Centers for Medicare & Medicaid Services (CMS) Healthcare Common Procedure Coding System (HCPCS) Application Summaries and Coding Decisions
Fourth 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' Fourth 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 April 2021 HCPCS Quarterly Update, pending publication by CMS in the coming weeks at: https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Alpha-Numeric-HCPCS.

Request # 20.021I

Topic/Issue

After further review of Medicare Part B policy, CMS is revising existing code J7321 to include Visco-3 and discontinuing code J7333, which reads "Hyaluronan or derivative, visco-3, for intra-articular injection, per dose".

Our recommendation improves consistency with policy at https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Downloads/051807_coding_announcement.pdf, which states: "Section 1847A requires single source drugs or biologicals that were within the same billing and payment code as of October 1, 2003, be treated as multiple source drugs, so the payment under Section 1847A for these drugs and biologicals is based on the volume weighted average of the pricing information for all of the products within the billing and payment code."

It has come to our attention that Visco-3 was approved by the FDA under a supplement premarket approval (PMA) number (P980044) on December 21, 2015 and not an original PMA. The original application supporting Visco-3 approval was PMA number P980044 for Supartz FX, approved on January 24, 2001. To maintain consistency with other decisions made in accordance with this policy and in light of the fact that the original PMA supporting the approval for Visco-3 was included within the same billing and payment code prior to October 1, 2003, CMS has determined that Visco-3 should be included in J7321 with Supartz.

We do not seek to change coding for J7332 Triluron because it was approved by the FDA under an original PMA (P180040) on March 26, 2019. Separate coding for this product is consistent with the policy described above.

Final Decision

1. Revise existing Level II HCPCS code J7321 which currently reads: "Hyaluronan or derivative, hyalgan or supartz, for intra-articular injection, per dose" to now read: "Hyaluronan or derivative, hyalgan, supartz or visco-3, for intra-articular injection, per dose."

Effective Date: 04/01/2021

2. Discontinue existing Level II HCPCS code J7333 "Hyaluronan or derivative, visco-3, for intra-articular injection, per dose."

Effective Date: 03/31/2021

Request # 20.174

Topic/Issue

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

Trade name: VILTEPSO

Applicant's suggested language: JXXXX "Injection, viltolarsen, 10 mg, for intravenous use."

Applicant's Summary

VILTEPSO is an antisense oligonucleotide that is designed to restore dystrophin production and halt muscle damage by binding to the exon 53 sequence of the target dystrophin premessenger ribonucleic acid (pre-mRNA), allowing removal of exon 53 by alternative splicing and enabling translation of a shortened dystrophin protein that contains the essential functional portions of the molecule. The resulting skipped protein resembles proteins observed in patients with Becker muscular dystrophy, a milder form of the disease than DMD.

VILTEPSO has a morpholino backbone that interacts with dystrophin pre-mRNA and alters the exon/intron splicing patterns. VILTEPSO contains 21 linked subunits. The molecular weight of VILTEPSO is 6,924.82 daltons. It is a sterile, aqueous solution administered as a 60-minute intravenous infusion with a recommended dose of 80 mg/kg once weekly for the treatment of DMD in patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping. VILTEPSO is supplied in single-dose vials of 250 mg/5 mL (50 mg/mL) viltolarsen in preservative-free solution.

Final Decision

Establish a new Level II HCPCS code J1427 "Injection, Viltolarsen, 10 mg."

Effective Date: 04/01/2021

Request # 20.176

Topic/Issue

Request to establish a new Level II HCPCS code to identify AmnioAMP-EXS and AmnioAMP-EXSP.

Applicant's suggested language: Q4XXX "AmnioAMP EXS."

Applicant's Summary

AmnioAMP-EXS is a 100% Human derived flowable tissue processed using aseptic techniques. This human allograft is cryopreserved and intended for homologous use only. This human tissue flowable allograft provides a combination of growth factors, interleukins, and hyaluronic acid that work together to promote the promote the body's natural healing properties. These combinations provide a protection, lubrication and cushioning of the site to reduce the inflamed or burned area. AmnioAMP EXS, for human tissue flowable allograft is intended for the treatment of chronic non-healing wounds, burn related injuries, degenerative tissue disorders, acute and soft tissue injuries, as well as other inflammatory conditions. AmnioAMP-EXS delivers a flowable dose of extracellular matrix proteins, interleukins, and hyaluronic acid to the wound site and works to reduce the inflammatory host issues. It is supplied in a single patient use dose ready to use vial with different dosages from 0.5cc – 2.0cc.

Final Decision

After review of FDA's guidance, it does not appear to CMS that AmnioAMP-EXS and AmnioAMP-EXSP are suitable for registration as the human cells, tissues, and cellular and tissue-based products (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 the FDA's written feedback, the applicant is welcome to submit a complete HCPCS code application in a subsequent coding cycle.

Information for submitting questions to the TRG is located at:

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

Request # 20.177

Topic/Issue

Request to establish a new Level II HCPCS code to identify tafasitamab-cxix.

Trade name: MONJUVI

Applicant's suggested language: J9XXX "Injection, tafasitamab-cxix, 2 mg."

Applicant's Summary

MONJUVI is a humanized Fc-modified cytolytic CD19-targeting monoclonal antibody. Fc-modification of MONJUVI leads to a significant potentiation of antibody-dependent cell-mediated cytotoxicity (ADCC) and antibody-dependent cellular phagocytosis (ADCP), thus improving a key mechanism of tumor cell killing.

MONJUVI is indicated in combination with lenalidomide for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) not otherwise specified, including DLBCL arising from low-grade lymphoma, and who are not eligible for autologous stem cell transplant (ASCT). MONJUVI is an Fc-modified monoclonal antibody that binds to the CD19 antigen expressed on the surface of pre-B and mature B lymphocytes and on several B-cell malignancies, including DLBCL. Upon binding to CD19, tafasitamab-cxix mediates B-cell lysis through apoptosis and immune effector mechanisms, including ADCC and ADCP. The recommended dosage of MONJUVI is 12 mg/kg. Administered by IV infusion. Supplied in a 200 mg single-dose vial. Each 200 mg vial is individually packaged in a carton (NDC 73535-0208-01).

Final Decision

Establish a new Level II HCPCS code J9349 "Injection, tafasitamab-cxix, 2 mg."

Effective Date: 04/01/2021

Request # 20.178

Topic/Issue

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

Applicant's suggested language: Q41XX "PureSkin per sq cm (human split-thickness allograft, cryopreserved)."

Applicant's Summary

PureSkin is a biological cadaveric split thickness allograft produced using a controlled-rate freezing process and protectants to preserve viable cells. PureSkin allograft is a natural skin replacement that can be used as temporary bridge to healing for regeneration of tissue to achieve wound closure of partial or full-thickness wounds due to tissue loss from burns or other major dermal defects. When applied to full-thickness burns, cryopreserved split-thickness allograft has several mechanisms of action that aid in wound healing until the wound/burn bed is ultimately closed, typically with an autograft. Mechanisms cited for split-thickness skin allografts include encouraging granulation formation, helping to guard against infection, conserving body heat, mitigating pain, and preserving fluid retention. The use of PureSkin allografts in the management of burn wounds allows early excision and wound covering, which may aid in the overall clinical management of the patient. PureSkin tissue allograft is surgically applied and secured to the skin by the anchoring method chosen by the surgeon (sutures, staples, adhesive glue, etc.). Clinical application will vary by the type of wound requiring the allograft; i.e. large area burns may require more frequent applications and for a longer period of time to achieve wound closure. The graft can be reapplied if needed.

Final Decision

After review of FDA's guidance, it does not appear to CMS that PureSkin is suitable for registration as 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 the FDA's written feedback, the applicant is welcome to submit a complete HCPCS code application in a subsequent coding cycle.

Information for submitting questions to the TRG is located at:

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

Request # 20.179

Topic/Issue

Request to establish a new Level II HCPCS code to identify immune globulin intravenous, human-slra 10%.

Trade name: ASCENIV

Applicant's suggested language: J1XXX "Injection, Immune Globulin (ASCENIV) Intravenous, 500 mg."

Applicant's Summary

ASCENIV is a purified, sterile, ready-to-use preparation of concentrated human immunoglobulin G (IgG) antibodies. The product is a clear to opalescent liquid, which is colorless to pale yellow. The distribution of IgG subclasses is similar to that of normal plasma. The active ingredient is human immunoglobulin purified from source human plasma and processed using a modified classical Cohn Method 6 / Oncley Method 9 fractionation procedure. ASCENIV contains 100 ± 10 mg/mL protein, of which not less than 96% is human immunoglobulin obtained from source human plasma. It is formulated in water for injection containing 0.100-0.140 M sodium chloride, 0.20-0.29 M glycine, 0.15–0.25% polysorbate 80, with pH 4.0–4.6. ASCENIV contains ≤ 200 μg/mL of IgA. ASCENIV (immune globulin intravenous, human – slra) 10% immune globulin liquid for intravenous injection, is indicated for the treatment of primary humoral immunodeficiency (PI) in adults and adolescents (12-17 years of age). PI includes, but is not limited to, the humoral immune defect in congenital agammaglobulinemia, common variable immunodeficiency (CVID), X-linked agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies (SCID).

ASCENIV dose adjustments may be required in patients who fail to maintain trough total IgG concentrations of at least 500 mg/dL with a target of 600 mg/dL. Starting with the second infusion, adjust the dose proportionally, targeting a trough of ≥ 600 mg/dL, based on the previous trough and the associated dose. ASCENIV is administered intravenously and it is supplied in a single-use, tamper-evident vial.

Final Decision

Establish a new Level II HCPCS code J1554 "Injection, immune globulin (ASCENIV), 500 mg."

Effective Date: 04/01/2021

Request # 20.180

Topic/Issue

Request to establish a new Level II HCPCS code to identify brexucabtagene autoleucel.

Trade name: Tecartus

Applicant's suggested language: "Brexucabtagene autoleucel, up to 200 million autologous anti-cd19 CAR-positive viable T cells, including leukapheresis and dose preparation procedures, per infusion."

Applicant's Summary

TECARTUS is a CD19-directed, genetically modified autologous T-cell immunotherapy indicated for the treatment of adult patients with relapsed/refractory mantle cell lymphoma. It is a distinct cellular product developed specifically for hematologic malignancies with CD19-expressing circulating tumor cells. TECARTUS was approved by the FDA on July 24, 2020, under Accelerated Approval based on overall response rate and durability of response. Previously, TECARTUS was granted Priority Review, Breakthrough Therapy Designation, and Orphan Drug Designation.

TECARTUS is administered through intravenous infusion and is measured as a single dose, i.e. the entire contents of the single-use, patient-specific infusion bag of TECARTUS contains a suspension of CAR-positive T cells in approximately 68 ml. The dose is 2 x 106 CAR-positive viable T cells per kg body weight, with a maximum of 2 x 108 CAR-positive viable T cells. Healthcare facilities that dispense and administer TECARTUS must be enrolled and comply with the Risk Evaluation and Management Strategy (REMS) program.

TECARTUS is the first and only FDA-approved CART-cell immunotherapy for this patient population. With currently available therapies, the prognosis for patients with relapsed/refractory MCL is poor. Overall, TECARTUS efficacy and safety data demonstrate a positive benefit-risk for patients with r/r MCL and provide a meaningful advantage over currently available therapies.

Final Decision

Establish Q2053 "Brexucabtagene autoleucel, up to 200 million autologous anti-cd19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose." The descriptor "per therapeutic dose" is consistent with the descriptors used for Level II HCPCS codes Q2041 and Q2042.

Effective Date: 04/01/2021

Request # 20.181

Topic/Issue

Request to establish a new Level II HCPCS code to identify a decellularized human placental matrix, CentaFlex.

Applicant's suggested language: Q4XXX "CentaFlex, sq cm for a decellularized human placental matrix."

Applicant's Summary

CentaFlex is a decellularized human placental matrix. This placental matrix is manufactured from umbilical cords from full-term human births umbilical cord of human placentas. CentaFlex is composed of predominately collagen and elastin. The matrix also contains fibronectin, laminin, glycosaminoglycans, and water. The laminins are important in extracellular matrix strength, cell attraction, and migration. The extracellular matrix provides a natural scaffold for cell attachment and proliferation needed for tissue repair with minimized inflammation and scarring. CentaFlex can be used as a barrier or wrap to provide a protective environment for the healing process.

CentaFlex is unique when compared to other decellularized human placental matrix products currently being marketed. The human placental matrix is manufactured by a proprietary process that allows for a five-year shelf-life at ambient temperature. CentaFlex does not require reconstitution or specific orientation prior to placement. This human placental matrix serves as support and framework for the recipient's cells to repopulate and revascularize the implanted material. Because it is not cross-linked, and does not contain cells or chorion, it greatly reduces the likelihood of immunogenicity.

According to the applicant, there are no current HCPCS codes to define a decellularized human placental matrix that is terminally E-beam sterilized, collagen-rich, non-cross-linked and composed of epithelial and stromal layers used as a barrier or wrap to provide a protective environment for the healing process.

Final Decision

After review of FDA's guidance, it does not appear to CMS that CentaFlex is suitable for registration as 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 the FDA's written feedback, the applicant is welcome to submit a complete HCPCS code application in a subsequent coding cycle.

Information for submitting questions to the TRG is located at:

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

Request # 20.182

Topic/Issue

Request to establish a new Level II HCPCS code to identify CTL AM 100.

Applicant's Summary

CTL AM 100 is a minimally manipulated, amniotic membrane derived, human tissue allograft suspension product. The product serves to provide a barrier/support function and to aid in healing of defect. It is intended to provide the extracellular matrix needed for the infiltration, attachment and proliferation of cells required for the repair of damaged tissue. Amniotic membrane human tissue based products have shown to reduce scarring, fibrosis, and adhesions in surgical and wound sites. It is administered through a syringe to the defect and the amount is determined by the clinician based on the size of the defect. Each human tissue based product distributed by Clinical Tissue Laboratories LLC is identified by its own unique serial number. The product is packaged in a transport protective pouch. The product is contained in a cryogenic primary tissue container, which contains a product label that includes the product details such as unique product number, storage requirements, and volume. Contents are aseptically processed and are not considered sterile. Currently available HCPCS codes for skin substitutes are product and brand specific; therefore, there is no code that can presently be used to identify this product.

Final Decision

After review of FDA's guidance, it does not appear to CMS that CTL AM 100 is suitable for registration as 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 the FDA's written feedback, the applicant is welcome to submit a complete HCPCS code application in a subsequent coding cycle.

Information for submitting questions to the TRG is located at:

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

Request # 20.184

Topic/Issue

Request to revise Level II HCPCS code Q4141 "Alloskin ac, per square centimeter" to add the two brand names/part codes "ProLayer Meshed Acellular Dermis 5x5CM <1mm 1:1 (Part Code: 3102-2555)" and "ProLayer Meshed Acellular Dermis 5x8CM <1mm 1:1 (Part Code: 3102-2558)"

Applicant's suggested language: "ProLayer Meshed Acellular Dermis 5x5CM <1mm 1:1 (Part Code: 3102-2555) and "ProLayer Meshed Acellular Dermis 5x8CM <1mm 1:1 (Part Code: 3102-2558)."

Applicant's Summary

ProLayer Meshed Acellular Dermis is a meshed dermis-only human skin allograft that has been decellularized while preserving the natural biologic components and structure of the dermal matrix. It may be used as a wound covering for partial and full thickness wounds, including chronic wounds, burns and traumatic injuries, or for other homologous uses.
The existing codes do not adequately describe the product because they are different brand names. It is used clinically in the treatment of partial and full-thickness burns, traumatic tissue loss due to injury and for chronic wounds such as pressure ulcers, diabetic foot ulcers, venous ulcers and arterial ulcers burns. Single use based on size of wound/burn. The material is applied to provide coverage of a tissue deficit and to promote wound closure through regeneration.

Final Decision

After review of FDA's guidance, it does not appear to CMS that ProLayer Meshed Acellular Dermis is suitable for registration as 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 the FDA's written feedback, the applicant is welcome to submit a complete HCPCS code application in a subsequent coding cycle.

Information for submitting questions to the TRG is located at:

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

Request # 20.185

Topic/Issue

Request to revise Level II HCPCS code Q4154 "Biovance, per square centimeter" to add Biovance 3L and several new sizes.

Applicant's Summary

Biovance is derived from placental tissue recovered, processed, by Celularity, Inc., according to the FDA regulations under 21 CFR Part 1271, Human Cells, Tissues, and Cellular and Tissue-Based Products. Biovance is marketed as a 361 HCT/P (human cell, tissue and cellular and tissue-based product) and is registered as such with the FDA.

Celularity needs to manufacture smaller sizes of its Biovance DHAM for use in ocular wound healing applications. The new sizes come in disc and rectangle configurations. The new disc sizes will be 10 mm, 12 mm, 15 mm, and the new rectangle sizes will be 15 mm x 20 mm, 25 mm x 25 mm, and 35 mm x 35 mm. The new SKUs are being requested for ASP reporting purposes. We are also requesting an additional branding name along with the new sizes to be known as Biovance 3L for all claims reporting purposes, while still reporting with the same Q4154 HCPCS Code.

Alongside the smaller sizes listed for ocular wound healing applications above, we are also requesting a new SKU for a 10 cm x 10 cm square size using the existing Biovance DHAM brand name.

Final Decision

After review of FDA's guidance, it does not appear to CMS that Biovance 3L is suitable for registration as 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 the FDA's written feedback, the applicant is welcome to submit a complete HCPCS code application in a subsequent coding cycle.

Information for submitting questions to the TRG is located at:

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

Request # 20.186

Topic/Issue

Request to establish a new Level II HCPCS code to establish FloLogix Flowable Multipurpose Allograft.

Applicant's Summary

FloLogix is composed of 100% human liquid amnion. Just as amniotic fluid protects and nourishes the fetus during development, FloLogix provides the same protection to injured or traumatized tissue. Amniotic fluid contains various proteins that support cell proliferation, movement and differentiation. Amniotic fluid includes collagen substrates, growth factors, amino acids, polyamines, lipids, carbohydrates, cytokines, extracellular matrix molecules, cells and other chemical compounds needed for tissue protection and repair. Amniotic fluid contains a broad spectrum of growth factors and cytokines that play important roles in wound healing, tissue protection and repair. These aid in the body's own rejuvenation and healing process.

FloLogix is intended for the treatment of non-healing wounds and burn injuries. The typical patient population may include chronic, partial or full-thickness diabetic ulcers or chronic, partial or full thickness skin ulcers due to venous insufficiency that have not responded to conventional wound treatment. Additional patients may include those with burn injuries.

FloLogix is an amniotic fluid product derived from donated human birth tissue. It is processed using aseptic techniques and packaged in tear pouches within peel pouches and frozen. The allograft is exposed to electron beam radiation at a dosage range of 15-20 kGy to ensure terminal sterilization and secured in an outer container. There are various sizes available. Since FloLogix is not currently micronized or lyophilized, there is no mg to cc conversion. FloLogix is prescribed by licensed healthcare professionals.

Final Decision

After review of FDA's guidance, it does not appear to CMS that FloLogix is suitable for registration as 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 the FDA's written feedback, the applicant is welcome to submit a complete HCPCS code application in a subsequent coding cycle.

Information for submitting questions to the TRG is located at:

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

Request # 20.187

Topic/Issue

Request to revise Level II HCPCS codes:

1. Reactivate Level II HCPCS code SI090 Mometasone furoate sinus implant, 370 micrograms with this revised descriptor adding the product name PROPEL, or
2. Create a new Level II HCPCS code SXXXX with the following descriptor to describe PROPEL "Mometasone furoate sinus implant, 370 micrograms (PROPEL)" and
3. Revise Level II HCPCS code J7401 to read: "Mometasone furoate, implant, 10 micrograms (SINUVA)."

Applicant's Summary

The PROPEL sinus implants, approved by the FDA under a PMA, are drug eluting sinus stents indicated to maintain patency and locally deliver steroid to the sinus mucosa in patients ≥ 18 years of age after sinus surgery: PROPEL is for the ethmoid sinus, PROPEL Mini is for the ethmoid sinus/frontal sinus opening, and PROPEL Contour for the frontal/maxillary sinus ostia. The PROPEL, PROPEL Mini, and PROPEL Contour sinus implants are stents used after sinus surgery to separate mucosal tissues, provide stabilization of the middle turbinate, prevent obstruction by adhesions, and reduce edema. The existing HCPCS code, J7401 "Mometasone Furoate sinus implant, 10 micrograms" became effective on 10/1/2019 and Level II HCPCS code S1090 was discontinued on 10/01/2019. These two changes effectively bundled both of Intersect ENT's products PROPEL and SINUVA under J740l and this has created coding confusion reporting problems for physicians. The PROPEL sinus implant is intended for use in patients ≥ 18 years of age following ethmoid sinus surgery to maintain patency, thereby reducing the need for post-operative intervention such as surgical adhesion lysis and/or use of oral steroids. All PROPEL sinus implants deliver 370µg mometasone furoate when placed after sinus surgery. PROPEL is a cylindrical-shaped implant, 23mm in nominal length, PROPEL Mini is a cylindrical-shaped implant, 16 mm in nominal length, and PROPEL Contour is an hourglass-shaped implant. All PROPEL products are packaged as sterile, single use units.

Final Decision

1. Establish a new Level II HCPCS code S1091 "Stent, non-coronary, temporary, with delivery system (propel)."

2. Discontinue Level II HCPCS code J7401 "Mometasone furoate sinus implant, 10 micrograms."

3. Establish new Level II HCPCS code J7402 "Mometasone furoate sinus implant, (sinuva), 10 micrograms."

Effective Date: 04/01/2021

Request # 20.188

Topic/Issue

Request to establish a new Level II HCPCS code to identify UCWJ 100.

Applicant's Summary

UCWJ 100 is regulated by the FDA as a human tissue product subject to Section 361 of the Public Service Act and 21 CFR 1271. Umbilical cord tissue matrix products have been shown to reduce fibrosis, scarring, and adhesions in wound and surgical sites. The product is intended to provide the extracellular matrix needed for the attachment, infiltration, and proliferation of cells required for repair of damaged tissues. This product is typically used for cartilage and muscle tears and help to repair damaged tissue. The product is used for wounds as well as tissue defects and is applied to the defect using a syringe. The amount of product used depends on the size of the defect and the clinicians' discretion. As per applicant, each human tissue based product distributed by Clinical Tissue Laboratories LLC is identified by its own unique serial number. The product is packaged in a transport protective pouch. The product is contained in a cryogenic primary tissue container, which contains a product label that includes the product details such as unique product number, storage requirements, and volume. Contents are aseptically processed and are not considered sterile. Currently available HCPCS codes for skin substitutes are product and brand specific; therefore, there is no code that can presently be used to identify this product.

Final Decision

After review of FDA's guidance, it does not appear to CMS that UCWJ 100 is suitable for registration as 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 the FDA's written feedback, the applicant is welcome to submit a complete HCPCS code application in a subsequent coding cycle.

Information for submitting questions to the TRG is located at:

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

Request # 20.189

Topic/Issue

Request to establish a new Level II HCPCS code to identify TWX 100

Applicant's Summary

TWX 100 is a minimally manipulated, amniotic membrane derived, human tissue allograft suspension product. The product serves to provide a barrier/support function and to aid in healing of defect. It is intended to provide the extracellular matrix needed for the infiltration, attachment and proliferation of cells required for the repair of damaged tissue. Amniotic membrane human tissue based products have shown to reduce scarring, fibrosis and adhesions in surgical and wound sites. It is administered through a syringe to the defect and the amount is determined by the clinician based on the size of the defect. Each human tissue based product distributed by Endow Tissue LLC is identified by its own unique serial number. The product is packaged in a transport protective pouch. The product is contained in a cryogenic primary tissue container, which contains a product label that includes the product details such as unique product number, storage requirements, and volume. Contents are aseptically processed and are not considered sterile. Currently available HCPCS codes for skin substitutes are product and brand specific; therefore, there is no code that can presently be used to identify this product.

Final Decision

After review of FDA's guidance, it does not appear to CMS that TWX 100 is suitable for registration as 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 the FDA's written feedback, the applicant is welcome to submit a complete HCPCS code application in a subsequent coding cycle.

Information for submitting questions to the TRG is located at:

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

Request # 20.190

Topic/Issue

Request to establish a new Level II HCPCS code to identify CWX 100.

Applicant's Summary

CWX 100 is regulated by the FDA as a human tissue product subject to Section 361 of the Public Service Act and 21 CFR 1271. Umbilical cord tissue matrix products have been shown to reduce fibrosis, scarring, and adhesions in wound and surgical sites. The product is intended to provide the extracellular matrix needed for the attachment, infiltration, and proliferation of cells required for repair of damaged tissues. This product is typically used for cartilage and muscle tears and help to repair damaged tissue. The product is used for wounds as well as tissue defects and is applied to the defect using a syringe. The amount of product used depends on the size of the defect and the clinicians' discretion. As per applicant, each human tissue based product distributed by Endow Tissue LLC is identified by its own unique serial number. The product is packaged in a transport protective pouch. The product is contained in a cryogenic primary tissue container, which contains a product label that includes the product details such as unique product number, storage requirements, and volume. Contents are aseptically processed and are not considered sterile. Currently available HCPCS codes for skin substitutes are product and brand specific; therefore, there is no code that can presently be used to identify this product.

Final Decision

After review of FDA's guidance, it does not appear to CMS that CWX 100 is suitable for registration as 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 the FDA's written feedback, the applicant is welcome to submit a complete HCPCS code application in a subsequent coding cycle.

Information for submitting questions to the TRG is located at:

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

Request # 20.191

Topic/Issue

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

Applicant's suggested language: QXXXX "VIM PER SQ CM."

Applicant's Summary

VIM human amniotic membrane is a minimally manipulated allograft sheet of human amnion that is terminally sterilized. Regulated under Public Health Service Act (PHS) 361, 21 CFR 1271.80, VIM human amniotic membrane allograft is derived from human tissue and is indicated for homologous use. Proprietary processing preserves the biological components and structure of the extracellular matrix (ECM) without disrupting tensile strength and elasticity. This process reserves structural and signaling proteins such as collagen, glycoproteins, proteoglycans, cytokines, and growth factors, which are crucial to the biochemical and biomechanical processes occurring at a cellular Level. VIM Human amniotic membrane allograft is intended for homologous use at the discretion of a physician where human amniotic membrane may be beneficial as a wound covering or barrier. The product is applied topically and held in place with normal fixation and sterile dressings. The product is provided sterile in 2x2cm and 4x4cm sizes and may be cut to size. Existing HCPCS Level II codes do not adequately describe VIM per sq cm. Product-specific coding is necessary to facilitate accurate reporting and payment under CMS Part B drugs and biologics ASP methodology, low/high cost assignment for OPPS payment and to facilitate coverage and payment from commercial insurers.

Final Decision

After review of FDA's guidance, it does not appear to CMS that VIM human amniotic membrane is suitable for registration as 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 the FDA's written feedback, the applicant is welcome to submit a complete HCPCS code application in a subsequent coding cycle.

Information for submitting questions to the TRG is located at:

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

Request # 20.192

Topic/Issue

Request to establish a new Level II HCPCS code to identify BLENREP (belantamab mafodotin-blmf).

Applicant's suggested language: JXXXX "Injection, belantamab mafodotin-blmf (BLENREP), 1 mg."

Applicant's Summary

BLENREP is a B-cell maturation antigen (BCMA)-directed antibody and microtubule inhibitor conjugate indicated for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior therapies including an anti-CD38 monoclonal antibody, a proteasome inhibitor, and an immunomodulatory agent. BLENREP was reviewed and approved by the Food and Drug Administration under a unique Biologic License Application (BLA) as a novel therapy. Therefore, no existing HCPCS code adequately describes belantamab mafodotin-blmf. Belantamab mafodotin-blmf is an antibody-drug conjugate (ADC). The antibody component is an afucosylated IgG1 directed against BCMA, a protein expressed on normal B lymphocytes and multiple myeloma cells. The small molecule component is MMAF, a microtubule inhibitor. Upon binding to BCMA, belantamab mafodotin-blmf is internalized followed by release of MMAF via proteolytic cleavage. The released MMAF intracellularly disrupts the microtubule network, leading to cell cycle arrest and apoptosis. Belantamab mafodotin-blmf had antitumor activity in multiple myeloma cells and mediated killing of tumor cells through MMAF-induced apoptosis, as well as by tumor cell lysis through antibody-dependent cellular cytotoxicity (ADCC) and antibody-dependent cellular phagocytosis (ADCP).

The recommended dosage of BLENREP is 2.5 mg/kg of actual body weight given as an intravenous infusion over approximately 30 minutes once every 3 weeks until disease progression or unacceptable toxicity. BLENREP for injection is a sterile, preservative-free, white to yellow lyophilized powder for reconstitution and further dilution prior to intravenous use and is supplied in a carton containing one 100-mg single-dose vial with a rubber stopper (not made with natural rubber latex) and aluminum over seal with removable cap.

Final Decision

Establish a new Level II HCPCS code J9037 "Injection, belantamab mafodontin-blmf, 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 Date: 04/01/2021

Request # 20.193

Topic/Issue

Request to revise Level II HCPCS code Q4132 "Grafix CORE and GrafixPL CORE, per square centimeter" to read: "Grafix CORE, per square centimeter" and

Request to establish a new Level II HCPCS code Q42XX "GrafixPL CORE, per square centimeter."

Applicant's Summary

The existing code descriptor for Q4132 is not adequate, and there is a programmatic need to separate these two products due to differences in product configuration, clinical use, patient population, and coverage by payers. GrafixPL CORE is a lyopreserved placental tissue derived from the chorion and stored at room temperature, retaining the extracellular matrix, growth factors, and endogenous viable cells of placental tissue. The product functions as a protective barrier supporting the repair of acute and chronic wounds. Unlike Grafix CORE, which is a cryopreserved (frozen) membrane packaged between plastic sheets to allow for easy sliding onto superficial wounds, GrafixPL CORE is packaged in a vial, lyophilized, requires rehydration prior to application, and is transferred from a vial into undermining or tunneling wounds. GrafixPL CORE is clinically indicated for the management of acute or chronic wounds, including but not limited to: diabetic foot ulcers, venous leg ulcers, pressure ulcers, burns, surgical and dehisced surgical wounds, and wounds with exposed tendon, bone, and/or muscle. GrafixPL CORE is an alternative to invasive procedures including autologous skin grafting and can prevent limb amputation. The quantity and size of product used will vary based upon wound size and physician recommendation. Unlike Grafix CORE, GrafixPL CORE is only available in the following larger sizes: 3cm x 4cm (12 sq cm), 5cm x 5cm (25 sq cm), and 7cm x 7cm (49 sq cm). GrafixPL CORE is transferred from the vial directly to the wound weekly for up to 12 weeks or until the wound is closed.

Final Decision

After review of FDA's guidance, it does not appear to CMS that Grafix CORE and GrafixPL CORE are suitable for registration as 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 the FDA's written feedback, the applicant is welcome to submit a complete HCPCS code application in a subsequent coding cycle.

Information for submitting questions to the TRG is located at:

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

Request # 20.194

Topic/Issue

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

Applicant's Summary

GeneXSTEM is regulated by the FDA as a human tissue product subject to Section 361 of the Public Service Act and 21 CFR 1271. Human umbilical cord tissue Wharton's jelly matrix products have been shown to reduce fibrosis, scarring, and adhesions in wound and surgical sites. The product is intended to provide the extracellular matrix needed for the attachment, infiltration, and proliferation of cells required for repair of damaged tissues. This product is typically used for cartilage and muscle tears and help to repair damaged tissue. The product is used for wounds as well as tissue defects and is applied to the defect using a syringe. The amount of product used depends on the size of the defect and the clinicians' discretion. Each human tissue based product distributed by Biointegrate is identified by its own unique serial number. The product is packaged in a transport protective pouch. The product is contained in a cryogenic primary tissue container, which contains a product label that includes the product details such as unique product number, storage requirements, and volume. Contents are aseptically processed and are not considered sterile. According to the applicant, currently available HCPCS codes for skin substitutes are product and brand specific; therefore, there is no code that can be used to identify this product.

Final Decision

After review of FDA's guidance, it does not appear to CMS that GeneXSTEM is suitable for registration as 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 the FDA's written feedback, the applicant is welcome to submit a complete HCPCS code application in a subsequent coding cycle.

Information for submitting questions to the TRG is located at:

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

Request # 20.195

Topic/Issue

Request to establish a new Level II HCPCS code to identify a new diagnostic radiopharmaceutical Copper Cu 64 dotatate injection.

Trade name: Detectnet

Applicant's suggested language: AXXXX "Copper Cu 64 dotatate, diagnostic, per study dose."

Applicant's Summary

Detectnet is indicated for use with positron emission tomography (PET) for the localization of somatostatin receptor positive neuroendocrine tumors (NETs) in adult patients. Dotatate ligand binds to SSTR receptors, which are over-expressed in NETs. During the normal decay of Cu 64, positrons are emitted which are immediately annihilated when they collide with electrons. This energy released can be detected through use of PET cameras, providing affirmation and location of NETs. Based upon the intensity of the signals, PET images obtained using this specific diagnostic radiopharmaceutical, Detectnet, indicate the presence and density of somatostatin receptors in tissues. Detectnet is injected intravenously and it is packaged as 4 mCi of copper Cu 64 dotatate in a single-dose vial. According to the applicant, Detectnet is the first diagnostic radiopharmaceutical that uses the Cu 64 radionuclide; therefore, there are no existing Level II HCPCS code with Cu 64 dotatate in the descriptor that can be used for billing purposes.

Final Decision

Establish a new Level II HCPCS code A9592 "Copper Cu-64, dotatate, diagnostic, 1 millicurie."

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. In addition, the smallest dose descriptor will helps in accurate reporting of amount of drugs administered and wasted from a single use vials.

Effective Date: 04/01/2021

Request # 20.196

Topic/Issue

Request to establish a new Level II HCPCS code to identify Biointegrate Amnionone.

Applicant's Summary

Biointegrate Amnionone is a minimally manipulated, amniotic membrane derived, human tissue allograft suspension product. The product serves to provide a barrier/support function and to aid in healing of defect. It is intended to provide the extracellular matrix needed for the infiltration, attachment and proliferation of cells required for the repair of damaged tissue. Amniotic membrane human tissue based products have shown to reduce scarring, fibrosis, and adhesions in surgical and wound sites. It is administered through a syringe to the defect and the amount is determined by the clinician based on the size of the defect. Each human tissue based product distributed by Biointegrate is identified by its own unique serial number. The product is packaged in a transport protective pouch. The product is contained in a cryogenic primary tissue container, which contains a product label that includes the product details such as unique product number, storage requirements, and volume. Contents are aseptically processed and are not considered sterile. According to the applicant, currently available Level II HCPCS codes for skin substitutes are product and brand specific; therefore, there is no code that can presently be used to identify this product.

Final Decision

After review of FDA's guidance, it does not appear to CMS that Biointegrate Amnionone is suitable for registration as 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 the FDA's written feedback, the applicant is welcome to submit a complete HCPCS code application in a subsequent coding cycle.

Information for submitting questions to the TRG is located at:

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

Request # 20.197

Topic/Issue

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

Applicant's suggested language: Q4XXX "Cytation Flowable Amnion, per 0.5 cc."

Applicant's Summary

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

Final Decision

After review of FDA's guidance, it does not appear to CMS that Cytation Flowable Amnion is suitable for registration as 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 the FDA's written feedback, the applicant is welcome to submit a complete HCPCS code application in a subsequent coding cycle.

Information for submitting questions to the TRG is located at:

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

Request # 20.200

Topic/Issue

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

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.

Final Decision

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

Request # 20.201

Topic/Issue

Request to establish a new Level II HCPCS code to identify Evolve AF.

Applicant's suggested language: QXXXX "Evolve AF, per 0.1cc."

Applicant's Summary

Evolve AF is an acellular, flowable allograft derived from the donation of consenting, pre-screened women at the time of an elective, live, Caesarian birth. It is a minimally manipulated, filtered, and cryopreserved allograft intended for homologous use and is regulated under section 361 of the Public Health Service Act.

Final Decision

After review of FDA's guidance, it does not appear to CMS that Evolve AF is suitable for registration as 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 the FDA's written feedback, the applicant is welcome to submit a complete HCPCS code application in a subsequent coding cycle.

Information for submitting questions to the TRG is located at:

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

Request # 20.202

Topic/Issue

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

Applicant's suggested language: Q4XXX "FactorFlo, per 0.1 cc."

Applicant's Summary

FactorFlo consists of decellularized, placental connective tissue particulate, extracellular matrix intended to replace or supplement damaged or inadequate tissue. FactorFlo is an ambient temperature tissue allograft. It can be used in and around acute and chronic injured soft tissue and surrounding space. FactorFlo is sterilized post-packaging, and supplied in single, one-time-use packaging in the following sizes: 0.5 cc, 1.0 cc, 2.0 cc. Dosing is dependent on the size and scope of desired treatment of the tissues involved. FactorFlo will fully resorb and does not require removal. The existing codes do not adequately describe FactorFlo, as it is a unique, ambient temperature, pre suspended, human connective tissue matrix allograft.

Final Decision

After review of FDA's guidance, it does not appear to CMS that FactorFlo is suitable for registration as 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 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