Centers for Medicare & Medicaid Services (CMS)
Healthcare Common Procedure Coding System (HCPCS)
Public Meeting Summary Report
Drugs, Biologicals, and Radiopharmaceuticals Radiologic Imaging Agents
Thursday, May 19, 2016

Introduction and Overview

Approximately 60 people attended. The agenda included 13 items.

Cindy Hake, Chair of the CMS HCPCS Coding Workgroup, provided an overview of the HCPCS public meeting procedures as it relates to the overall HCPCS coding process.

Felicia Eggleston, from the Division of CMM's Hospital and Ambulatory Policy Group provided an overview of Medicare's Part B Drugs payment (DAS), provided an overview of the Medicare payment methodology for Part B drugs, biologicals, and radiopharmaceuticals. A copy of the overview was provided in a written document and is attached to this summary.

Prior to the Public Meetings, over the course of several months, the CMS HCPCS Workgroup convene, discuss, and establish preliminary coding recommendations on all HCPCS code applications and make preliminary coding recommendations. At the same time, CMS assigns preliminary recommendations regarding the applicable Medicare payment category and methodology that will be used to set a payment amount for the items on the agenda. The preliminary coding and payment recommendations are posted on the CMS HCPCS web site, specifically at www.cms.gov/medhcpcsgeninfo/08_HCPCSPublicMeetings.asp#TopOfPage, as part of the HCPCS public meeting agendas.

Information provided at the CMS HCPCS Public Meetings is considered by the CMS HCPCS Coding Workgroup at a subsequent workgroup meeting. The Workgroup reconvenes after the public meetings, and reconsiders its preliminary coding recommendations in light of any new information provided, and formulates its final coding decisions.

CMS maintains the permanent HCPCS Level II codes, and reserves final decision making authority concerning requests for permanent HCPCS codes. Final decisions regarding Medicare payment are made by CMS and must comply with the Statute and Regulations. Payment determinations for non-Medicare insurers, (e.g., state Medicaid Agencies or Private Insurers) are made by the individual state or insurer.

In November, all requestors will be notified in writing of the final decision regarding the HCPCS code modification request(s) they submitted. At about the same time, the HCPCS Annual Update is published at: www.cms.gov/HCPCSReleaseCodeSets/ANHCPCS/itemdetail.asp.

The latest information on the process for developing agendas and speaker lists for the public meetings, as well as the Guidelines for Proceedings at these CMS' Public Meetings, can be

found on the CMS HCPCS web site, specifically at: http://cms.gov/medhcpcsgeninfo/08_HCPCSPublicMeetings.asp#TopOfPage. In addition, the standard application format for requesting a modification to the HCPCS Level II Code Set, along with instructions for completion and background information regarding the HCPCS Level II coding process is available at: http://cms.gov/medhcpcsgeninfo/01_overview.asp#TopOfPage. The application form is updated annually and posted on the CMS HCPSC website sometime in the summer. A decision tree, outlining CMS' decision-making criteria is also available at: http://cms.gov/medhcpcsgeninfo/downloads/decisiontree.pdf.

HCPCS Public Meeting Agenda Item # 1

Thursday, May 19, 2016

Applications # 16.012 and 16.013

TOPIC

Request to revise existing Level II HCPCS code Q4120, so as to include the new commercial brand name “Cytal” with existing commercial brand name “MatriStem”.

Applicant's suggested language: “Q4120, MatriStem/Cytal Burn Matrix, per square centimeter”.

BACKGROUND

ACell, Inc. submitted a request to revise the existing code Q4120 which currently reads, “Matristem burn matrix, per square centimeter”, to instead to read, “MatriStem/Cytal Burn Matrix, per square centimeter”. ACell is changing the product brand name MatriStem to Cytal over 2016. Both brand names will be commercially available during 2016. As of 1/1/17, wound and burn products with the brand name Matristem will be completely phased out.

According to the applicant, MatriStem/Cytal Burn Matrix is composed of a porcine-derived extracellular matrix, also known as urinary bladder matrix. MatriStem/Cytal Burn Matrix is intended for the management of wounds and second-degree burns and injuries. The primary advantage of MatriStem/Cytal products is that they maintain their natural collagen structure and components that are gradually incorporated within the patients’ body while replacing the product with site-appropriate tissue. The result is constructively remodeled, site-specific tissue.

MatriStem/Cytal burn matrix is supplied in a sheet configuration in 5 cm x 5 cm, 7 cm x 10 cm, and 10 cm x 15 cm sizes.

The applicant comments that a code revision is warranted because the existing code does not adequately describe new and existing brand names.

PRELIMINARY HCPCS CODING RECOMMENDATION

This request to revise the descriptor to an existing Level II HCPCS code has not been approved, because the proposed revision does not improve the code.

1) Discontinue Q4120 "MatriStem burn matrix, per square centimeter". Effective 12/31/16.

2) Establish Q41XX "Cytal, per square centimeter". Effective 1/1/17.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

There was no primary speaker for this item. The applicant submitted written comments in agreement with the CMS preliminary decision for both applications 16.012 and 16.013.

TOPIC

Request to revise existing Level II HCPCS code Q4119, so as to include the new brand name “Cytal” and add “Multilayer” to the code descriptor.

Applicant's suggested language: “Q4119, MatriStem/Cytal Wound Matrix and Multilayer Wound Matrix, per square centimeter”.

HCPCS Public Meeting Agenda Item # 2

Thursday, May 19, 2016

Application# 16.021

TOPIC

Request to establish a new level II HCPCS code to identify a cryopreserved human skin allograft, Trade Name: TruSkin™.

Applicant's suggested language: "Qxxxx - TruSkin™, per square centimeter."

BACKGROUND

Osiris Therapeutics, Inc. submitted a request to establish a new level II HCPCS code to identify TruSkin. According to the applicant, TruSkin is a split-thickness cryopreserved human skin allograft, intended for the replacement or reconstruction of inadequate or damaged integumental tissue. An advanced skin substitute, TruSkin is easy-to-use, off-the-shelf alternative to fresh skin allograft. TruSkin addresses biological deficiencies in the wound, assists in epithelialization, and aids in preserving surrounding tissue. The key differentiating feature of TruSkin from all other preserved skin allografts is the proprietary processing, which retains all components of fresh skin in their native state, including: collagen-rich skin Extracellular Matrix (ECM), endogenous bioactive factors, and endogenous living skin cells. The applicant claims that TruSkin is indicated for patients with acute and chronic wounds, who have limited treatment options and are at great risk for wound-related morbidities and mortality. TruSkin offers patients an alternative to invasive procedures, including autologous skin grafting or limb amputation.

The quantity and size of the product used will vary based upon wound size and physician recommendation. Application of TruSkin is recommended weekly or bi-weekly for up to 12 weeks or until the wound is closed.

TruSkin is supplied as a graft in two sizes: 32 cm^2 and 8cm^2.

The applicant comments that a new code is warranted because there are no existing brand-specific code that identifies TruSkin.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish Q41XX "TruSkin, per square centimeter".

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

There was no primary speaker for this item. The applicant submitted an email in agreement with the CMS preliminary decision.

HCPCS Public Meeting Agenda Item # 3

Thursday, May 19, 2016

Application# 16.033

TOPIC

Request to establish a new Level II HCPCS code to identify a cryopreserved human placental matrix, Trade Name: AmnioBand™ Viable.

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

BACKGROUND

The Musculoskeletal Transplant Foundation submitted a request to establish a new level II HCPCS code to identify AmnioBand Viable. According to the applicant, AmnioBand Viable is a placental matrix derived from human donated amnion membranes originating from the inner lining of the placenta. AmnioBand Viable is intended for internal and external tissue defects, including acute, chronic, and surgically-created wounds. It is used as a natural wound scaffold to support the body's inherent ability to restore and remodel tissue through components that have been preserved in the native tissue. AmnioBand Viable contains biological extracellular matrix proteins, cytokines, growth factors, and viable endogenous cells that work to support host tissue remodeling. This provides a barrier to infections and helps to maintain a moist wound environment for healing.

AmnioBand Viable is supplied in 2 cm x 2 cm and 5 cm x 5 cm sizes.

The applicant comments that a new code is warranted because no existing code describes AmnioBand Viable. For human allografts used in wound care, Medicare and private payers administer coverage and payment policies on a brand-name basis; therefore, these wound allografts must be issued a brand-specific HCPCS code to be eligible for claims submission and reimbursement.

PRELIMINARY HCPCS CODING RECOMMENDATION

The request to establish a new Level II HCPCS code has not been approved. Existing code Q4151 "Amnioband or guardian, per square centimeter" adequately describes the product that is the subject of this request, and is available for assignment by insurers if they deem appropriate.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The applicant agreed with the CMS preliminary decisions for applications 16.033, 16.034, and 16.035.

HCPCS Public Meeting Agenda Item # 3

Thursday, May 19, 2016

Application# 16.034

TOPIC

Request to establish a new Level II HCPCS code to identify a human placental matrix allograft, Trade Name: AmnioBand SL.

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

BACKGROUND

The Musculoskeletal Transplant Foundation submitted a request to establish a level II HCPCS code to identify AmnioBand SL. According to the applicant, AmnioBand SL is a dehydrated single amnion layer matrix derived from human donated amnion membranes originating from the inner lining of the placenta. It is indicated for patients who present with chronic wounds caused by diabetes, obesity, COPD, obstructed blood flow and other underlying conditions. AmnioBand SL is a minimally processed human allograft which retains the structural properties of the amnion extracellular matrix. The resulting dehydrated allograft serves as a wound scaffold. AmnioBand SL contains growth factors and cytokines that support the membrane's native function to promote cell proliferation and tissue remodeling during the wound healing phase.

AmnioBand SL is available in rectangular and circular shapes ranging from 0.79 square centimeter to 49 square centimeters.

The applicant comments that existing codes are inadequate, as they must be used in the absence of brand-specific codes.

PRELIMINARY HCPCS CODING RECOMMENDATION

The request to establish a new Level II HCPCS code has not been approved. Existing code Q4151 "Amnioband or guardian, per square centimeter" adequately describes the product that is the subject of this request, and is available for assignment by insurers if they deem appropriate.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The applicant agreed with the CMS preliminary decisions for applications 16.033, 16.034, and 16.035.

HCPCS Public Meeting Agenda Item # 3

Thursday, May 19, 2016

Application# 16.035

TOPIC

Request to establish a new Level II HCPCS code to identify a lyophilized placental matrix allograft, Trade Name: AmnioBand Particulate.

Applicant's suggested language: "QXXXX, AmnioBand Particulate, 1 mg".

BACKGROUND

The Musculoskeletal Transplant Foundation submitted a request to establish a new level II HCPCS code to identify AmnioBand Particulate. According to the applicant, AmnioBand Particulate is derived from human donated amnion membrane originating from the inner lining of the placenta. AmnioBand Particulate is an allograft membrane scaffold for wounds, including use as a scaffold for a surgical site. It is a lyophilized placental matrix in particulate form, aseptically processed to preserve the tissue's natural cytokines and tissue matrix.

AmnioBand Particulate is intended to be used as a wound care scaffold for the replacement of damaged or inadequate integumental tissue, such as diabetic foot ulcers venous leg ulcers, pressure ulcers, or for other homologous use, particularly irregularly-shaped or crevassing wounds.

AmnioBand Particulate is available in a variety of masses, ranging from 40mg to 160mg.

The applicant comments that there are no existing codes to describe AmnioBand Particulate.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish Q41XX "AmnioBand, 1 mg".

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The applicant agreed with the CMS preliminary decisions for applications 16.033, 16.034, and 16.035.

HCPCS Public Meeting Agenda Item # 4

Thursday, May 19, 2016

Application# 16.037

TOPIC

Request to establish a new Level II HCPCS code to identify a human amniotic membrane allograft, Trade Name: Artacent™ Wound.

Applicant's suggested language: "QXXXX Artacent™ Wound, per sq cm".

BACKGROUND

Tides Medical submitted a request to establish a new level II HCPCS code to identify Artacent Wound. According to the applicant, Artacent Wound is a dual-layer human amniotic membrane graft used for acute and chronic wound applications. It is derived from the submucosa of donated human placenta. It consists of collagen layers, including basement membrane and stromal matrix. Its dual layer and bilateral application improves handling, while its unique design permits easy manipulation and placement onto the wound bed. The applicant claims that Artacent Wound contains essential growth factors “shown to stimulate wound healing”.

Artacent Wound is supplied in the following sizes: 1 cm x 1 cm, 2 cm x 2 cm, 2 cm x 3 cm, 4 cm x 4 cm, 4 cm x 6 cm, 4 cm x 8 cm, 10 mm disk, and 16 mm disk.

The applicant comments that no currently available permanent HCPCS code appropriately defines Artacent Wound.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish Q41XX "Artacent, per square centimeter".

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker agreed with CMS 'preliminary decision to establish a new code to identify Artacent, but asked that the full name "Artacent Wound" be included in the code text as per the original request, to distinguish Artacent Wound from other, different Artacent products on the market.

HCPCS Public Meeting Agenda Item # 5

Thursday, May 19, 2016

Application# 16.044

TOPIC

Request to establish a new level II HCPCS code to identify a human amniotic tissue allograft, Trade Name: CYGNUS.

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

BACKGROUND

Vivex Biomedical, Inc. submitted a request to establish a new level II HCPCS code to identify CYGNUS. According to the applicant, CYNGNUS is an amniotic tissue allograft with innate regenerative capability to support healing without adhesion or scar formation. It is used most often to treat acute wounds, chronic wounds, and burns, and it can serve as an adhesion barrier to keep potentially adherent surfaces apart.

CYGNUS is a dried human amnion membrane allograft composed of a single layer of epithelial cells, a basement membrane, and an avascular connective tissue matrix. It is a minimally manipulated, dried non-viable cellular amniotic membrane allograft that preserves and delivers multiple extracellular matrix proteins, growth factors, cytokines, and other specialty proteins present in amniotic tissue to help regenerate soft tissue.

CYGNUS is supplied in a variety of sizes, ranging from 1 cm x 2 cm to 7 cm x 7 cm.

The applicant comments that the existing HCPCS codes do not adequately describe CYGNUS, since Q codes are product-specific to facilitate proper billing and coding to all payers. Currently, providers must use Q4100 “skin substitute, not otherwise specified”.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish Q41XX "Cygnus, per square centimeter".

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker agreed with CMS' preliminary decision to establish a new code.

HCPCS Public Meeting Agenda Item # 6

Thursday, May 19, 2016

Application# 16.045

TOPIC

Request to establish a new level II HCPCS code to identify decellularized particulate human placental connective tissue matrix, Trade Name: Interfyl.

Applicant's suggested language: "QXXXX - Interfyl, 1 mg".

BACKGROUND

Alliqua Biomedical, Inc. submitted a request to establish a new level II HCPCS code to identify Interfyl. According to the applicant, Interfyl is a decellularized and dehydrated placental disc (chorionic plate) derived extracellular matrix (ECM). Its connective-tissue matrix (CTM) serves as a scaffold for recipient cells in the wound to regenerate soft tissue. Because it is not cross-linked and does not contain cells, Interfyl reduces the likelihood of immunogenic and inflammatory responses as compared to other HCT/Ps, thereby minimizing inflammation and scarring.

Interfyl is intended for use as the replacement or supplementation of damaged or inadequate integumental tissue by providing support for the body’s normal healing processes. Indications for Interfyl include treatment of deep dermal wounds, irregularly-shaped and tunneling wounds, augmentation of deficient/inadequate soft tissue, and the repair of small surgical defects.

Interfyl is supplied as single-dose flowable product syringes containing 250 mg in 1.5 mL, and as particulate product in vials containing 50 mg and 100 mg.

The applicant comments that a new code is warranted because no existing HCPCS code describes Interfyl.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish Q41XX "Interfyl, 1 mg".

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The speaker agreed with CMS' preliminary decision to establish a new code.

HCPCS Public Meeting Agenda Item # 7

Thursday, May 19, 2016

Application# 16.046

TOPIC

Request to establish new Level II HCPCS code to identify fenestrated porcine collagen products, Trade Names: PuraPly™ Antimicrobial Wound Matrix (PuraPly AM) and PuraPly™ Wound Matrix (PuraPly).

Applicant's suggested language: "QXXXX PuraPly, and PuraPly Antimicrobial, any type, per square centimeter".

BACKGROUND

Organogenesis, Inc. submitted a request to establish a new level II HCPCS code to identify PuraPly Antimicrobial Wound Matrix (PuraPly AM) and PuraPly Wound Matrix (PuraPly). According to the applicant, PuraPly is a single-layer fenestrated sheet of porcine collagen. PuraPly Am is a double-layer fenestrated and cross-linked sheet of porcine collagen, coated with polyhexamethylene biguanide hydrochloride (PHMB) to resist microbial colonization and reduce microbial penetration within the matrix.

The two products are prescribed by a physician or other qualified health care professional and indicated for the management of wounds. They are typically administered in an outpatient setting but may be administered inpatient or in the office setting. PuraPly and PuraPly AM are administered by applying the product to a wound using sutures or other fixation methods.

PuraPly AM and PuraPly are supplied in a single-layer or double-layer fenestrated sheet of porcine intestinal collagen, approximately 0.05 to 0.07 rnm in thickness. The products are available in a range of sizes from 2 cm x 4 cm to 6 cm x 9 cm.

The applicant comments that a unique Q code is necessary to appropriately identify and reimburse PuraPly and PuraPly AM in the full range of site of care settings and to provide coding consistent with other clinically similar products. Previously, CMS established C9349 for PuraPly and PuraPly AM to reflect its status as a pass-through biologic, but this code is recognized only on hospital outpatient claims.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish Q41XX "PuraPly, per square centimeter".

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker agreed with the CMS preliminary decision to establish a new code, but reiterated the original request that the new code specify both of the product brand names "Puraply and Puraply Antimicrobial." The speaker stated that this would minimize confusion about the appropriate use of the new code and allow for a seamless transition from the existing C code to the new Q code.

HCPCS Public Meeting Agenda Item # 8

Thursday, May 19, 2016

Application# 16.048

TOPIC

Request to revise code Q4105, “Integra dermal regeneration template (drt), per square centimeter”.

Applicant's suggested language: "Integra dermal regeneration template (drt) or Integra Omnigraft dermal regeneration matrix, per square centimeter".

BACKGROUND

Integra LifeSciences Corporation (Integra) submitted a request to revise the descriptor of existing code Q4105, which currently reads, “Integra dermal regeneration template (drt), per square centimeter”, to instead read, “Integra dermal regeneration template (drt) or Integra Omnigraft dermal regeneration matrix, per square centimeter".

According to the applicant, Omnigraft Dermal Regeneration Matrix (Omnigraft) is an advanced wound care device, comprised of a porous matrix of cross-linked bovine tendon collagen and glycosaminoglycan with a polysiloxane (silicone) layer. The collagen-glycosaminoglycan biodegradable matrix provides a scaffold for cellular invasion and capillary growth.

Integra Dermal Regeneration Template (IDRT) is indicated for the treatment of burns and scar contractures and is currently billed using Q4105. Through a supplemental PMA to IDRT, Omnigraft is indicated for use in the treatment of partial and full-thickness neuropathic diabetic foot ulcers that are greater than six weeks in duration, with no capsule, tendon or bone exposed, when used in conjunction with standard diabetic ulcer care. This new indication expands the use of the product to hospital outpatient departments and physician offices. Given the different brand name, the applicant believes that it is necessary to add the new trade name to the descriptor of Q4105.

The applicant comments that the language of existing code Q4105 is insufficient to describe Omnigraft, because the descriptor is focused on IDRT and coders may not view it as an appropriate code to bill for Omnigraft. The suggested revision to the descriptor for Q4105 should facilitate proper billing for Omnigraft.

PRELIMINARY HCPCS CODING RECOMMENDATION

Revise existing code Q4105 which currently reads: "Integra Dermal Regeneration Template (drt), per square centimeter": to instead read: "Integra dermal regeneration template (drt) or Integra Omnigraft dermal regeneration matrix, per square centimeter".

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

There was no primary speaker for this item. The applicant submitted written comments in support of CMS' preliminary coding decision and asked that it be finalized.

HCPCS Public Meeting Agenda Item # 9

Thursday, May 19, 2016

Application# 16.050

TOPIC

Request to establish a new level II HCPCS code to identify a human umbilical cord allograft, Trade Name: EpiCord™.

Applicant's suggested language: "QXXXX - EpiCord™, per square centimeter".

BACKGROUND

MiMedx Group, Inc. submitted a request to establish a level II HCPCS code to identify EpiCord. According to the applicant, EpiCord is a lyophilized, non-viable cellular umbilical cord allograft that provides a natural biological barrier and protective structure for wound healing environments. EpiCord is comprised of the protective elements of the umbilical cord with a thin amnion layer and a thicker Wharton Jelly mucopolysaccaride component. EpiCord provides an extracellular matrix (ECM) as a scaffold in the form of collagen types, fibronectin, laminins, and proteoglycans. This structure provides a natural wound covering and scaffold for cellular growth.

EpiCord is indicated for diabetic elderly patients who are affected by slow healing wounds. It is to be used in the treatment and management of chronic and acute wounds, burns as well as a natural biological barrier to protect tendons. EpiCord would be used in the treatment of a chronic leg ulcer that requires debridement, topical care and an allograft placement and dressing for proper management.

EpiCord can be stored in ambient conditions.

The applicant comments that a new code is warranted because there is no available HCPCS code that appropriately describes EpiCord.

PRELIMINARY HCPCS CODING RECOMMENDATION

Revise existing Q4131, which currently reads, "Epifix, per square centimeter", to instead read, "Epifix or Epicord, per square centimeter".

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker agreed with the CMS preliminary decision to establish a new code.

HCPCS Public Meeting Agenda Item # 9

Thursday, May 19, 2016

Application# 16.051

TOPIC

Request to establish a new level II HCPCS code to identify an injectable amniotic fluid derived product, Trade Name: OrthoFlo.

Applicant's suggested language: "JXXXX - OrthoFlo, per mL".

BACKGROUND

MiMedx Group, Inc. submitted a request to establish a new level II HCPCS code to identify OrthoFlo. According to the applicant, OrthoFlo is an amniotic fluid derived allograft used to "supplement the ability of existing synovial fluid to lubricate and protect". OrthoFlo protects, reduces inflammation, lubricates and addresses pain of the joints. OrthoFlo is clinically intended for patients with joint pain due to disease or trauma, resulting in the reduction in lubricating properties of the synovial fluid. OrthoFlo is an amniotic fluid product that is optimally filtered to retain the natural macromolecular and physiologically active components of amniotic fluid, while removing low molecular weight by-products produced in utero.

OrthoFlo is administered by a physician. It is injected in the joint with or without ultrasound guidance, as needed, to protect, lubricate, and reduce inflammation. Dosage is determined by the physician. OrthoFlo is supplied in single-use 0.5 mL, 1 mL, 2 mL, and 4 mL vials.

MiMedx describes OrthoFlo as a Human Tissue Product for which FDA premarket approval is not required. While MiMedx's packaging information describes OrthoFlo as an amniotic fluid derived product indicated for "homologous use", the stated indication is supplementation of synovial fluid in the knee joint in order to cushion, lubricate and reduce inflammation.

The applicant comments that a new code is warranted because no available HCPCS code appropriately describes OrthoFlo or similar amniotic products.

PRELIMINARY HCPCS CODING RECOMMENDATION

This request to establish a new Level II HCPCS code to separately identify OrthoFlo has not been approved, because this application is incomplete. This product does not have the FDA clearance that is required for the indication specified in the code application.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagreed with the CMS preliminary decision. The speaker stated that "FDA approval is not required prior to marketing" and further indicated that "CMS focused on homologous use" and wants to withdraw the clinical indication of viscosupplementation."

HCPCS Public Meeting Agenda Item # 10

Thursday, May 19, 2016

Application# 16.052

TOPIC

Request to establish one new level II HCPCS code to identify human amnion allografts, Trade Names: PalinGen® Membrane and PalinGen® Hydromembrane.

Applicant's suggested language: "QXXXX - PalinGen® Membrane and PalinGen® Hydromembrane, per square centimeter".

BACKGROUND

On behalf Amnio Technology LLC, an applicant submitted a request to establish a new level II HCPCS code to identify PalinGen Membrane and PalinGen Hydromembrane. According to the applicant, PalinGen Membrane and PalinGen Hydromembrane are human allografts comprised of amniotic membrane, providing a wound covering and support for native tissues. These human allografts provide a biological and physical barrier to support and protect naturally occurring and surgical wounds in vivo.

PalinGen Membrane and PalinGen Hydromembrane are commonly used in the treatment of chronic wounds, and they are also indicated for the repair and reconstruction of a recipient’s cells or tissues, including venous leg ulcers, diabetic ulcers, pressure ulcers and in orthopedic, cardiac and ophthalmologic conditions.

PalinGen Membrane and PalinGen Hydromembrane are supplied in ten different sizes, ranging from 1 sq.cm to 64 sq.cm.

The applicant comments that a new code is warranted because there is no existing code to describe these products.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish Q41XX "PalinGen, per square centimeter."

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagreed with CMS' preliminary decision to establish 2 new codes to identify all 7 brands that are the subject of application numbers 16.052-16.055, based on whether the products are provided in sheet vs flowable form. The speaker stated that PalinGen and PalinGen Hydromembrane differ in structure (biological cross-linking) and resultant differences in in tensile strength and tissue support; and that the 3 flowable products differ based on live cell populations and availability of DMSO, and resultant differences in thermostablity and clinical

flexibility. The speaker requested modifications to CMS' proposed codes that would result in the establishment of the 4 new codes originally requested.

HCPCS Public Meeting Agenda Item # 10
Thursday, May 19, 2016

Application# 16.054

TOPIC

Request to establish one new level II HCPCS code to identify human amnion allografts, Trade Names: PalinGen® XPlus Membrane and PalinGen® XPlus Hydromembrane.

Applicant's suggested language: "QXXXX - PalinGen® XPlus Membrane and PalinGen® XPlus Hydromembrane, per square centimeter".

BACKGROUND

On behalf of Amnio Technology, an applicant submitted a request to establish a level II HCPCS code to identify PalinGen XPlus Membrane and PalinGen XPlus Hydromembrane. According to the applicant, PalinGen XPlus Membrane and PalinGen XPlus Hydromembrane are human allografts comprised of amniotic membrane. They provide a wound covering and support for native tissues. They are used to repair or replace soft tissue defects, soft trauma defects, tendinitis, tendinosis, chronic wound repair and localized inflammation.

The patient population for the item are older Type I patients with diabetes for the treatment of chronic wounds. These products have also been used in the repair and reconstruction of a recipient’s cells or tissues including venous leg ulcers, diabetic ulcers, pressure ulcers, and in orthopedic, cardiac and ophthalmologic conditions.

PalinGen XPlus Membrane and PalinGen XPlus Hydromembrane are supplied in ten different sizes, ranging from 1 sq.cm to 64 sq.cm.

The applicant comments that a new code is warranted because no existing code describes these products.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish Q41XX "PalinGen, per square centimeter."

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagreed with CMS' preliminary decision to establish 2 new codes to identify all 7 brands that are the subject of application numbers 16.052-16.055, based on whether the products are provided in sheet vs flowable form. The speaker stated that PalinGen and PalinGen Hydromembrane differ in structure (biological cross-linking) and resultant differences in in tensile strength and tissue support; and that the 3 flowable products differ based on live cell populations and availability of DMSO, and resultant differences in thermostablity and clinical

flexibility. The speaker requested modifications to CMS' proposed codes that would result in the establishment of the 4 new codes originally requested.

HCPCS Public Meeting Agenda Item # 10

Thursday, May 19, 2016

Application# 16.053

TOPIC

Request to establish a new level II HCPCS code to identify a liquid human amnion and amniotic fluid allograft, Trade Name: ProMatrX™ ACF.

Applicant's suggested language: "QXXXX - ProMatrX™ ACF, 0.25 cc."

BACKGROUND

On behalf of Amnio Technology, an applicant submitted a request to establish a level II HCPCS code to identify ProMatrX ACF. According to the applicant, ProMatrX ACF is a human allograft comprised of amnion and amniotic fluid, providing a liquid allograft to "aid in the healing" and repair of chronic wounds. ProMatrX ACF contains key growth factors, cytokines, amino acids, carbohydrates, hyaluronic acid, extracellular matrix proteins, and cellular components recognized as intrinsic to the complex wound healing process.

ProMatrX ACF is commonly used in the treatment of chronic wounds that are most prevalent in older populations, particularly in patients with Type I diabetes.

ProMatrX ACF is amniotic membrane and fluid suspended in liquid. The product is applied directly on or in the wound with a 20-23 gauge needle. The prescribed dosage varies by the size of the wound. Typical doses range from 0.25 cc to 4.0 cc, depending on the size, depth and type of wound.

ProMatrX ACF is supplied in liquid form in vials containing 0.25 cc, 0.5 cc, 1 cc, 2 cc, and 4 cc. These products are cryopreserved and should be stored frozen at a temperature at -80°C +/- 15°.

The applicant comments that a new code is warranted because, as with other bioengineered skin substitutes, ProMatrX ACF requires a brand-specific HCPCS code in order to be readily identifiable for third party claims processing.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish Q41XX "PalinGen or ProMatrX, 0.36 mg per 0.25 cc".

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagreed with CMS' preliminary decision to establish 2 new codes to identify all 7 brands that are the subject of application numbers 16.052-16.055, based on whether

the products are provided in sheet vs flowable form. The speaker stated that PalinGen and PalinGen Hydromembrane differ in structure (biological cross-linking) and resultant differences in in tensile strength and tissue support; and that the 3 flowable products differ based on live cell populations and availability of DMSO, and resultant differences in thermostability and clinical flexibility. The speaker requested modifications to CMS' proposed codes that would result in the establishment of the 4 new codes originally requested.

HCPCS Public Meeting Agenda Item # 10
Thursday, May 19, 2016

Application# 16.055

TOPIC

Request to establish one new level II HCPCS code to identify liquid human amnion allografts, Trade Names: PalinGen® Flow and PalinGen® SportFlow.

Applicant's suggested language: "QXXXX - PalinGen® Flow and PalinGen® SportFlow, 0.25 cc."

BACKGROUND

On behalf of Amnio Technology, an applicant submitted a request to establish a level II HCPCS code to identify PalinGen Flow and PalinGen SportFlow. According to the applicant, PalinGen Flow and PalinGen SportFlow are human allografts comprised of amnion and amniotic fluid components, providing a liquid allograft to “aid in the healing” and repair of chronic wounds. PalinGen Flow and PalinGen SportFlow contain key growth factors, cytokines, amino acids, carbohydrates, hyaluronic acid, extracellular matrix proteins, and cellular components recognized as intrinsic to the complex wound healing process.

PalinGen Flow and PalinGen SportFlow are commonly used in the treatment of chronic wounds that are most prevalent in older populations, particularly in patients with Type I diabetes.

PalinGen Flow and PalinGen SportFlow are amniotic membrane and fluid that are suspended in liquid. The product is applied directly on or in the wound with a 20-23 gauge needle. The prescribed dosage varies by the size of the wound. Typical doses range from 0.25 cc to 4.0 cc, depending on the size, depth and type of wound.

PalinGen Flow and PalinGen SportFlow are similar, but separate, products. They are supplied in liquid form in vials containing 0.25 cc, 0.5 cc, 1 cc, 2 cc, and 4 cc. These products are cryopreserved and should be stored frozen at a temperature of -80°C +/- 15°.

The applicant comments that a new code is warranted because, as with other bioengineered skin substitutes, PalinGen Flow and PalinGen SportFlow require a brand-specific HCPCS code in order to be readily identifiable for third party claims processing.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish Q41XX "PalinGen or ProMatrX, 0.36 mg per 0.25 cc".

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagreed with CMS' preliminary decision to establish 2 new codes to identify all 7 brands that are the subject of application numbers 16.052-16.055, based on whether the products are provided in sheet vs flowable form. The speaker stated that PalinGen and PalinGen Hydromembrane differ in structure (biological cross-linking) and resultant differences in in tensile strength and tissue support; and that the 3 flowable products differ based on live cell populations and availability of DMSO, and resultant differences in thermostablity and clinical flexibility. The speaker requested modifications to CMS' proposed codes that would result in the establishment of the 4 new codes originally requested.

HCPCS Public Meeting Agenda Item # 11

Thursday, May 19, 2016

Application# 16.060

TOPIC

Request to establish one new Level II HCPCS code to identify both fenestrated and non-fenestrated forms of a porcine derived extracellular wound matrix, Trade Name: MIRODERM™.

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

BACKGROUND

On behalf of Miromatrix Medical, an applicant submitted a request to establish a new level II HCPCS code to identify MIRODERM. According to the applicant, MIRODERM is a non-crosslinked acellular wound matrix that is derived from porcine liver and is processed and stored in a phosphate buffered aqueous solution. It is clinically indicated for the management of wounds. MIRODERM is used on a chronic wound where it provides a scaffold to maintain and support a healing environment through constructive remodeling. It is used to cover the entire surface of the wound bed and extend slightly beyond all wound margins.

MIRODERM is available in fenestrated and non-fenestrated form, in seven sizes ranging from 9 cm^2 to 120 cm^2.

The applicant comments that a new code is warranted because there are no existing codes to describe MIRODERM.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish Q41XX "Miroderm, per square centimeter".

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item # 12

Thursday, May 19, 2016

Application# 16.067

TOPIC

Request to establish a new level II HCPCS code to identify placental tissue, Trade Name: STRAVIX.

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

BACKGROUND

Osiris Therapeutics Inc. submitted a request to establish a new level II HCPCS code to identify Stravix. According to the applicant, Stravix is a cryopreserved human placental tissue, composed of the Wharton's jelly and umbilical amniotic membrane. Stravix is processed from human umbilical cord and contains: a collagen and hyaluronic acid-rich extracellular matrix; endogenous biofactors with anti-inflammatory, angiogenic, anti-scarring, and anti-microbial properties; and viable endogenous cells, including mesenchymal stem cells.

The applicant provided information that Stravix is currently used in inpatient surgical applications only, including: as a wound cover in deep, acute wounds; surgical wound repair; and the majority of applications are surgical, below the knee, leg and foot tendon repairs, and neurovascular repair.

Stravix is supplied as a cryopreserved placental tissue packaged in a wide-mouth jar. It is available in two sizes (3 x 6 cm, 2 x 4 cm). When stored frozen at -80°C, Stravix has a two year shelf-life.

The applicant comments that a new code is warranted because there are no existing HCPCS codes that appropriately define Stravix.

PRELIMINARY HCPCS CODING RECOMMENDATION

This request to establish a new Level II HCPCS code to separately identify Stravix has not been approved. The product is included in the inpatient surgical procedure. Separate reporting could be considered duplicative and inappropriate.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item # 13

Thursday, May 19, 2016

Application# 16.069

TOPIC

Request to establish a new level II HCPCS code to identify an “alloplastic” wound and burn dressing, Trade Name: SUPRATHEL.

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

BACKGROUND

Polymedics Innovations Inc. submitted a request to establish a level II HCPCS code to identify Suprathel. According to the applicant, Suprathel is a copolymer of polylactides, trimethlene carbonate, and ε-caprolactone. It is an alloplastic, absorbable “skin substitute” with properties similar to the skin. It is highly permeable to oxygen and water vapor, providing a particularly favorable environment for wound healing. Suprathel is used for epidermal and dermal wounds, such as split skin graft donor sites and partial thickness burns. Suprathel may also be used for partial and full thickness wounds.

Depending on the wound size, the appropriate square centimeters of the Suprathel membrane(s) shall be applied. A protective gauze should be applied over Suprathel on areas subject to mechanical stress, such as the extremities and the dorsal side of the torso. This protective dressing should comprise a fatty gauze and absorbent gauze. Suprathel, together with the gauze, shall remain unchanged until wound healing is completed. If Suprathel remains longer on the skin, it will be absorbed completely in approximately 60 days, without irritation to the upper epithelial layers.

Suprathel is available in four sizes: 5 x 5 cm; 9 x 10 cm; 18 x 10 cm; and 18 x 23 cm square sheet membranes. Suprathel is also available in hand-shaped pads that can be used on the flexor and/or exterior side of the hand.

The applicant comments that a new code is warranted because none of the existing brand-specific Q codes for skin substitutes appropriately describes Suprathel.

PRELIMINARY HCPCS CODING RECOMMENDATION

A national program operating need was not identified by Medicare, Medicaid or the Private Insurance sector to establish a new HCPCS code to separately identify this synthetic product. Existing code A4649 "Surgical supply; miscellaneous" is available for assignment by insurers if they deem appropriate.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagreed with CMS' preliminary decision and reiterated the original request to establish a unique code to identify Suprathel in order to "enable providers and insurers to submit and process claims that indicate it is used instead of a biologic skin substitute."