XX "Enverse™ per square centimeter."

Applicant's Summary

StimLabs, LLC submitted a request to establish a new HCPCS Level II code to identify Enverse™. Enverse™ is comprised of dehydrated human amniotic membrane obtained from donated placental tissue. Enverse™ contains non-viable cells and is to be used as a wound covering or barrier membrane, over chronic and acute wounds, including dermal ulcers or defects. No viable or non-viable cells are added to the harvested amniotic membrane. The processed membrane is dehydrated and cut into various sizes, and presented in a sterilized, dehydrated sheet graft form. Enverse™ is classified by the FDA as Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/P) that is regulated solely under Section 361 of the Public Health Service (PHS) Act. We are requesting a new HCPCS code for Enverse™ in the absence of a specific HCPCS code that appropriately identifies Enverse™. Enverse™ is packaged as individual sheets in a range of sizes (2x2 cm to 9x15 cm); each sheet is presented in a configuration for various applications. Enverse™ is for single patient use only. The amount of Enverse™ used will be determined by the treating health care provider based on the size of the wound. Enverse™ can be applied over the wound area either wet or dry. If hydration is preferred, sterile solution is used to hydrate the graft after placement on the wound site. Enverse™ should be maintained in its original packaging and stored at ambient temperature (0°C to 38°C) until ready to use. When stored properly in their original packaging, Enverse™ allografts are shelf-stable.

Final Decision

Based on written feedback from the FDA's Tissue Reference Group (TRG), Enverse™, when intended for use as a barrier membrane or wound covering and "not intended for wound healing", meets the criteria for regulation solely under section 361 of the Public Health Service (PHS) Act and the regulations in 21 CFR part 1271. As a result of our review of the TRG's feedback, CMS has decided to:

Establish new HCPCS Level II code Q4258 "Enverse, per square centimeter"

Effective: 4/1/2022

MLG Complete™ - HCP21092045NQA

Topic/Issue

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

Applicant's suggested language: QXXXX "MLG Complete™, per sq. cm."

Applicant's Summary

Samaritan Biologics LLC submitted a request to establish a new HCPCS Level II code to identify MLG Complete™. MLG Complete™ is a full thickness amnion-chorion derived allograft for management of wounds and burn injuries. MLG Complete™ is a sterile, single use, dehydrated allograft derived from donated human amnion-chorion membrane. MLG Complete™ acts as a cover and a barrier that offers protection from the surrounding environment. There is currently no HCPCS code available to describe MLG Complete™. The intended use of MLG Complete™ includes the management of wounds, such as, partial and full thickness wounds, pressure sores/ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds (e.g. donor site/grfts, post-laser surgery, post-Mohs surgery, podiatric wounds, wound dehiscence), trauma wounds, (e.g., abrasions, lacerations, partial thickness burns, skin tears), and draining wounds. MLG Complete™ dosage is per sq. cm, depending on the size of the wound. MLG Complete™ graft can be reapplied as needed. MLG Complete™ is intended for external application. Following standard wound preparation, MLG Complete™ is applied directly to the wound. MLG Complete™ adheres to the wound bed without fixation. MLG Complete™ is fully resorbable and does not have to be removed from the wound bed. MLG Complete™ is supplied sterile, in a single use package in a variety of sizes.

Final Decision

Based on written feedback from the FDA's Tissue Reference Group (TRG), MLG Complete™ for use to serve as a barrier and provide protective coverage from the surrounding environment for acute and chronic wounds, appears to be regulated solely under section 361 of the Public Health Service (PHS) Act and the regulations in 21 CFR part 1271. As a result of our review of the TRG's feedback, CMS has decided to:

Establish new HCPCS Level II code Q4256 "Mlg complete, per square centimeter"

Effective: 4/1/2022

AmnioBind™ - HCP21090861EG3

Topic/Issue

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

Applicant's suggested language: Q4XXX "AmnioBind™ per sq cm."

Applicant's Summary

Predictive Biotechnology submitted a request to establish a new HCPCS Level II code to identify AmnioBind™. AmnioBind™ is a terminally sterilized, dehydrated, full thickness placental membrane (PM) allograft consisting of amnion, chorion, and the associated intermediate (spongy) layer (IL). Typically, following debridement, PM allografts are applied to the wound surface to provide a barrier to the environment. AmnioBind™ should always be maintained within closed packaging until just prior to administration. At the time of administration, the product can be removed (using proper sterile technique) by pulling the membrane out of the packaging. The allograft is intended to remain on the site for five to seven days. It is designed for application directly to acute and chronic wounds, is flexible, and is a conforming cover that adheres to complex anatomies. AmnioBind™ membrane is intended for use as a wound covering. This product is an allograft tissue intended for homologous use for the repair, reconstruction, and replacement of the recipient's tissue at the discretion of a physician.

Final Decision

Based on written feedback from the FDA's Tissue Reference Group (TRG), AmnioBind™, when intended for "repair, reconstruction and replacement of the recipient's tissue" and "as a covering", appears to meet the criteria for regulation solely under section 361 of the Public Health Service (PHS) Act and the regulations in 21 CFR part 1271. As a result of our review of the TRG's feedback, CMS has decided to:

Establish new HCPCS Level II code Q4225, "Amniobind, per square centimeter"

Effective: 4/1/2022

Human Health Factor 10 Amniotic Patch™ [HHF10-P™] - HCP2109174Y0E9

Topic/Issue

Request to establish a new HCPCS Level II code to identify Human Health Factor 10 Amniotic Patch™ (HHF10-P™).

Applicant's suggested language: The applicant requested a Q code, but did not suggest specific descriptor language.

Applicant's Summary

Wolver and Poole Distribution, LLC submitted a request to establish a new HCPCS Level II code to identify Human Health Factor 10 Amniotic Patch™, HHF10-P™. HHF10-P™. It is a single-layer amniotic allograft derived from donated and screened, full-term human birth tissue, specifically the immunoprivileged amnion layer. It is a semi-transparent, minimally manipulated, terminally sterilized membrane allograft. HHF10-P™ is intended for homologous use to act as a covering or barrier to offer protection from the surrounding environment in clinical applications. There is currently no HCPCS code that adequately describe HHF10-P™. We respectfully request a Q-code, since these are product-specific and will facilitate proper coding and billing to payers. Currently, providers utilize Q4100 "skin substitute, not otherwise specified." HHF10-P™ is supplied at either a 2 cm x 2 cm or 4 cm x 4 cm size in dual-layer, sterile 4 mm packaging.

Final Decision

Based on written feedback from the FDA's Tissue Reference Group (TRG), HHF10-P™, when intended "to act as a covering or barrier to offer protection from the surrounding environment" appears to meet the criteria for regulation solely under section 361 of the Public Health Service (PHS) Act and the regulations in 21 CFR part 1271. As a result of our review of the TRG's feedback, CMS has decided to:

Establish new HCPCS Level II code Q4224, "Human health factor 10 amniotic patch (hhf10-p), per square centimeter"

Effective: 4/1/2022

NEXVIAZYME - HCP210917MQTB3

Topic/Issue

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

Applicant's suggested language: JXXXX "Injection, avalglucosidase alfa-ngpt,10 mg, for intravenous use."

Applicant's Summary

Sanofi submitted a request to establish a new HCPCS Level II code to identify NEXVIAZYME. NEXVIAZYME is a hydrolytic lysosomal glycogen-specific enzyme indicated for the treatment of patients 1 year of age and older with late-onset Pompe disease (lysosomal acid alpha-glucosidase [GAA] deficiency). Late-onset Pompe disease is a rare metabolic muscle disease inherited in an autosomal recessive manner defined by a deficiency of acid α -glucosidase (GAA), which is necessary for the degradation of lysosomal glycogen. NEXVIAZYME provides an exogenous source of GAA. Patients are dosed every other week on a mg/kg basis; the recommended dosage for patients weighing ≥ 30 kg is 20 mg/kg (of actual body weight). For patients weighing < 30 kg, the recommended dosage is 40 mg/kg (of actual body weight). The product is administered by controlled intravenous infusion over approximately four to seven hours. NEXVIAZYME is supplied as a sterile, white to pale-yellow lyophilized powder in 100 mg single-dose vials for reconstitution. After reconstitution, the resultant solution concentration is 10 mg/mL. There is no other avalglucosidase alfa-ngpt approved by the FDA in the United States. A new HCPCS code is required to accurately describe the product.

Final Decision

1. Establish new HCPCS Level II code J0219 "Injection, avalglucosidase alfa-ngpt, 4 mg"

Effective: 4/1/2022

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

Under long-standing policy, CMS assigns the dose descriptor in the smallest amount that could be billed in multiple units to accommodate a variety of doses, thus making coding more robust, and facilitating accurate payment and reporting of the exact dose administered.

2. Discontinue existing HCPCS Level II code C9085 "Injection, avalglucosidase alfa-ngpt, 4 mg".

Effective: 3/31/2022

ExEm® Foam - HCP210813CU4RH

CMS is removing this decision from the Q4 2021 coding cycle. After the publication of our initial coding decision, we received additional information from the applicant. We will consider further action on this application in a later coding cycle.

Cyclophosphamide - HCP2109305HC8R

Topic/Issue

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

Applicant's suggested language: J9XXX, "Cyclophosphamide Injection, 0.1ml."

Applicant's Summary

AuroMedics submitted a request to establish a new HCPCS Level II code to identify Cyclophosphamide Injection. The New Drug Application (NDA) was approved by the FDA on August 25, 2021, and is indicated for the treatment of malignant lymphomas: Hodgkin's disease, lymphocytic lymphoma, mixed-cell type lymphoma, histiocytic lymphoma, Burkitt's lymphoma; multiple myeloma, leukemias, mycosis fungoides, neuroblastoma, adenocarcinoma of ovary, retinoblastoma, and breast carcinoma. A HCPCS Q-code has been requested to resolve potential provider confusion as there are other Cyclophosphamide Injection products on the market. AuroMedics believes there is a programmatic need for this Q-code and then a permanent J-code to differentiate our FDA approved 505(b)(2) single source product from the other products to comply with the reimbursement requirements of the ASP statute and CMS' current implementation policies and procedures. Action--The liver is the major site of cyclophosphamide activation. Approximately 75% of the administered dose of cyclophosphamide is activated by hepatic microsomal cytochrome P450s including CYP2A6, 2B6, 3A4, 3A5, 2C9, 2C18 and 2C19, with 2B6 displaying the highest 4-hydroxylase activity. Cyclophosphamide is activated to form 4-hydroxycyclophosphamide, which is in equilibrium with its ring-open tautomer aldophosphamide. 4-hydroxycyclophosphamide and aldophosphamide can undergo oxidation by aldehyde dehydrogenases to form the inactive metabolites 4-ketocyclophosphamide and carboxyphosphamide, respectively. Aldophosphamide can undergo β -elimination to form active metabolites phosphoramidate mustard and acrolein. This spontaneous conversion can be catalyzed by albumin and other proteins. Less than 5% of cyclophosphamide may be directly detoxified by side chain oxidation, leading to the formation of inactive metabolites 2-dechloroethylcyclophosphamide. At high doses, the fraction of parent compound cleared by 4-hydroxylation is reduced resulting in non-linear elimination of cyclophosphamide in patients. Cyclophosphamide appears to induce its own metabolism. Auto-induction results in an increase in the total clearance, increased formation of 4-hydroxyl metabolites and shortened t1/2 values following repeated administration at 12- to 24-hour interval.

Final Decision

1. Establish new HCPCS Level II code J9071 "Injection, cyclophosphamide, (auromedics), 5 mg"

Effective: 4/1/2022

Under long-standing policy, CMS assigns the dose descriptor in the smallest amount that could be billed in multiple units to accommodate a variety of doses, thus making coding more robust, and facilitating accurate payment and reporting of the exact dose administered. CMS determined that 5 mg would be the smallest amount that could be

billed in multiple units to accommodate a variety of doses and support streamlined billing, as only 999 units can appear on a claim line for Medicare fee-for-service.

2. Discontinue existing HCPCS Level II code C9087 “Injection, cyclophosphamide, (auromedics), 10 mg”

Effective: 3/31/2022

KORSUVA™ - HCP210920MDYHC

Topic/Issue

Request to establish a new HCPCS Level II code is to identify difelikefalin.

Applicant's suggested language: JXXXX "difelikefalin injection, 0.1 mL"

Applicant's Summary

Vifor (International) Inc. is requesting a new HCPCS code for KORSUVA™, which significantly reduces itch intensity in hemodialysis patients with chronic kidney disease-associated pruritis (CKD-aP). CKD-aP is a severe, intractable systemic itching in many patients with CKD, often associated with poor quality of sleep, depression, reduced quality of life, increased risk of infection and an increased risk of death. KORSUVA™ was approved by the FDA on August 23, 2021 under a Type 1 New Drug Application (NDA).

As a first in class, single source drug product, there are currently no HCPCS codes that adequately describe KORSUVA™. KORSUVA™ is indicated for the treatment of moderate-to-severe CKD-aP in adults undergoing hemodialysis (HD). KORSUVA™ has not been studied in patients on peritoneal dialysis and is not recommended for use in this population. The mechanism of action of KORSUVA™ is a kappa opioid receptor (KOR) agonist. The recommended dosage of KORSUVA™ is 0.5 mcg/kg administered by intravenous bolus injection into the venous line of the dialysis circuit at the end of each HD treatment. Total Injection Volume (mL) = Patient Target Dry Body Weight (kg) x 0.01, rounded to the nearest tenth (0.1 mL). In clinical trials, the average dry body weight was 86 kg, equivalent to a KORSUVA™ dose of 0.9 mL. Given the practicality of dosing and administering KORSUVA™, it is expected that the dose will be based on volume. The KORSUVA™ Dosing Summary (included with application) will be the standard dosing utilized by dialysis providers and therefore the billable unit should align with the standard dosing. KORSUVA™ (difelikefalin) injection, 65 mcg/1.3 mL (50 mcg/mL), is supplied as a sterile, clear and colorless solution in 1.3 mL single-dose, glass vials.

Final Decision

In December 2021, CMS approved KORSUVA™ (difelikafalin) for the Transitional Drug Add-on Payment Adjustment (TDAPA) under the ESRD PPS. Implementation direction pertaining to this approval will be made available to ESRD facilities through a CMS Change Request Transmittal with an effective date targeted for April 1, 2022, pending approval of the HCPCS code. The TDAPA payment period will begin on April 1, 2022 and will apply for a period of two years.

As such, we recommend the establishment of HCPCS Level II code J0879 "Injection, difelikefalin, 0.1 microgram, (for esrd on dialysis)"

Effective: 4/1/2022

Under long-standing policy, CMS assigns the dose descriptor in the smallest amount that could be billed in multiple units to accommodate a variety of doses, thus, making coding more robust, and facilitating accurate payment and reporting of the exact dose administered.

Furthermore, considering the single-use packaging for KORSUVA™, the JW modifier should be used by facilities on the 72x claim to report the amount of KORSUVA™ that is discarded and eligible for payment under the ESRD PPS.

VENDAJE OPTIC™ - HCP21092098RWJ

Topic/Issue

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

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

Applicant's Summary

BioStem Technologies, Inc. submitted a request to establish a new HCPCS Level II code to identify VENDAJE OPTIC™. VENDAJE OPTIC™ is a sterile, single use, dehydrated human amniotic membrane composed of the amnion layer. VENDAJE OPTIC™ is a structural tissue allograft intended for homologous use as a wound covering for ocular surfaces. VENDAJE OPTIC™ is functioned as a protective barrier by resorbing into ophthalmic wounds and repairing the surface of the ocular system. VENDAJE OPTIC™ provides a scaffold of extracellular matrix proteins, active growth factors and cytokines. These crucial components support healing and infection control. Existing HCPCS codes do not adequately describe VENDAJE OPTIC™, a dehydrated amnion layer with a nominal average thickness of 30 microns. VENDAJE OPTIC™ is a skin substitute for repairing and reconstructing the surface of the eye concerning ophthalmic conditions with conjunctival tissue, abnormal epithelium development, non-healing corneal ulcers, post-surgical wounds, and trauma wounds. The product acts on the patient as an effective protective covering. VENDAJE OPTIC™ creates an ideal microenvironment by preventing pathogens and irritants from entering. The amniotic membrane offers a vapor barrier preventing unwanted water loss from excessive evaporation at the wound thus reducing pain and inflammation caused by friction of the eyelids. VENDAJE OPTIC™ is available in sizes of 8mm, 10mm, and 12mm discs and dosage is based on the size of the wound. The route of administration is topically applying the membrane over the wound or within the surgical site. It is affixed by hydrostatic tension with or without sutures and sterile dressings. VENDAJE OPTIC™ is aseptically packaged and sealed in an inner poly/foil peel pouch. An irradiation indicator is fixed on the inner package and then sealed with an outer poly/foil peel pouch. The packaged allograft is terminally sterilized by electron beam irradiation, labeled, and sealed in a dust cover containing instructions, patient labels, and a tissue tracking card.

Final Decision

After review of the FDA's Tissue Reference Group (TRG) letter submitted by the applicant, it appears to CMS that the VENDAJE OPTIC™ product information submitted to CMS may differ from the information that was submitted to the FDA. Based on written feedback from the TRG, VENDAJE OPTIC™, when intended for "use as a protective covering during the repair of ocular surfaces" appears to meet the criteria for regulation solely under section 361 of the Public Health Service (PHS) Act and the regulations in 21 CFR part 1271. However, in the HCPCS Level II application for VENDAJE OPTIC™, the applicant referenced additional intended uses. The application stated that VENDAJE OPTIC™ is used to facilitate healing, decrease the formation of scarring, control infections, and reduce pain and inflammation. Based on this information, it appears that VENDAJE OPTIC™ is not suitable for registration as a Human Cells, Tissues, and Cellular and Tissue-Based Product (HCT/P). CMS refers the applicant back to the FDA's TRG to obtain written feedback regarding how the product, consistent with its intended uses described in the HCPCS Level II application, is

appropriately regulated. After obtaining the FDA's written feedback, the applicant is welcome to submit a complete HCPCS 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>.

VENDAJE AC™ - HCP210920LJ3TU

Topic/Issue

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

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

Applicant's Summary

BioStem Technologies, Inc. submitted a request to establish a new HCPCS Level II code to identify VENDAJE AC™, a sterile, single use, dehydrated human amnion and chorion membrane allograft. VENDAJE AC™ is a structural tissue allograft utilized as a skin substitute under homologous use. VENDAJE AC™ functions as a protective barrier by resorbing into the wound and repairing dermal and soft tissue wounds. VENDAJE AC™ provides a scaffold of extracellular matrix proteins, active growth factors and cytokines. These crucial components support healing and infection control. No existing HCPCS code adequately defines VENDAJE AC™, a dehydrated amnion and chorion layer with a nominal average thickness of 140 micrometers. VENDAJE AC™ is a skin substitute for repairing and reconstructing the integumentary system concerning chronic and acute pressure sores/ulcers related to disease processes, partial thickness burns to full thickness burns, draining wounds, post-surgical wounds, and trauma wounds. The product acts on the patient as an effective protective covering. VENDAJE AC™ creates an ideal microenvironment for the wound bed by preventing pathogens and irritants from entering. The amnion and chorion membrane prevent unwanted diffusion of moisture at the wound thus reducing pain and inflammation. VENDAJE AC™ is available in sizes of 1x1cm, 2x2cm, 2x4cm, 4x4cm, 4x6cm, 4x8cm, 6x6cm, and 7x15cm. The dosage is based on the size of the wound. The route of administration is by topically applying the membrane over the wound or applying within the surgical site. It is affixed by hydrostatic tension with or without sutures. VENDAJE AC™ is aseptically packaged and sealed in an inner peel pouch. An irradiation indicator is fixed on the inner package and then sealed with an outer peel pouch. The packaged allograft is terminally sterilized by electric beam, labeled, and sealed in a paperboard box containing instructions, patient labels, and a tissue tracking card.

Final Decision

After review of the FDA's Tissue Reference Group (TRG) letter submitted by the applicant, it appears to CMS that the VENDAJE AC™ product information submitted to CMS may differ from the information that was submitted to the FDA. Based on written feedback from the TRG, VENDAJE AC™, when intended "to be used topically or on the surface of the skin as a protective/wound covering or barrier," appears to meet the criteria for regulation solely under section 361 of the Public Health Service (PHS) Act and the regulations in 21 CFR part 1271. However, in the HCPCS Level II application for VENDAJE AC™, the applicant referenced additional intended uses. The application stated that VENDAJE AC™ is used to facilitate healing, reduce scar tissue formation, reduce infection, and reduce pain and inflammation. Based on this information, it appears that VENDAJE AC™ is not suitable for registration as a Human Cells, Tissues, and Cellular and Tissue-Based Product (HCT/P). CMS refers the applicant back to the FDA's TRG to obtain written feedback regarding how the product, consistent with its intended uses described in the HCPCS Level II application, is appropriately regulated. After obtaining the FDA's written feedback, the applicant is

welcome to submit a complete HCPCS code application in a subsequent coding cycle.
Information for submitting questions to the TRG is located at:
<https://www.fda.gov/vaccinesbloodbiologics/tissue-tissue-products/tissue-reference-group>.

VIA DERMIS - HCP210922YEV7E

Topic/Issue

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

Applicant's suggested language: Q4XXX "VIA DERMIS, Per square centimeter."

Applicant's Summary

VIVEX submitted a request to establish a new HCPCS Level II code to identify a human tissue allograft (trade name VIA DERMIS Dermal Matrix Allograft). The purpose of this HCPCS Level II application is to establish a new code for VIA DERMIS Dermal Matrix. VIA DERMIS Dermal Matrix is an acellular dermal matrix allograft recovered with consent from qualified donors. VIA DERMIS Dermal Matrix is processed in accordance with FDA regulations and American Association of Tissue Banks standards. VIA DERMIS Dermal Matrix is shipped in a single use package with one unit per package and may be stored at ambient conditions for up to five years; a variety of VIA DERMIS Dermal Matrix sizes are available. Existing HCPCS codes do not adequately describe VIA DERMIS Dermal Matrix since Q codes are product specific. Currently, providers must utilize HCPCS Q4100 (Skin substitute, not otherwise specified), which results in the inability for providers to specifically report which product is being used for treatment. HCPCS Q4100 is inadequate to describe VIA DERMIS Dermal Matrix because this code does not allow for accurate cost data to be collected for the product alone. A product-specific Q code will allow VIVEX to work directly with third party payers to establish medical necessity criteria and coverage for VIA DERMIS Dermal Matrix for use during integumentary augmentation applications.

Final Decision

The FDA's Tissue Reference Group (TRG) letter submitted by the applicant does not identify VIA DERMIS as the product that was reviewed by the TRG. The TRG letter references the "allogenic Dermal Matrix" as the subject of review. CMS refers the applicant back to the FDA's TRG to obtain written feedback regarding how VIA DERMIS 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>.

mVASC® - HCP210916URQ2X

Topic/Issue

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

Applicant's suggested language: QXXXX "mVASC® per cc."

Applicant's Summary

Microvascular Tissues, Inc. submitted a request to establish HCPCS Level II code to identify mVASC®. mVASC® consists of voluntarily donated human cadaveric microvascular tissue that has been aseptically processed, lyophilized to remove moisture, while preserving its structural and inherent biologic components and terminally sterilized to a sterility assurance level (SAL) of 10⁻⁶. mVASC® microvascular tissue transfers are intended to re-establish blood flow via creation of new functional microcirculations that repair, replace, reconstruct or supplement deficient tissue. Currently there is no HCPCS code for microvascular tissue products. mVASC® is intended for the repair, reconstruction, replacement or supplementation of microvascular tissue in the body. Microvascular tissue serves as the foundation for granulation and remodeling during healing. Optimal restoration of microvascular structure and function is essential for healing and to mitigate tissue vulnerability in a newly epithelialized wound. This is especially true when the tissue microenvironment is compromised by advanced age, diabetes, small vessel disease or radiation. mVASC® microvascular tissue transfers are intended to re-establish blood flow via creation of new functional microcirculations that repair, replace, reconstruct or supplement deficient tissue. mVASC® should be applied topically to wounds. mVASC® is packaged in a glass vial that is stoppered and crimped. The vial is packaged in a polyethylene terephthalate glycol (PETG) tray that is sealed with a Tyvek® lid.

Final Decision

After review of the FDA's guidance, it does not appear to CMS that mVASC® microvascular tissue 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 written feedback from the TRG, 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>.

Pepaxto® - HCP210920HGA4Y

Topic/Issue

Request to revise existing HCPCS Level II code J9247 “Injection, melphalan flufenamide, 1 mg”

Applicant’s suggested language: Revise existing HCPCS Level II code J9247 which currently reads “Injection, melphalan flufenamide, 1 mg” to include brand name, to instead read “Injection, melphalan flufenamide (pepaxto®), 1 mg”.

Applicant’s Summary

Oncopeptides Inc submitted a request to revise an existing HCPCS Level II code J9247 “Injection, melphalan flufenamide, 1 mg” to include the brand name “Pepaxto®”. CMS established a new HCPCS Level II code in Quarter 2 2021 Drugs and Biologics, J9247 “Injection, melphalan flufenamide, 1mg.” to identify Pepaxto®. The similarity of Pepaxto’s® generic name, melphalan flufenamide, to melphalan has resulted in compendia misclassifications, medication errors and prior authorization errors. At least one patient was incorrectly dosed with the similarly named drug, Evomela (melphalan). To prevent future errors, Oncopeptides requests that the short and long descriptors be clarified. Oncopeptides’ requested change is modeled on Evomela, where the precedent was established by CMS’ decision to allow the trade name in the descriptor, as published in 2020 HCPCS Application Summary for Quarter 1 2020 Drugs and Biologics, Request #20.043. Pepaxto® is indicated in combination with dexamethasone for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy and whose disease is refractory to at least one proteasome inhibitor, one immunomodulatory agent, and one CD38-directed monoclonal antibody. Melphalan flufenamide is a peptide conjugated alkylating drug. Due to its lipophilicity, melphalan flufenamide is passively distributed into cells and thereafter enzymatically hydrolyzed to melphalan. The recommended dosage of Pepaxto® is 40 mg administered intravenously over thirty minutes on Day 1 of each 28-day cycle until disease progression or until unacceptable toxicity. Pepaxto® is a white to off-white lyophilized powder for reconstitution (after reconstitution the solution is clear and colorless to light yellow) supplied in a 50 mL single dose vial containing 20 mg melphalan flufenamide. Each 20 mg vial is packaged in a single carton.

Final Decision

Based on our research into publicly available information on this product, Pepaxto® is no longer marketed in the United States. See: <https://www.oncopeptides-us.com/en/media-center/important-information-regarding-pepaxto-in-the-united-states>. Because this product is not marketed in the United States, we are considering this application for a HCPCS Level II code to be withdrawn.