Centers for Medicare & Medicaid Services (CMS)
Healthcare Common Procedure Coding System (HCPCS)
Application Summaries for Drugs, Biologicals and Radiopharmaceuticals

Thursday, May 18, 2017

This HCPCS Code Application Summary document includes a summary of each HCPCS code application discussed at the May 18, 2017 HCPCS Public Meeting for Drugs, Biologicals and Radiopharmaceuticals and Radiologic Imaging Agents. HCPCS code applications are presented within the summary document in the same sequence as the Agenda for this Public Meeting. Each individual summary includes: the application number, topic; background/discussion of the applicant's request; CMS' published preliminary HCPCS coding recommendation; CMS' published preliminary Medicare payment recommendation; a summary of comments offered on behalf of each applicant at CMS' HCPCS public meeting in response to our preliminary recommendations; and CMS' final HCPCS coding decision. We publish a separate HCPCS Code Application Summary document for each HCPCS Public Meeting held. This is one of a series of five HCPCS Code Application Summaries for CMS' 2017-2018 HCPCS coding cycle.

Introduction and Overview

Approximately 59 people attended. The agenda included 11 or 17 items.

Cindy Hake, Director, CMS National Level II HCPCS Coding Program and Deputy Director, Division of DMEPOS Policy, provided an overview of the HCPCS public meeting procedures as it relates to the overall HCPCS coding process.

Felicia Eggleston, of Ambulatory Services (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.

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: www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/HCPCSPublicMeetings.html. 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: HCPCS Decision Tree - cms.gov.

May 18, 2017

Agenda Item # 1

Application# 17.015

TOPIC

Request to establish a new Level II HCPCS code to identify a new human placental membrane tissue comprised of both amnion and chorion allograft, Trade Name: NeoPatch Chorioamniotic Membrane Allograft.

Applicant's suggested language: QXXXX "NeoPatch, per sq cm".

BACKGROUND

On behalf of Cryolife, Inc. a request was submitted to establish a new Level II HCPCS code to identify the NeoPatch Chorioamniotic Membrane Allograft. According to the applicant, NeoPatch is a wound covering derived from terminally sterilized, dehydrated human placental membrane tissue comprised of both amnion and chorion. NeoPatch is an allograft intended for use as a wound covering, and applied externally to the wound. The constituent epithelium, basement membranes and collagen-rich extracellular matrix provide a protective covering to the wound. Individuals presenting with wounds including lower extremity ulceration caused by diabetes, chronic venous disease, and other chronic conditions, or who present with acute wounds may be appropriate for treatment with NeoPatch.

NeoPatch is supplied in the following sizes: 14mm round, 18mm round, 24mm round, 2cm x 3cm, 3cm x 5cm, 4cm x 4cm, 5cm x 6cm.

The applicant comments that no existing code adequately describes NeoPatch.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish QXXX, "NeoPatch, per sq centimeter". Effective 1/1/18.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker thanked CMS' HCPCS workgroup for granting (NeoPatch Chorioamniotic Membrane Allograft) a unique Q code and indicated agreement with the preliminary coding recommendation.

FINAL DECISION

Establish Q4176, "NeoPatch, per sq centimeter". Effective 1/1/18.

May 18, 2017

Agenda Item # 2

Application# 17.017

TOPIC

Request to revise existing Level II HCPCS code Q4162, which currently reads, "AmnioPro Flow, Bioskin Flow, BioRenew Flow, Woundex Flow, AmnioGen-A, AmnioGen-C, 0.5 cc", to omit discontinued products AmnioGen-A, AmnioGen-C, BioRenew Flow, and AmnioPro Flow.

Applicant's suggested language: Q4162, "WoundEx Flow, BioSkin Flow, 0.5 cc".

BACKGROUND

Human Regenerative Technologies, LLC submitted a request to revise existing code Q4162 to omit discontinued products: AmnioGen-A, Amnio Gen-C, BioRenew Flow, and AmnioPro Flow. According to the applicant, WoundEx Flow is a wound covering consisting of placental connective tissue matrix intended to replace or supplement damaged or inadequate connective tissue. WoundEx Flow is processed with proprietary HydraTek technology, creating a unique ambient temperature flowable tissue allograft. It is ideal for use in difficult to reach, irregularly shaped or tunneled wounds. WoundEx Flow is supplied in single use: 0.5cc, 1.0 cc, 1.5 cc, 2.0 vials. WoundEx Flow is stored at ambient temperature and has a 5-year shelf life.

The applicant comments that the requested revision of existing code Q4162 is necessary in order to capture only products currently marketed.

PRELIMINARY HCPCS CODING RECOMMENDATION

Revise existing code Q4162, which currently reads, "Amniopro flow, bioskin flow, biorenew flow, woundex flow, amniogen-a, amniogen-c, 0.5 cc", to instead read, "WoundEx Flow, BioSkin Flow, 0.5 cc". Effective 1/1/18.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

There was no primary speaker for this item. No comments were offered at CMS' HCPCS Public Meeting in response to our preliminary decision.

FINAL DECISION

Revise existing code Q4162, which currently reads, "Amniopro flow, bioskin flow, biorenew flow, woundex flow, amniogen-a, amniogen-c, 0.5 cc", to instead read, "WoundEx Flow, BioSkin Flow, 0.5 cc". Effective 1/1/18.

May 18, 2017

Agenda Item # 2 (continued)

Application# 17.018

TOPIC

Request to revise existing HCPCS Level II code Q4163, which currently reads: "Amniopro, bioskin, biorenew, woundex, AmnioGen-45, amniogen-200, per square centimeter", to omit discontinued brand names: AmnioGen-45, AmnioGen-200, BioRenew and AmnioPro.

Applicant's suggested language: Q4163 "WoundEx, Bioskin per square centimeter".

BACKGROUND

Human Regenerative Technologies, LLC submitted a request to revise existing code Q4163, by omitting the following Brand Names that are no longer marketed: AmnioGen-45, AmnioGen-200, BioRenew, and AmnioPro. According to the applicant, WoundEx consists of placental connective tissue matrix intended to replace or supplement damaged or inadequate connective tissue. WoundEx membrane allograft consists of dehydrated and decellularized human amniotic membrane that has been processed with proprietary HydraTek technology. "WoundEx Thin Membrane is designed as a single layer wound covering for common wounds, and WoundEx Thick Membrane is designed as a thicker single layer wound covering, for deeper wounds where more tissue bulk is required." WoundEx membrane is intended to be used as a wound covering in the treatment of chronic and acute wounds. Both the thin and thick membranes are supplied in the following sizes: 1 x1 cm; 2 X 2 cm; 2 X 4 cm; 4 X 4 cm 4 X 6 cm and 4 X 8 Cm. WoundEx is stored at ambient temperature and has a 5-year shelf life.

The applicant comments that the requested revision of existing code Q4163 is necessary in order to capture only the products currently marketed.

PRELIMINARY HCPCS CODING RECOMMENDATION

Revise existing code Q4163, which currently reads, "Amniopro, bioskin, biorenew, woundex, amniogen-45, amniogen-200, per square centimeter", to instead read, "WoundEx, BioSkin, per square centimeter".

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

There was no primary speaker for this item. No comments were offered at CMS' HCPCS Public Meeting in response to our preliminary decision.

FINAL DECISION

Revise existing code Q4163, which currently reads, "Amniopro, bioskin, biorenew, woundex, amniogen-45, amniogen-200, per square centimeter", to instead read, "WoundEx, BioSkin, per square centimeter".

May 18, 2017

Agenda Item # 3

Application# 17.026

TOPIC

Request to establish a new Level II HCPCS code to identify acellular liquid amnion, Trade Name:FlowerFlo™.

Applicant's suggested language: QXXXX "FlowerFlo™ injectable, per cc."

BACKGROUND

The Flower Orthopedics Corporation submitted a request to establish a new Level II HCPCS code to identify FlowerFlo. According to the applicant, FlowerFlo is a 100% acellular liquid amniotic fluid allograft intended for the treatment of non-healing wounds and burn injuries. FlowerFlo delivers cytokines, proteins and growth factors to help generate soft tissue. The typical patient population includes: Patients with chronic, non-infected, full thickness diabetic lower extremity ulcers, patients with chronic, non-infected, partial or full-thickness diabetic lower extremity skin ulcers due to venous insufficiency which have not adequately responded following conventional ulcer therapy and patients with second and third degree burns. FlowerFlo delivers cytokines, proteins and growth factors to help regenerate soft tissue.

FlowerFlo is prescribed by a qualified health care profession for injection on or in the wound site, in a physician office, outpatient, or inpatient setting. The dosage is per cubic centimeter (cc), depending on the size of the wound, intended for external application. As FlowerFlo is not micronized or lyophilized, there is no mg to cc conversion. FlowerFlo is supplied in 0.5cc, 1.0cc and 2.0 cc single use vials and stored at ambient temperature.

The applicant comments that no currently available HCPCS code describes FlowerFlo.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish QXXXX, "FlowerFlo, 0.1 cc". Effective 1/1/18.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker thanked CMS's workgroup for granting (FlowerFlo # 17.026 and FlowerPatch # 17.027) unique Q codes and indicated agreement with the preliminary recommendation for these two items. The primary speaker suggested that the workgroup revise the proposed text to reflect the two new product brand names, FlowerAmnioFlo and Flower AmnioPatch, in place of the originally requested brand names FlowerFlo and FlowerPatch, respectively.

FINAL DECISION

Establish Q4177, "FlowerAmnioFlo, 0.1 cc". Effective 1/1/18.

May 18, 2017

Agenda Item # 3 (continued)

Application# 17.027

TOPIC

Request to establish a new Level II HCPCS code to identify a dehydrated amniotic membrane allograft, Trade Name: FlowerPatch™.

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

BACKGROUND

Flower Orthopedics, Inc., submitted a request to establish a new Level II HCPCS code to identify FlowerPatch™. According to the applicant, FlowerPatch™ is a dehydrated (human) amniotic membrane allograft used for the treatment of non-healing wounds and burn injuries. FlowerPatch™ delivers cytokines, proteins and growth factors help generate soft tissue.

The product is directed to patients with chronic, non-infected, full thickness diabetic lower extremity ulcers, Patients with chronic, non-infected, partial or full-thickness diabetic lower extremity skin ulcers due to venous insufficiency which have not adequately responded following conventional ulcer therapy and patients with second and third degree burns. FlowerPatch is transported and stored at ambient temperature. It is supplied in single-use packages in the following sizes: 2 cm X 2 cm, 2 cm X 4 cm, 4 cm X 6 cm, 4 cm X 8 cm.

FlowerPatch™ is prescribed by a qualified health care professional for administration in a physician office, outpatient, or inpatient setting. FlowerPatch may be cut and shaped to the appropriate size. It is applied over the wound site following wound preparation. Absorbable/non-absorbable suture material and/or tissue adhesives may be used to apply the graft to the site, if necessary.

The applicant comments that no currently available HCPCS code appropriately defines FlowerPatch.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish QXXXX, "FlowerPatch, per sq centimeter". Effective 1/1/18.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker thanked CMS's workgroup for granting (FlowerFlo #17.026 and FlowerPatch # 17.027) unique Q codes and indicated agreement with the preliminary recommendation for these two items. The primary speaker suggested that the workgroup revise the proposed text to reflect the two new product brand names, FlowerAmnioFlo and Flower

AmnioPatch, in place of the originally requested brand names FlowerFlo and FlowerPatch, respectively.

FINAL DECISION

Establish Q4178, "FlowerAmnioPatch, per sq centimeter". Effective 1/1/18.

May 18, 2017

Agenda Item # 3 (continued)

Application# 17.032

TOPIC

Request to establish a new Level II HCPCS code to identify a hydrated acellular (human) dermal allograft matrix, Trade Name: FlowerDerm

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

BACKGROUND

The Flower Orthopedics Corporation submitted a request to establish a new Level II HCPCS code to identify FlowerDerm. According to the applicant, FlowerDerm is a hydrated acellular (human) dermal allograft matrix used for the treatment of non-healing wounds and burn injuries. FlowerDerm contains extracellular matrix (ECM) that provides a scaffold for cellular ingrowth vascularization, tissue regeneration and formation of granulation tissue.

The typical patient population includes: Patients with chronic, non-infected, full thickness diabetic lower extremity ulcers, Patients with chronic, non-infected, partial or full-thickness diabetic lower extremity skin ulcers due to venous insufficiency which have not adequately responded following conventional ulcer therapy and patients with second and third degree burns. FlowerDerm allografts are hydrated in saline and transported and stored at ambient temperature. FlowerDerm is supplied as a thin (0.5mm) allograft, meshed and unmeshed, in a variety of sizes; as a medium (1 mm) allograft, meshed or unmeshed, in a variety of sizes; and as a thick (2 mm) unmeshed allograft in several sizes.

FlowerDerm may be cut and shaped to the appropriate size. It is applied over the wound site following wound bed preparation. Absorbable/non-absorbable suture material and/or tissue adhesives may be used to apply the graft to the site, if necessary.

The applicant comments that no currently available HCPCS code describes FlowerDerm.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish QXXXX, "FlowerDerm, per sq centimeter". Effective 1/1/18.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker thanked CMS's workgroup for granting (FlowerFlo # 17.026 and FlowerPatch # 17.027) unique Q codes and indicated agreement with the preliminary

recommendation for these two items. The primary speaker suggested that the workgroup revise the proposed text to reflect the two new product brand names, FlowerAmnioFlo and Flower AmnioPatch, in place of the originally requested brand names FlowerFlo and FlowerPatch, respectively.

FINAL DECISION

Establish Q4179, "FlowerDerm, per sq centimeter". Effective 1/1/18.

May 18, 2017

Agenda Item # 4

Application# 17.034

TOPIC

Request to revise existing Level II HCPCS code Q4133, which currently reads: “Grafix Prime, per square centimeter,” to add another configuration of Grafix Prime: Grafix PL Prime.

Applicant's suggested language: Q4133, "Grafix PRIME and GrafixPL PRIME, per square centimeter.

BACKGROUND

Osiris Therapeutics, Inc., submitted a request to revise existing HCPCS code Q4133 to add GrafixPL PRIME, as another configuration of Grafix Prime. According to the applicant, the functionality, clinical use, and patient population of GrafixPL PRIME is the same as for Grafix.

GrafixPL Prime is a placental tissue allograft categorized as a skin substitute and intended for homologous use as a wound cover. It is a three-dimensional matrix, designed for application directly to acute and chronic wounds, including but not limited to diabetic foot ulcers, (DFUs), venous leg ulcers (VLUs), pressure ulcers, surgical wounds, burns, dehisced wounds, and wounds with exposed tendon, bone, and/or muscle by acting as a wound cover or barrier. It is applied directly to the wound weekly for up to 12 weeks or until the wound is closed.

Grafix PL Prime is supplied as a lyopreserved amnion-derived placental membrane between two pieces of plastic mesh backing, packaged in a sealed foil pouch. It is available in 3 sizes: 16mm disc, 2cm X 3cm, and 5 cm X 5 cm.

The applicant comments that the requested revision is needed in order to have a mechanism to identify GrafixPL Prime.

PRELIMINARY HCPCS CODING RECOMMENDATION

Revise existing code Q4133, which currently reads, "Grafix prime, per square centimeter", to instead read, "Grafix prime and Grafixpl prime, per square centimeter." Effective 1/1/18.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The speaker thanked CMS' HCPCS workgroup and expressed agreement with the preliminary recommendation to revise existing Level II HCPCS codes Q4133 and Q4132.

FINAL DECISION

Revise existing code Q4133, which currently reads, "Grafix prime, per square centimeter", to instead read, "Grafix prime and Grafixpl prime, per square centimeter." Effective 1/1/18.

May 18, 2017

Agenda Item # 4 (continued)

Application# 17.044

TOPIC

Request to revise existing Level II HCPCS code Q4132, which currently reads, "Grafix CORE, per square centimeter", to add another configuration of Grafix CORE, Trade Name: GrafixPL CORE.

Applicant's suggested language: Q4132, "Grafix CORE and GrafixPL CORE, per square centimeter".

BACKGROUND

Osiris Therapeutics, Inc. submitted a request to revise existing HCPCS code Q4132 "Grafix CORE, per square centimeter" to add another configuration of Grafix CORE: GrafixPL CORE. According to the applicant, Grafix Core is a human cellular and tissue based product (HCT/P). GrafixPL CORE is another configuration of Grafix CORE.

The functionality, clinical use, and patient population of GrafixPL CORE is the same as Grafix CORE. GrafixPL CORE is a lyopreserved chorion-derived placental membrane retaining the extracellular matrix, growth factors, and endogenous viable cells of the native tissue. The product functions as a protective barrier supporting the repair of acute and chronic wounds. GraflixPL Core is available in 3 sizes: 16 mm disc, 2 cm x 3 cm, and 5 cm x 5 cm. GrafixPL CORE is applied directly to the wound on a weekly basis for up to 12 weeks or until the wound is closed, the same as Grafix CORE.

The applicant comments that the requested revision is needed in order to have a mechanism to identify and report GrafixPL CORE.

PRELIMINARY HCPCS CODING RECOMMENDATION

Revise existing code Q4132, which currently reads, "Grafix core, per square centimeter", to instead read "Grafix CORE and GrafixPL CORE, per square centimeter." Effective 1/1/18.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The speaker thanked CMS' HCPCS workgroup and expressed agreement with the preliminary recommendation to revise existing Level II HCPCS codes Q4133 and Q4132.

FINAL DECISION

Revise existing code Q4132, which currently reads, "Grafix core, per square centimeter", to instead read "Grafix CORE and GrafixPL CORE, per square centimeter." Effective 1/1/18.

May 18, 2017

Agenda Item # 5

Application# 17.039

TOPIC

Request to establish a new Level II HCPCS code to identify a terminally sterilized, dehydrated human placental allograft, Trade Name: Revita

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

BACKGROUND

StimLabs, LLC. submitted a request to establish a new level II HCPCS code to identify Revita. According to the applicant, Revita is a HCT/P, donated allograft placental tissue. Revita is comprised of dehydrated, sterile human amniotic membrane and chorionic membrane obtained from donated human placental tissue. Revita is comprised of all three layers of placental membrane (amnion, intermediate, and chorion layers).

Revita allograft is intended to be used as a wound covering, or barrier membrane, over chronic and acute wounds, including dermal ulcers or defects. It is supplied in 2x2 cm, 2x3 cm, 4x4 cm, 4x6 cm, and 6x8 cm sheets.

The applicant comments that a new code is needed as a mechanism to identify and report Revita.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish QXXXX, "Revita, per square centimeter". Effective 1/1/18.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

There was no primary speaker for this item. No comments were offered at CMS' HCPCS Public Meeting in response to our preliminary decision.

FINAL DECISION

Establish Q4180, "Revita, per square centimeter". Effective 1/1/18.

May 18, 2017

Agenda Item # 6

Application# 17.042

TOPIC

Repeat request to establish a new Level II HCPCS code to identify lyophilized, terminally sterilized amniotic fluid, Trade Name: OrthoFlo.

Applicant's suggested language: QXXXX, "OrthoFlo, (terminally sterilized lyophilized amniotic fluid) per mL".

BACKGROUND

MiMedx, Inc. submitted a repeat request to establish a new Level II HCPCS code to identify OrthoFlo. According to the applicant, OrthoFlo is a unique human tissue allograft that is derived from amniotic fluid. Amniotic fluid is the liquid contained within the amniotic sac during pregnancy, which protects, cushions, reduces inflammation and enhances the mobility of the fetus. Key elements of amniotic fluid include growth factors, carbohydrates, proteins, lipids, electrolytes, and hyaluronic acid.

The stated intended use of OrthoFlo is in patients with moderate to severe osteoarthritis in the knee, as a homologous use to cushion and lubricate the synovial joint to improve function as assessed by range of motion. The applicant discussed that OrthoFlo contains regulatory proteins, cytokines and chemokines, and it has "biological activity" in that it promotes proliferation of human synoviocytes, and it "physiologically supplements the synovial fluid in the knees which has been substantially diminished by osteoarthritis." The applicant further states that "OrthoFlo qualifies as a minimally manipulated product" and is registered and marketed solely under Section 361 of the PHS Act and the regulations contained in 21 CFR Part 1271.

OrthoFlo is supplied in 0.5 mL, 1 mL, 2 mL, and 4 mL single-use vials of aseptically processed, terminally sterilized, lyophilized product.

The applicant comments that "all biologic HCPCS codes are brand-specific" and there are no existing HCPCS codes that describe OrthoFlo.

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 identify OrthoFlo. For coding guidance, contact the individual insurance contractor in whose jurisdiction a claim would be filed. For Medicaid, contact the Medicaid Agency in the state in which a claim would be filed. For private insurance, contact the individual insurance contractor. For Medicare, contact the Medicare contractor.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

There was no primary speaker for this item. No comments were offered at CMS' HCPCS Public Meeting in response to our preliminary decision.

FINAL DECISION

A national program operating need was not identified by Medicare, Medicaid, or the private insurance sector to establish a new HCPCS code to identify OrthoFlo. For coding guidance, contact the individual insurance contractor in whose jurisdiction a claim would be filed. For Medicaid, contact the Medicaid Agency in the state in which a claim would be filed. For private insurance, contact the individual insurance contractor. For Medicare, contact the Medicare contractor.

May 18, 2017

Agenda Item # 7

Application# 17.048

TOPIC

Request to establish a single new Level II HCPCS code to identify two porcine-derived extracellular matrices also known as urinary bladder matrix (UBM), Trade Names: Cytal3L and Cytal6L.

Applicant's suggested language: QXXXX "Cytal 3-Layer/6 Layer, per square centimeter."

BACKGROUND

ACell, Inc. submitted a request to establish a single new Level II HCPCS code to identify Cytal Wound Matrix 3-Layer (Cytal 3L) and Cytal Wound Matrix 6-Layer (Cytal 6L).

Cytal 3L and Cytal 6L are generally intended for the management of wounds (both acute & chronic) including: partial and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds (donor site/grafts, post-Mohs surgery, post laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, second-degree burns, skin tears) and draining wounds. Cytal 3L and Cytal 6L are composed of animal derived, extracellular matrix, and are skin substitutes. They are comprised of naturally-occurring urinary bladder matrix (UBM), and maintain an intact epithelial basement membrane to maintain and support a healing environment through constructive remodeling.

Cytal 3L and Cytal 6L are supplied in multi-layer single-use sheet configuration in sizes up to 10m x 15 cm. The devices are terminally sterilized using electron beam irradiation.

The applicant comments that Cytal 3L and Cytal 6L should be separately coded from Cytal 1 and 2 layers, and Cytal burn products, as they are clinically and scientifically distinct.

PRELIMINARY HCPCS CODING RECOMMENDATION

This request to establish a new Level II HCPCS code to separately identify Cytal Wound Matrix 3-Layer (Cytal3L) and Cytal Wound Matrix 6-Layer (Cytal6L) has not been approved. Existing code Q4166 "Cytal, per square centimeter" adequately describes these products and 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 to combine both of these products into a single code. The applicant reiterated the original request indicating that these two products are scientifically, functionally, and clinically distinct, and therefore require separate Q codes and descriptors to allow for greater physician choice and patient access.

FINAL DECISION

This request to establish a new Level II HCPCS code to separately identify Cytal Wound Matrix 3-Layer (Cytal3L) and Cytal Wound Matrix 6-Layer (Cytal6L) has not been approved. Existing code Q4166 "Cytal, per square centimeter" adequately describes these products and is available for assignment by insurers if they deem appropriate.

May 18, 2017

Agenda Item # 7 (continued)

Application# 17.083

TOPIC

Request to revise existing Level II HCPCS code Q4166 which currently reads, "Cytal, per square centimeter", to instead read, "Cytal 1-Layer/2-Layer/Burn, per square centimeter."

BACKGROUND

ACell, Inc. submitted a request to revise the descriptor of existing code Q4166 to clarify that this code category includes the following products: Cytal Wound Matrix 1-Layer, Cytal Wound Matrix 2-Layer, and Cytal Burn Matrix; and also to create a coding distinction between these products and the Cytal 3 Layer and Cytal 6 Layer products.

According to the applicant, Cytal 1 Layer; 2 Layer and burn products are intended for the management of wounds (both acute and chronic). They are comprised of naturally-occurring urinary bladder matrix (UBM), and maintain an intact epithelial basement membrane to maintain and support a healing environment through constructive remodeling.

These devices are cut to the desired size and applied directly to the wound bed by the treating clinician after removal of wound exudate and debris. They are intended for single use as they are applied and resorb into the patient's body.

The applicant is also making a claim of significant functional therapeutic distinction between Cytal 1 Layer and 2 Layer and Cytal Burn products, and Cytal 3 and 6 Layer products, on the basis of different manufacturing processes, (Cytal1, Cytal 2 and Cytal Burn) are freeze dried and lyophilized; whereas Cytal 3L and Cytal 6L are vacuum-pressed and have a fenestration pattern to aid in suturing. According to the applicant, "these difference result in function al and therapeutic distinctions." As such, the products should be separately coded.

PRELIMINARY HCPCS CODING RECOMMENDATION

This request to revise the descriptor of existing code Q4166 has not been approved. Existing code Q4166 "Cytal, per square centimeter" adequately describes the products that are the subject of this request, and it 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 to combine both of these products into a single code. The applicant reiterated the original request indicating that these two products are scientifically, functionally, and clinically distinct, and therefore require separate Q codes and descriptors to allow for greater physician choice and patient access.

FINAL DECISION

This request to revise the descriptor of existing code Q4166 has not been approved. Existing code Q4166 "Cytal, per square centimeter" adequately describes the products that are the subject of this request, and it is available for assignment by insurers if they deem appropriate.

May 18, 2017

Agenda Item # 8

Application# 17.053

TOPIC

Request to establish a new level II HCPCS code to identify a multi-layer lyophilized human amniotic membrane allograft, Trade Name: Amnio Wound.

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

BACKGROUND

Alpha Tissue, LLC submitted a request to establish a new level II HCPCS code to identify Amnio Wound. According to the applicant, Amnio Wound is a lyophilized human amniotic membrane allograft comprised of an epithelial layer and two fibrous connective tissue layers specifically processed to be used for the repair and replacement of lost or damaged dermal tissue.

Amnio Wound is intended for use in the following conditions: neuropathic ulcers, venous stasis ulcers, post-traumatic wounds, pre-and post-surgical wounds and pressure ulcers, diabetic wounds, burn wounds, scar tissue, scarring, and adhesion barrier. The graft is administered by placing the stromal side onto the external wound area followed by the clinician's standard closing procedures. It is stored at ambient temperature.

The applicant commented that existing HCPCS codes do not describe Alpha Tissue's unique product.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish QXXXX, "Amnio wound, per square centimeter". Effective 1/1/18.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

There was no primary speaker for this item. No comments were offered at CMS' HCPCS Public Meeting in response to our preliminary decision.

FINAL DECISION

Establish Q4181, "Amnio wound, per square centimeter". Effective 1/1/18.

May 18, 2017

Agenda Item # 9

Application# 17.054

TOPIC

Request to revise existing Level II HCPCS code Q4148, which currently reads, "Neox 1k, per square centimeter", to add NEOX CORD RT and CLARIX CORD 1K, and also to add the word "CORD" to NEOX 1K.

Applicant's suggested language: Q4148 "NEOX CORD 1K, NEOX CORD RT, or CLARIX CORD 1K, per square centimeter".

BACKGROUND

Amniox Medical, Inc. submitted a request to revise existing Level II HCPCS code Q4148 to include NEOX CORD RT and CLARIX CORD 1K and also to add the word "CORD" to NEOX 1K. According to the applicant, NEOX CORD RT and CLARIX CORD 1K are also non-implantable biological products used for wound healing and surgical coverings. NEOX CORD 1K is the updated Brand Name for NEOX 1K, the same product. NEOX CORD RT is similar to NEOX CORD 1K, but it is terminally sterilized in addition to the NEOX CORD 1K aseptic process. CLARIX CORD 1K is identical to NEOX CORD 1K, but it used as a surgical covering, wrap, or barrier.

NEOX CORD RT and CLARIX CORD 1K are supplied as single-use grafts in sizes ranging from 2.0 cm^2 to 24.0 cm^2. The graft is placed to completely cover the site, and is secured using sutures or surgical staples.

The applicant comments that the requested revision is needed in order to adequately describe NEOX CORD 1K, NEOX CORD RT and CLARX CORD 1K.

PRELIMINARY HCPCS CODING RECOMMENDATION

Revise existing code Q4148, which currently reads, "NEOX 1k, per square centimeter", to instead read, "NEOX CORD 1K, NEOX CORD RT, or CLARIX CORD 1K, per square centimeter". Effective 1/1/18.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

There was no primary speaker for this item. No comments were offered at CMS' HCPCS Public Meeting in response to our preliminary decision.

FINAL DECISION

Revise existing code Q4148, which currently reads, "NEOX 1k, per square centimeter", to instead read, "NEOX CORD 1K, NEOX CORD RT, or CLARIX CORD 1K, per square centimeter". Effective 1/1/18.

May 18, 2018

Agenda Item # 9

Application# 17.059

TOPIC

Request to revise existing Level II HCPCS code Q4156 to include a cryopreserved, human amniotic membrane graft, Trade Name: CLARIX 100.

Applicant's suggested language: revise existing HCPCS code Q4156 which currently reads Q4156 "NEOX 100, per square centimeter," to instead read "NEOX 100 or CLARIX 100, per square centimeter".

BACKGROUND

Amninox Medical Inc., submitted a request to revise existing Level II HCPCS code Q4156 to include CLARIX 100.

According to the applicant, CLARIX 100 is a cryopreserved human amniotic membrane tissue product regulated as a 361 HCT/P.

CLARIX 100 is comprised of human amniotic tissue that contains biology which modulates inflammation and permits rapid regenerative healing of surgical wounds. CLARIX 100 differs from NEOX in that rather than being used as a wound covering for dermal ulcers and defects, and CLARIX 100 is a surgical covering, wrap, or barrier to modulate inflammation and promote healing.

It is supplied as a single use graft in differing sizes, and stored at 80 degrees C to 4 degrees C. The dosage per administration depends on the size of the surgical site; the graft is placed to completely cover the site, and is secured using sutures or surgical staples, at the discretion of the physician. The grafts are supplied cryopreserved in a sealed foil pouch.

The applicant comments that the requested revision is warranted to describe CLARIX 100.

PRELIMINARY HCPCS CODING RECOMMENDATION

Revise existing code Q4156, which currently reads, "NEOX 100, per square centimeter," to instead read, "NEOX 100 or CLARIX 100, per square centimeter". Effective 1/1/18.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

There was no primary speaker for this item. No comments were offered at CMS' HCPCS Public Meeting in response to our preliminary decision.

FINAL DECISION

Revise existing code Q4156, which currently reads, "NEOX 100, per square centimeter," to instead read, "NEOX 100 or CLARIX 100, per square centimeter". Effective 1/1/18.

May 18, 2017

Agenda Item # 10

Application# 17.104

TOPIC

Request to establish a new level II HCPCS code to identify a human fibroblast-derived temporary wound cover, Trade Name: TransCyte.

Applicant's suggested language: QXXXX, "TransCyte, any type, per square centimeter".

BACKGROUND

Organogenesis, Inc. submitted a request to establish a new level II HCPCS code to identify TransCyte. According to the applicant, TransCyte is a human fibroblast-derived temporary wound cover consisting of polymer membrane and donated neonatal human fibroblast cells cultured under aseptic conditions in vitro on a nylon mesh. As fibroblasts proliferate within the nylon mesh, they secrete human dermal collagen, matrix proteins and growth factors. Following freezing, no cellular metabolic activity remains; however, the tissue matrix and bound growth factors are left intact. TransCyte provides a temporary protective barrier for the wound.

TransCyte is intended for use as a temporary wound covering for surgically excised full-thickness and deep partial-thickness thermal burn wounds in patients who require such a covering prior to autograft placement. TransCyte is also intended for the treatment of mid-dermal to indeterminate depth burn wounds that typically require debridement and that may be expected to heal without autografting. TransCyte is applied to a wound using sutures or other fixation method based on the size of the wound being treated. It is supplied in a cassette containing two aseptically processed sheets, each approximately 5 inches by 7.5 inches.

The applicant comments that a new code is warranted to appropriately identify and reimburse TransCyte in the full range of care settings and to provide coding consistent with other clinically similar products.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish QXXXX, "TransCyte, per square centimeter". Effective 1/1/18.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The speaker thanked CMS' HCPCS workgroup for the preliminary recommendation and agrees with the decision and urged the Committee to finalize the decision to create a new Q code for Transcyte.

FINAL DECISION

Establish Q4182, "TransCyte, per square centimeter". Effective 1/1/18.

May 18, 2017

Agenda Item # 11

Application# 17.050

TOPIC

Request to revise the existing Level II HCPCS code Q4158, which currently reads “Marigen, per square centimeter,” to instead read, “Kerecis Omega3, per square centimeter”.

BACKGROUND

Kerecis Inc., submitted a request to revise the text of existing code Q4158 to reflect a product name change from "Marigen" to "Kerecis Omega3". According to the applicant, Kerecis Omega3 is an extracellular matrix (ECM) xenograft made from fish (piscine) dermis designed for transplant into damaged tissue such as chronic wounds. Keresis Omega3 contains natural insoluble proteins such as collagen and proteoglycans, glycosaminoglycans, and fibronectin. Kerecis Omega3 Wound ECM also contains growth factors such as IGF-1 and TGFf32.

Kerecis Omega3 acellular fish skins refocus the healing process of the tissue damage. The skin acts as a scaffold for revascularization and repopulation of the patient's cells, which are under attack from matrix metalloproteinases (MMPs) in the inflamed wound. It is used as a wound covering and wound matrix for full thickness wounds and burns as a covering for damaged membranes.

Omega 3 is supplied in a sealed, sterilized package in the following sizes: 3 X 3.5cm (10 per package); 3 X 7 cm (10 per package); and 7 X 10cm (10 per package). The product is shipped freeze dried and must be rehydrated before it is applied.

The request to revise code Q4158 is to reflect a product name change only. The product is manufactured by the same company.

PRELIMINARY HCPCS CODING RECOMMENDATION

Revise existing code Q4158, which currently reads, "Marigen, per square centimeter," to instead read, "Kerecis Omega3, per square centimeter". Effective 1/1/18.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The applicant submitted written comments in agreement with the CMS' preliminary coding recommendation.

FINAL DECISION

Revise existing code Q4158, which currently reads, "Marigen, per square centimeter," to instead read, "Kerecis Omega3, per square centimeter". Effective 1/1/18.