Centers for Medicare & Medicaid Services (CMS)
Healthcare Common Procedure Coding System (HCPCS)
Public Meeting Summary Report
Drugs, Biologicals, and Radiopharmaceuticals
Tuesday, May 20, 2014

Introduction and Overview

Approximately 75 people attended. The agenda included 15items.

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.

Anne Hauswald, Acting Director of the Division 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.

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.

Centers for Medicare & Medicaid Services (CMS) Healthcare Common Procedure Coding System (HCPCS) Public Meeting Agenda
for Drugs, Biologicals and Radiopharmaceuticals
Tuesday, May 20, 2014 9:00 am – 5:00 pm
CMS Auditorium
7500 Security Boulevard
Baltimore (Woodlawn), Maryland 21244-1850

8:15 a.m. Arrival and sign-in

9:00 a.m. Welcome
Background and purpose of meeting
Meeting Format and Ground Rules

For each agenda item, a written overview of the request and CMS' preliminary coding decision is provided. Preliminary decisions are not final or binding upon any payer, and are subject to change. Meeting participants will hear presentations about the agenda item from the registered primary speaker and other speakers (if any). Presentations will be followed by an opportunity for questions regarding that particular agenda item. The public meetings provide an opportunity for the general public to provide additional input related to requests to modify the HCPCS code set. Final decisions are not made at the public meetings. Applicants will be notified of final decisions in November.

The agenda includes a summary of each HCPCS code application on the agenda. The information provided in each summary reflects claims made by the applicant and should not be construed as a statement of fact or an endorsement by the federal government.

AGENDA ITEM #1
Attachment# 14.024
Request to establish a new Level II HCPCS to identify an acellular dermal matrix, trade name: Helicoll. Applicant's suggested language: Q41XX Helicoll Acellular Dermal Matrix, Per Square Centimeter.

Primary Speaker: Jeremy Gove of Continent Technologies, LLC

AGENDA ITEM #2
Attachment# 14.028
Request to establish a new Level II HCPCS code to identify decellularized dermal allograft, trade name: DermaPure. Applicant's suggested language: Q4XXX DermaPure, Per Square Centimeter.

No Primary Speaker

AGENDA ITEM #3
Attachment# 14.029
Request to establish two new Level II HCPCS codes to identify human placental connective tissue matrix to be marketed under the trade names: Dermavest (for sizes 1.5 cm^2 to 6cm^2); and Dermavest2 (for sizes greater than 6 cm^2). Applicant's suggested language: QXXXX Dermavest™, Per Square Centimeter and QXXXX Dermavest 2™, Per Square Centimeter.

Primary Speaker: Daniel A. Grande of Feinstein Institute for Medical Research

AGENDA ITEM #4
Attachment# 14.035
Request to establish a new Level II HCPCS to identify a human Amniotic Membrane Allograft, trade name: Biovance. Applicant's suggested language: QXXXX Biovance, Per Square cm^2 For A Decelluarized Dehydrated Human Amniotic Membrane Allograft.

Primary Speaker: Jodi Gurney of Celgene Cellular Therapeutics

AGENDA ITEM #5
Attachment# 14.038
Request to establish a new Level II HCPCS code to identify a cryopreserved, injectable allograft, trade name: NuCel™. Applicant's suggested language: Q41XX NuCel, Injectable, 0.5cc.

Primary Speaker: Howard Walthall, Jr., of NuTech Medical, Inc.

AGENDA ITEM #6
Attachment# 14.046
Requesting to establish four new Level II HCPCS codes to identify varying thicknesses of acellular tissue surgical mesh devices, trade names: MatriStem® Surgical Matrix RS, PSM (Plastic Surgery Matrix), PSMX (Plastic Surgery Matrix) and Thick Mesh. The applicant also requests revision of existing code Q4119 which currently reads: "MatriStem Wound Matrix, PSMX, RS, or PSM, Per Square Centimeter" to instead read "MartiStem Multi-Layer Wound Matrix, Per Square Centimeter".

Primary Speaker: Cory West of ACell, Inc.

AGENDA ITEM #7
Attachment# 14.053
Request to establish a new Level II HCPCS to identify a human amniotic tissue allograft, trade name: AlloWrap DS. Applicant's suggested language: Q41XX Allowrap DS, Per cm^2.

Attachment# 14.054
Request to establish a new Level II HCPCS code to identify a human amniotic tissue allograft,

trade name: AlloWrap Dry. Applicant's suggested language: Q41XX AlloWrap Dry, Per Square Centimeter.

No Primary Speaker

AGENDA ITEM #8
Attachment# 14.058
Request to establish a new Level II HCPCS code to identify human placental allografts, trade names: AmnioBand and Guardian. Applicant's suggested language: Q41XX AmnioBand and Guardian, Per Square Centimeter.

No Primary Speaker

AGENDA ITEM #9
Attachment# 14.019
Request to establish a new Level II HCPCS for Clarix™ 100. Applicant's suggested language: QXXXX Clarix 100, Per Square Centimeter.

Attachment# 14.020
Request to establish a new Level II HCPCS for Neox® Flo. Applicant's suggested language: QXXXX Neox® Flo, 1mg.

Attachment# 14.021
Request to establish a new Level II HCPCS for Clarix Flo. Applicant's suggested language: JXXXX Clarix™Flo, 1mg.

Attachment# 14.022
Request to establish a new Level II HCPCS for CLARIX™CORD 1k. Applicant's suggested language: QXXXX Clarix Cord 1k, Per Square Centimeter.

Attachment# 14.023
Request to establish a new Level II HCPCS for Neox 100. Applicant's suggested language: QXXXX Neox 100, Per Square Centimeter.

Primary Speaker: Aaron Smith of Amniox Medical, Inc.

AGENDA ITEM #10
Attachment# 14.010
Request to establish four new Level II HCPCS codes for use to categorize all skin substitute products except Apligraft, FortaDerm, and FortaDerm Antimicrobial. Applicant's suggested language for the 4 new code categories:

AXXX1 Skin Substitute, Tissue Of Human Origin, Cadaver Skin, Not Bioengineered, Any Type Of Processing, Per Square Centimeter.

AXXX2 Skin Substitute, Tissue Of Human Origin, Other Than Cadaver Skin (e.g., Amniotic/Placental Tissue), Not Bioengineered, Any Type Of Processing, Per Square Centimeter.

AXXX3 Skin Substitute, Tissue Of Non-Human Origin, Other Than Cadaver Skin (e.g., Bovine, Porcine, Equine), Any source (e.g., Intestine, Bladder, Tendon, Skin), Any Type Of Processing - No Living Cells, Per Square Centimeter.

AXXX4 Miscellaneous Wound Dressing Or Covering, Not Otherwise Specified.

Primary Speaker: Dr. Paul Rudolf of Arnold & Porter, LLP

AGENDA ITEM #11
Attachment# 14.011
Request to establish a new Level II HCPCS for FortaDerm™ Antimicrobial PHMB. Applicant's suggested language: Q41XX FortaDerm Antimicrobial PHMN, Per Square Centimeter.

Attachment# 14.012
Request to establish a new Level II HCPCS for FortaDerm™. Applicant's suggested language: Q41XX FortaDerm, Per Square Centimeter.

Primary Speaker: Dr. Paul Rudolf of Arnold & Porter, LLP

AGENDA ITEM #12
Attachment# 14.025
Request to establish a new Level II HCPCS to identify a human tissue Allograft, trade name: Revitalon. Applicant's suggested language: Q41XX Revitalon, Per Square Centimeter.

Attachment# 14.026
Request to establish a new Level II HCPCS code to identify a piscine (fish) dermis extracellular xenograft, trade name: Alphaplex with MariGen Omega3 (alternately referred to as Alphaplex ECM or Alphaplex pECM. Applicant's suggested language: Q41XX Alphaplex with MariGen Omega3, Per Square Centimeter.

Primary Speaker: Paul Kim of OBER/KALER

AGENDA ITEM #13
Attachment# 14.016
Request to establish a new Level II HCPCS for Architect PX. Applicant's suggested language: QXXXX Architect PX, Per Square Centimeter.

Attachment# 14.050
Architect FX. Applicant's suggested language: QXXXX Architect FX, Per Square Centimeter.

No Primary Speaker

AGENDA ITEM #14
Attachment# 14.040
Request to establish a new Level II HCPCS code to identify an amniotic membrane allograft, trade name: Affinity. Applicant's suggested language: Q41XX Affinity, Per Square Centimeter.

Attachment# 14.041
Request to establish a new Level II HCPCS code to identify a dehydrated human placental membrane allograft, trade name: NuShield™. Applicant's suggested language: Q41XX NuShield, Per Square Centimeter.

Primary Speaker: Howard Walthall, Jr., of NuTech Medical, Inc.

AGENDA ITEM #15
Attachment# 14.031
Request to establish a new Level II HCPCS code to identify collagen matrix, trade name: Ologen. Applicant's suggested language: QXXXX Ologen Collagen Matrix, Per Square Centimeter.

Primary Speaker: Kenn Curt of Aeon Astron

HCPCS Public Meeting Agenda Item #1

May 20, 2014

Attachment# 14.024

Topic/Issue:

Request to establish a new Level II HCPCS to identify an acellular dermal matrix, trade name: Helicoll. Applicant's suggested language:

Q41XX Helicoll Acellular Dermal Matrix, Per Square Centimeter.

Background/Discussion:

According to the requester Helicoll™ Collagen Wound Dressing is a high purity bovine Type-I collagen product that is >97% pure, non-cross-linked, and acellular in construction which is highly bioactive, cell conductive, and supportive towards enhancing tissue generation. Helicoll™ is a semi-occlusive, self-adhering, and ready to use pre-sterilized Type-1 Collagen Sheet. It is flexible, has tensile strength adequate to accept sutures and staples and has moderate tackiness. Helicoll™ is considered for the following indications: partial-thickness and Full-thickness Wounds, Pressure Ulcers, Venous Ulcers, Chronic Vascular Ulcers, Diabetic Ulcers, Trauma Wounds, Surgical Wounds; including wounds with exposed tendon, muscle, bone or other vital structures and other soft tissue defects. Treatment course typically involves 1-4 applications. The product is sterile packaged for single use and is available in sizes 2x2in, 4x2in, 4x4in, and in 8x8in.

Preliminary Decision:

Existing code A6021 "Collagen dressing, sterile, size 16 sq. in. or less, each" or A6023 "Collagen dressing, sterile, size more than 48 sq. in., each" are available for assignment by insurers if deemed appropriate, depending on size.

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with CMS' preliminary decision not to establish a HCPCS code. The speaker commented that Helicoll™ is recognized as a skin substitute by FDA. Although the FDA classified Helicoll as a collagen wound dressing. Helicoll™ is applied, in an operating room. The speaker reiterated the original request that CMS establish a Q code to identify Helicoll™.

HCPCS Public Meeting Agenda Item #2

May 20, 2014

Attachment# 14.028

Topic/Issue:

Request to establish a new Level II HCPCS code to identify decellularized dermal allograft, trade name: DermaPure. Applicant's suggested language:

Q4XXX DermaPure, Per Square Centimeter.

Background/Discussion:

According to the requester DermaPure is a single layer decellularized dermal allograft for the treatment of acute and chronic wounds such as diabetic foot ulcers, venous stasis ulcers, and additional wounds that are refractory to more conservative care. DermaPure is derived from split thickness grafts harvested from cadaveric human tissue donors. DermaPure is supplied in the following allograft sizes: 2x3cm, 3x4cm, and 4x6cm.

Preliminary Decision:

Establish Q41XX Dermapure, per Square Centimeter.

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item. However, a representative of the manufacturer offered a comment in agreement with CMS' preliminary decision.

HCPCS Public Meeting Agenda Item #3

May 20, 2014

Attachment# 14.029

Topic/Issue:

Request to establish two new Level II HCPCS codes to identify human placental connective tissue matrix to be marketed under the trade names: Dermavest (for sizes 1.5 cm^2 to 6cm^2); and Dermavest2 (for sizes greater than 6 cm^2). Applicant's suggested language:

QXXXX Dermavest™, Per Square Centimeter.

QXXXX Dermavest 2™, Per Square Centimeter.

Background/Discussion:

According to the requester Dermavest is a human placental connective tissue matrix intended to replace or supplement damaged or inadequate integumental tissue (skin substitute) and re-stabilize a debrided wound. Dermavest is comprised of a different source of human connective tissue than the other products. It has up to 5 times more (mg) human connective tissue matrix per square cm. It is supplied as a single dehydrated, 2cmx3cm sterile pad.

Preliminary Decision:

Existing code A6021 "Collagen dressing, sterile, size 16 sq. in. or less, each"; A6022 "Collagen dressing, sterile, size more than 16 sq. in. but less than or equal to 48 sq. in., each"; and A6023 "Collagen dressing, sterile, size more than 48 sq. in., each" are available for assignment by insurers if deemed appropriate, depending on size; and if supported based on collagen content.

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with CMS' preliminary decision not to establish a HCPCS code. According to the speaker, Dermavest should not have been classified as a "collagen dressing" and instead should have been assigned a Q-code consistent with the practice of assigning product specific codes to other amniotic/chorionic/placental allograft tissue. Dermavest is incorporated into the wound bed. It is applied in the facility or physician's office setting. The speaker requested that CMS reconsider its initial recommendation and instead assign a unique Q-code.

HCPCS Public Meeting Agenda Item #4

May 20, 2014

Attachment# 14.035

Topic/Issue:

Request to establish a new Level II HCPCS to identify a human Amniotic Membrane Allograft, trade name: Biovance. Applicant's suggested language:

QXXXX Biovance, Per Square cm^2 For A Decelluarized Dehydrated Human Amniotic Membrane Allograft.

Background/Discussion:

According to the requester BIOVANCE® is a decellularized dehydrated human amniotic membrane (DDHAM) used in the repair or replacement of damaged or lost soft tissue. This allograft is derived from the placental amnion and includes epithelial and stromal components that provide a collagen-rich extracellular matrix. In addition to the natural scaffold being a physical conduit for infiltrating cells, BIOVANCE contains extracellular proteins such as elastin, fibronectin, proteoglycans, glycosaminoglycans, and laminins important in extracellular matrix strength, cell attraction, and migration. BIOVANCE is sterilized and available in four sizes: 1x2 cm, 2x3 cm, 4x4 cm and 6x6 cm.

Preliminary Decision:

Existing code A6021 "Collagen dressing, sterile, size 16 sq. in. or less, each" or A6022 "Collagen dressing, sterile, size more than 16 sq. in. but less than or equal to 48 sq. in., each", are available for assignment by insurers if deemed appropriate, depending on size.

Summary of Primary Speaker Comments at the Public Meeting:

The speaker disagreed with CMS' preliminary decision not to establish a HCPCS code. According to the speaker, BIOVANCE® shares similar characteristics with other cellular and/or tissue based products for wounds (CPTs) which have been assigned to Q codes. As such, the speaker requested that BIOVANCE® receive a Q code.

HCPCS Public Meeting Agenda Item #5

May 20, 2014

Attachment# 14.038

Topic/Issue:

Request to establish a new Level II HCPCS code to identify a cryopreserved, injectable allograft, trade name: NuCel™. Applicant's suggested language:

Q41XX NuCel, Injectable, 0.5cc.

Background/Discussion:

According to the requester, NuCel™ is a cryopreserved placental allograft prepared from human amniotic membrane and cellular material extracted from human amniotic fluid of the same donor. NuCel™ is delivered in a liquid form and may be mixed with saline and applied to the wound bed to enhance healing of skin and soft tissue defects resulting from neuropathic ulcers, venous stasis ulcers, pressure ulcers, burns, post-traumatic wounds and post-surgical wounds. It is intended to support wound repair and healing, and also offers anti-scarring and anti-inflammatory properties. The product is sterilely packaged for single use and available in the following sizes: 0.5cc, 1 cc, 2 cc and 2.5 cc.

Preliminary Decision:

A national program operating need was not identified by Medicare, Medicaid or the Private Insurance sector to establish a HCPCS code to identify NuCel.

Summary of Primary Speaker Comments at the Public Meeting:

The applicant disagreed with CMS' preliminary decision not to establish a HCPCS code. Although the application provides information that that NuCel™ is not used in physicians offices, the applicant commented that. NuCel™ is increasingly being used for the treatment of chronic wounds in the outpatient/wound clinic settings

HCPCS Public Meeting Agenda Item #6

May 20, 2014

Attachment# 14.046

Topic/Issue:

Requesting to establish four new Level II HCPCS codes to identify varying thicknesses of acellular tissue surgical mesh devices, trade names: MatriStem® Surgical Matrix RS, PSM (Plastic Surgery Matrix), PSMX (Plastic Surgery Matrix) and Thick Mesh. The applicant also requests revision of existing code Q4119 which currently reads: "MatriStem Wound Matrix, PSMX, RS, or PSM, Per Square Centimeter" to instead read "MartiStem Multi-Layer Wound Matrix, Per Square Centimeter".

Background/Discussion:

According to the requester, MatriStem® Surgical RS, PSM, PSMX & Thick Mesh are a sterile, porcine-derived, naturally occurring dehydrated extracellular matrix that maintains and supports a healing environment for wound management. MatriStem Surgical Mesh devices are unique from other scaffold technologies in that they fundamentally change healing by triggering abundant new blood vessel formation and recruiting numerous cell types to the site of the injury wound. MatriStem surgical devices, which have a 510(k) clearance for soft tissue repair from the FDA, are intended for implantation to reinforce soft tissues.

Preliminary Decision:

Revise Q4119 which currently reads "Matristem wound matrix, psmx, rs, or psm, per square centimeter" to read "Matristem wound matrix, psmx, rs, psm, or thick mesh, per square centimeter".

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with CMS' preliminary decision not to establish 4 new HCPCS codes and reiterated the original request for 4 new codes and to also establish 2 additional new codes for new surgical products not included in the incoming application. According to the speaker, the indications for use; size; and cost of the product varies across the MaritStem line of products and as such ,multiple codes are needed. In addition, new HCPCS "Q" codes will allow for more evidence generation for approved products.

HCPCS Public Meeting Agenda Item #7

May 20, 2014

Attachment# 14.053

Topic/Issue:

Request to establish a new Level II HCPCS to identify a human amniotic tissue allograft, trade name: AlloWrap DS. Applicant's suggested language:

Q41XX Allowrap DS, Per cm^2.

Background/Discussion:

According to the requester, AlloWrap™ DS consists of human amniotic membrane that has been processed using a proprietary technology, and is designed with two layers of amniotic tissue with the epithelial layers facing outward. AlloWrap™ DS tissue allograft is surgically applied to the skin. Most wounds respond with one application; however it can be reapplied if needed. AlloWrap DS is supplied in the following sizes: 2cm x 2cm; 2cm x 4cm; 4cm x 4cm; and 4cm x 8cm.

Preliminary Decision:

Establish Q41XX Allowrap DS or Dry, 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 #7

May 20, 2014

Attachment# 14.054

Topic/Issue:

Request to establish a new Level II HCPCS code to identify a human amniotic tissue allograft, trade name: AlloWrap Dry. Applicant's suggested language:

Q41XXAlloWrap Dry, Per Square Centimeter.

Background/Discussion:

According to the requester, AlloWrap™Dry consists of human amniotic membrane that has been processed using a proprietary technology, and is designed with two layers of amniotic tissue with the epithelial layers facing outwards. AlloWrap™Dry tissue is surgically applied to the skin and is supplied in a range of sizes: 1 x 1cm; 1 x 2cm; 1.5 x 2cm; 1 x 4cm; 2 x2cm; 2 x 4cm; 4 x 4cm; 6 x 6cm; and 4 x 8cm. It can be used in a variety of procedures as a wound cover or barrier.

Preliminary Decision:

Establish Q41XX Allowrap DS or Dry, 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 #8

May 20, 2014

Attachment# 14.058

Topic/Issue:

Request to establish a new Level II HCPCS code to identify human placental allografts, trade names: AmnioBand and Guardian. Applicant's suggested language:

Q41XX AmnioBand and Guardian, Per Square Centimeter.

Background/Discussion:

According to the requester AmnioBand and Guardian are human tissue allografts made of donated placental membrane. The allograft is comprised of native human amnion and chorion. The amnion and the chorion together create a membrane in which the amnion serves as a covering epithelium The membrane is hydrophilic and can be used in a hydrated or dehydrated state. Although marketed under two different brand names, the products are identical. Amniobrand and Guardian are allograft membrane coverings intended for interior or exterior wounds including use as a covering for the surgical site. Usage includes various wounds and ulcers and other soft tissue defects. Both AmnioBrand and Guardian are processed and packaged under aseptic conditions, and are available in the same five sizes: 2x2 cm, 3x4 cm, 3x8 cm, 4x4 cm, and 4x6 cm.

Preliminary Decision:

Establish Q41XX AmnioBand or Guardian, 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 #9

May 20, 2014

Attachment# 14.019

Topic/Issue:

Request to establish a new Level II HCPCS for Clarix™ 100. Applicant's suggested language:

QXXXX Clarix 100, Per Square Centimeter.

Background/Discussion:

According to the requester CLARIX™100 is a cryopreserved human amniotic membrane product derived from placental tissue that is electively donated post cesarean section and is utilized as a surgical covering, wrap or barrier. CLARIX™100 is preserved through a proprietary and patented thermal preservation method called CRYOTEK™. Cryopreservation devitalizes the cells thus preventing immune rejection of the product. It also preserves the vital and functional components of the extracellular matrix such as collagens, hyaluronan, fibronectin, laminin, proteoglycans and growth factors. CLARIX™100 is a thin product (100 microns). It is supplied as a single-use biologic in three different sizes: 2.0x2.0 cm, 4.0x4.0 cm, and 7.0x7.0 cm.

Preliminary Decision:

A national program operating need was not identified by Medicare, Medicaid or the Private Insurance sector to establish a HCPCS code to identify Clarix100, which is included as part of a surgical procedure.

Summary of Primary Speaker Comments at the Public Meeting:

The applicant disagreed with CMS' preliminary decision for Clarix 100. There are sufficient similarities between Clarix 100 and Neox 100 as such, CMS should include Clarix 100 within the proposed new "Q" code for Neox 100.

HCPCS Public Meeting Agenda Item #9

May 20, 2014

Attachment# 14.020
Topic/Issue:

Request to establish a new Level II HCPCS for Neox® Flo. Applicant's suggested language:

QXXXX Neox® Flo, 1mg.

Background/Discussion:

According to the requester Neox®Flo is a human amniotic membrane and umbilical cord product in particulate form obtained from donated human placental tissue. It is intended to be used as a wound covering for dermal ulcers and defects such as diabetic ulcers. Neox®Flo can be prepared by the physician as a suspension with normal saline for topical application or applied in dry form topically. It is especially useful in difficult to reach wounds that are either irregularly shaped or tunneled. Neox® Flo it is supplied in a single-use vial in three different doses: 25mg, 50mg and 100mg. The typical chronic wound patient will receive an average of 1-2 applications of Neox®Flo to facilitate healing. The dosage depends on the wound size.

Preliminary Decision:

Establish QXXXX NeoxFlo or ClarixFlo, 1 mg

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker offered a brief comment at the public meeting agreeing with CMS' preliminary decision.

HCPCS Public Meeting Agenda Item #9

May 20, 2014

Attachment# 14.021

Topic/Issue:

Request to establish a new Level II HCPCS for Clarix Flo. Applicant's suggested language:

JXXXX Clarix™Flo, 1mg.

Background/Discussion:

According to the requester CLARIX™FLO is a biological particulate amniotic membrane and umbilical cord product derived from human placental tissue. It is intended to facilitate replacement or supplement damaged or inadequate integumental tissue. CLARIX™FLO is supplied in a single-use vial in three different doses: 25mg, 50mg and 100mg. It is prepared by the physician as a suspension with normal saline for injection into the tissue. The typical patient will receive one treatment of CLARIX™FLO to facilitate healing. Dosing is dependent upon the size of the damaged or inadequate integumental tissue.

Preliminary Decision:

Establish QXXXX, NeoxFlo or ClarixFlo, 1 mg

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker offered a brief comment at the public meeting agreeing with CMS' preliminary decision.

HCPCS Public Meeting Agenda Item #9

May 20, 2014

Attachment# 14.022

Topic/Issue:

Request to establish a new Level II HCPCS for CLARIX™CORD 1k. Applicant's suggested language:

QXXXX Clarix Cord 1k, Per Square Centimeter

Background/Discussion:

According to the requester, CLARIX™CORD 1k is a cryopreserved ultra-thick amniotic membrane and umbilical cord product derived from donated human placentas. It is utilized as a surgical covering, wrap or barrier in reconstructive surgeries, particularly in foot and ankle surgeries such as tendon repair and/or nerve decompression procedures. CLARIX™CORD 1k is supplied in five different sizes: 1.5x1.5 cm, 2.5x2.5 cm, 4.0x3.0 cm and 6.0x3.0 cm.

Preliminary Decision:

A national program operating need was not identified by Medicare, Medicaid or the Private Insurance sector to establish a HCPCS code to identify CLARIX™CORD, which is included as part of a procedure.

Summary of Primary Speaker Comments at the Public Meeting:

The applicant disagreed with CMS' preliminary decision for Clarix Cord 1k. There are sufficient similarities between Clarix Cord 1k and Neox 1k and as such, CMS should include Clarix Cord 1k within Q4148 and add the word "Cord" to Neox 1k in the code text.

HCPCS Public Meeting Agenda Item #9

May 20, 2014

Attachment# 14.023

Topic/Issue:

Request to establish a new Level II HCPCS for Neox 100. Applicant's suggested language:

QXXXX Neox 100, Per Square Centimeter

Background/Discussion:

According to the requester NEOX®100 is a cryopreserved skin graft substitute comprised of human amniotic membrane used as a wound covering in chronic non-healing dermal wounds, such as diabetic foot and venous leg ulcers, to modulate inflammation and encourage healing. NEOX®100 is supplied in three different sizes: 2 x2 cm, 4.0x4.0 cm, and 7.0x7.0 cm. NEOX®100 is administered by placing the appropriately sized product to completely cover the wound bed after debridement, and is secured to the wound edges using sutures or surgical staples, at the discretion of the physician.

Preliminary Decision:

Revise existing code Q4148 which currently reads "Neox 1k, per square centimeter" to instead read "Neox 1k or Neox 100, per square centimeter". Revised code Q4148 adequately describes the product that is the subject of this request.

Summary of Primary Speaker Comments at the Public Meeting:

The applicant disagreed with CMS' preliminary decision for Neox 100. The preliminary decision to include Neox 100 as part of the existing code for Neox 1k fails to recognize the important differences between the products, and is inconsistent with coding for other similarly situated products. While there are important differences between Neox 1k and Neox 100 there are sufficient similarities between Clarix 100 and Neox 100 to share the same code. You suggested that CMS create a, "Q" code for Neox 100 and that CMS include Clarix 100 within the new "Q" code for Neox 100.

HCPCS Public Meeting Agenda Item #10

May 20, 2014

Attachment# 14.010

Topic/Issue:

Request to establish four new Level II HCPCS codes for use to categorize all skin substitute products except Apligraft, FortaDerm, and FortaDerm Antimicrobial. Applicant's suggested language for the 4 new code categories:

AXXX1 Skin Substitute, Tissue Of Human Origin, Cadaver Skin, Not Bioengineered, Any Type Of Processing, Per Square Centimeter

AXXX2 Skin Substitute, Tissue Of Human Origin, Other Than Cadaver Skin (e.g., Amniotic/Placental Tissue), Not Bioengineered, Any Type Of Processing, Per Square Centimeter

AXXX3 Skin Substitute, Tissue Of Non-Human Origin, Other Than Cadaver Skin (e.g., Bovine, Porcine, Equine), Any source (e.g., Intestine, Bladder, Tendon, Skin), Any Type Of Processing - No Living Cells, Per Square Centimeter

AXXX4 Miscellaneous Wound Dressing Or Covering, Not Otherwise Specified

Background/Discussion:

Organogenesis Inc. requests four new permanent national HCPCS supply codes, each of which would describe interchangeable skin substitute products. The new codes would replace Q4102 through Q4105; and Q4107 through Q4149. The proposed new codes would be for two types of products; (1) products that are 510(k)-cleared dressings or coverings for the management of wounds and (2) Human Cell Tissue Products (HCT/Ps). "These products do not meet Medicare's definition of biologics and should instead be considered supplies". According to the requester, "the 510(k) products have been determined by the FDA to be substantially equivalent to a common pool of predicate devices. Those predicate devices are collagen, alginate, hydrogel, and hydrocolloid wound dressings, all of which are considered supplies by Medicare and are described by Level II HCPCS "A" codes. HCT/Ps are harvested tissues subject to restrictions requiring that they be minimally processed and intended for homologous use. The HCT/P products are interchangeable with the only difference among these products being the method of processing (e.g., irradiation, cryopreservation, salt-processing)".

Preliminary Decision:

A national program operating need was not identified by Medicare, Medicaid or the Private Insurance sector to establish 4 new HCPCS codes or to categorize skin substitute products among the suggested four new HCPCS codes.

Summary of Primary Speaker Comments at the Public Meeting:

The speaker disagreed with CMS' preliminary decision. The speaker has stated the HCPCS Workgroup has not articulated criteria that it follows in determining code assignment for skin substitutes, an d as a result, coding determinations lack transparency and consistency. The speaker presents two options to resolve the significant flaws in the current approach:

Option A:

Create code for categories of skin substitutes consistent with its approach for prothetics, orthotics, DME, etc. that codes should describe broad categories of items

Option B:

Create product-specific codes for all products to avoid arbitrarily granting or denying new codes and creating market winners and losers

HCPCS Public Meeting Agenda Item #11

May 20, 2014

Attachment# 14.011

Topic/Issue:

Request to establish a new Level II HCPCS for FortaDerm™ Antimicrobial PHMB. Applicant's suggested language:

Q41XX FortaDerm Antimicrobial PHMN, Per Square Centimeter

Background/Discussion:

According to the requester, FortaDerm™ Antimicrobial PHMB is a sterile single-use sheet dressing made of collagen matrix and is coated with polyhexamethylene biguanide hydrochloride (PHMB). It is intended for the management of wounds and as an effective barrier to resist microbial colonization within the dressings and reduce microbes penetrating through the dressing. It is supplied dry in sheet form in sizes ranging from 4x4 cm to 12x36 cm. FortaDerm™ Antimicrobial PHMB is packaged in sterile, sealed single pouches. FortaDerm™ Antimicrobial PHMB Wound Dressing is a skin substitute designed for use on acute and chronic, partial and full-thickness wounds. It is surgically applied and fixed to a wound using sutures or other fixation method based on the size of the wound being treated.

Preliminary Decision:

A national program operating need was not identified by Medicare, Medicaid or the Private Insurance sector to establish a HCPCS code to identify FortaDerm Antimicrobial PHMB.

Summary of Primary Speaker Comments at the Public Meeting:

The speaker disagreed with CMS' preliminary decision. The speaker has stated the HCPCS Workgroup has not articulated criteria that it follows in determining code assignment for skin substitutes, an d as a result, coding determinations lack transparency and consistency. The speaker presents two options to resolve the significant flaws in the current approach:

Option A:

Create code for categories of skin substitutes consistent with its approach for prothetics, orthotics, DME, etc. that codes should describe broad categories of items

Option B:

Create product-specific codes for all products to avoid arbitrarily granting or denying new codes and creating market winners and losers

HCPCS Public Meeting Agenda Item #11

May 20, 2014

Attachment# 14.012

Topic/Issue:

Request to establish a new Level II HCPCS for FortaDerm™. Applicant's suggested language:

Q41XX FortaDerm, Per Square Centimeter

Background/Discussion:

According to the requester, FortaDerm™ is a single-layer fenestrated sheet of porcine collagen. FortaDerm™ is a skin substitute intended for the management of wounds including: partial and full thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, wound dehiscence), trauma wounds (abrasions, lacerations, second-degree burns, and skin tears) and draining wounds. It is supplied dry in sheet form in sizes ranging from 5x5 cm to 12x36 cm. FortaDerm™ is packaged in sterile, sealed single pouches and is administered by surgically applying and fixing it to a wound using sutures or other fixation method. According to the requester, FortaDerm™ is used similarly to other collagen wound dressings, such as Oasis, Integra Bilayer Matrix Wound Dressing, and Primatrix, all of which have product-specific HCPCS codes.

Preliminary Decision:

A national program operating need was not identified by Medicare, Medicaid or the Private Insurance sector to establish a HCPCS code to identify FortaDerm.

Summary of Primary Speaker Comments at the Public Meeting:

The speaker disagreed with CMS' preliminary decision. The speaker has stated the HCPCS Workgroup has not articulated criteria that it follows in determining code assignment for skin substitutes, an d as a result, coding determinations lack transparency and consistency. The speaker presents two options to resolve the significant flaws in the current approach:

Option A:

Create code for categories of skin substitutes consistent with its approach for prothetics, orthotics, DME, etc. that codes should describe broad categories of items

Option B:

Create product-specific codes for all products to avoid arbitrarily granting or denying new codes and creating market winners and losers

HCPCS Public Meeting Agenda Item #12

May 20, 2014

Attachment# 14.025

Topic/Issue:

Request to establish a new Level II HCPCS to identify a human tissue Allograft, trade name: Revitalon. Applicant's suggested language:

Q41XX Revitalon, Per Square Centimeter.

Background/Discussion:

According to the requester Revitalon is a human tissue allograft made of donated amniotic membrane derived from the inner lining of donated placenta. Revitalon can be used as a covering for full-thickness wounds, damaged membranes, and as a dressing for burns. It is comprised of native human amnion and chorion consisting of collagen types I, III, IV, V, VI, laminin, fibronectin, nidogen, and proteoglycans. The amnion is comprised of five layers of collagen and fibronectin and is tough, transparent, nerve-free, and nonvascular. Revitalon allografts are supplied in a single-sized package and provided in the following sizes: 1 cm round dot, 2x2 cm, 4x4 cm, and 4x6 cm.

Preliminary Decision:

Establish Q41XX Revitalon, 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

May 20, 2014

Attachment# 14.026

Topic/Issue:

Request to establish a new Level II HCPCS code to identify a piscine (fish) dermis extracellular xenograft, trade name: Alphaplex with MariGen Omega3 (alternately referred to as Alphaplex ECM or Alphaplex pECM. Applicant's suggested language:

Q41XX Alphaplex with MariGen Omega3, Per Square Centimeter.

Background/Discussion:

According to the requester Alphaplex ECM is an extra cellular matrix xenograft made from fish (piscine) dermis. Alphaplex contains natural insoluble proteins such as collagen as well as proteoglycans, glycosaminoglycans, and fibronectin. Alphaplex ECM is used as a wound covering and wound matrix for full-thickness wounds and burns, or as a covering for damaged membranes. It is supplied in the following sizes: 3x3.5cm, 3x7cm, and 7x10cm.

Preliminary Decision:

Existing codes A6021 "Collagen dressing, sterile, size 16 sq. in. or less, each"; A6022 "Collagen dressing, sterile, size more than 16 sq. in. but less than or equal to 48 sq. in., each"; and A6023 "Collagen dressing, sterile, size more than 48 sq. in., each" are available for assignment by insurers if deemed appropriate, depending on size.

Summary of Primary Speaker Comments at the Public Meeting:

The speaker disagreed with CMS' preliminary decision not to establish a HCPCS code, and claimed that collagen dressings contain "processed collagen"; whereas products identified by Q codes do not contain processed collagen, rather they contain harvested, acellular, intact tissue. Alphaplex is made of fish skin manufactured into an acellular dermal matrix and as such, a Q code is warranted.

HCPCS Public Meeting Agenda Item #13

May 20, 2014

Attachment# 14.016

Topic/Issue:

Request to establish a new Level II HCPCS for Architect PX. Applicant's suggested language:

QXXXX Architect PX, Per Square Centimeter.

Background/Discussion:

According to the requester, Architect™ PX is a partially stabilized extracellular matrix ("ECM") comprised of equine pericardium that is indicated for the local management of moderately to heavy exuding wounds. By partially stabilizing its equine pericardium ECM, Architect™ PX can maintain its natural ECM tissue regeneration properties longer on the wound. The applicant claims that "this "partially" stabilized extracellular matrix more quickly adheres to the wound bed than Architect, thereby fitting more closely into established wound care protocol". Products that adhere more slowly may require more provider training to achieve optimal results. Architect™ PX can limit the inflammatory response, thereby enabling the ECM components to support tissue regeneration longer during the healing process. Architect PX is also engineered to provide structural and functional proteins which can stimulate and support tissue regeneration for a longer duration than non-stabilized products.

Preliminary Decision:

Revise existing code Q4147 which currently reads: "Architect extracellular matrix, per square centimeter", to instead read: Architect, Architect PX, or Architect FX, extracellular matrix, per square centimeter. Revised code Q 4147 adequately describes the product that is the subject of this application.

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item #13

May 20, 2014

Attachment# 14.050

Topic/Issue:

Request to establish a new Level II HCPCS code for Architect FX. Applicant's suggested language:

QXXXX Architect FX, Per Square Centimeter.

Background/Discussion:

According to the requester, Architect™ FX is a stabilized extracellular matrix ("ECM") comprised of equine pericardium that is indicated for the local management of moderately to heavy exuding wounds. FX can maintain its natural ECM tissue regeneration properties longer on the wound. When compared to other "skin substitute" products, stabilized Architect FX reduces the potential for an inflammatory response when applied to a chronic wound. It is engineered to provide structural and functional proteins which can stimulate support tissue regeneration for a longer duration than non-stabilized products. Architect FX more quickly adheres to the wound bed than Architect, thereby fitting more closely into established wound care protocol. Products that adhere more slowly may require more provider training to achieve optimal results.

Preliminary Decision:

Revise existing code Q4147 which currently reads: "Architect extracellular matrix, per square centimeter," to instead read: "Architect, Architect PX, or Architect FX, extracellular matrix, per square centimeter". Revised code Q4147 adequately describes the product that is the subject of this request.

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item #14

May 20, 2014

Attachment# 14.040

Topic/Issue:

Request to establish a new Level II HCPCS code to identify an amniotic membrane allograft, trade name: Affinity. Applicant's suggested language:

Q41XX Affinity, Per Square Centimeter.

Background/Discussion:

According to the requester Affinity, amniotic fluid membrane allograft is minimally processed for clinical use in wound repair and healing. Affinity is comprised of the amniotic epithelial layer, the amniotic basement membrane, and the amniotic stroma. This membrane contains (1) collagen types III, IV, laminin and proteglycans; (2) cross-linked hyaluronic acid; (3) trophic proteins; (4) growth factors; (5) Tissue Inhibitors of Matrix metallo-proteinases (TIMPs); and (6) multipotential cells. Affinity is intended to be applied as an on-lay graft for acute and chronic wounds, including, but not limited to, neuropathic ulcers, venous stasis ulcers, pressure ulcers, burns, post-traumatic wounds and post-surgical wounds. The product will be sterilely packaged for single-use and available in the following size: 2.5 x 2.5 cm.

Preliminary Decision:

Establish Q41XX Affinity, Per Square Centimeter

Summary of Primary Speaker Comments at the Public Meeting:

The applicant offered a brief comment agreeing with CMS' preliminary decision.

HCPCS Public Meeting Agenda Item #14

May 20, 2014

Attachment# 14.041

Topic/Issue:

Request to establish a new Level II HCPCS code to identify a dehydrated human placental membrane allograft, trade name: NuShield™. Applicant's suggested language:

Q41XX NuShield, Per Square Centimeter.

Background/Discussion:

According to the requester nushield is produced from human placental membrane and includes the amniotic epithelial layer, the amniotic basement membrane, the amniotic stroma, the chorionic basement membrane, and the chorionic stroma. This membrane contains (1) collagen types III, IV, laminin and proteglycans; (2) cross-linked hyaluronic acid; (3) trophic proteins; (4) growth factors; (5) Tissue Inhibitors of Matrix metallo-proteinases (TIMPs); and (6) multipotential cells. Affinity is intended to be applied as an on-lay graft for acute and chronic wounds, including, but not limited to, neuropathic ulcers, venous stasis ulcers, pressure ulcers, burns, post-traumatic wounds and post-surgical wounds. The product will be sterilely packaged for single-use and available in the following sizes: 2x3 cm, 4x4 cm, and 6x6 cm. Nushield will also be expandable (meshed) form.

Preliminary Decision:

Establish Q41XX NuShield, Per Square Centimeter

Summary of Primary Speaker Comments at the Public Meeting:

The applicant offered a brief comment agreeing with CMS' preliminary decision.

HCPCS Public Meeting Agenda Item #15

May 20, 2014

Attachment# 14.031

Topic/Issue:

Request to establish a new Level II HCPCS code to identify collagen matrix, trade name: Ologen. Applicant's suggested language:

QXXXX Ologen Collagen Matrix, Per Square Centimeter.

Background/Discussion:

According to the requester Ologen® Collagen Matrix (CM) is a medical device made of atellocollagen which is derived from porcine skin. This atelocollagen is cross-linked and lyophilized with glycosaminoglycan to obtain Ologen® collagen matrix. The use of Ologen® collagen matrix induces a non-scarring wound healing process without the use of anti-fibrotic agents, such as to heal a prominent filtering bleb to enable successful glaucoma filtering surgeries. Ologen® collagen matrix is supplied in a sterile double-bagged packages containing 6mm x 2mm; 12mm x 1mm; or 10mm x 10mm x 2mm. It is used in ophthalmic surgery for eye wound healing.

Preliminary Decision:

Existing code A6021 "Collagen dressing, sterile, size 16 sq. in. or less, each", or A6022 "Collagen dressing, sterile, size more than 16 sq. in. but less than or equal to 48 sq. in., each" are available for assignment by insurers if deemed appropriate, depending on size.

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with CMS' preliminary decision not to establish a HCPCS code. The speaker stated that indications for use of Ologen CM differs from that of collagen dressings coded at A6021 and A6022. Ologen is used exclusively for wound "healing" in ophthalmic surgeries for procedures such as healing a prominent filtering bleb to enable a successful glaucoma filtering surgery. The speaker reiterated the original request to establish a unique "Q" code.

PAYMENT FOR PART B DRUGS, BIOLOGICALS AND RADIOPHARMACEUTICALS

Background

Medicare Part B currently covers a limited number of prescription drugs. For the purpose of this discussion, the term “drugs” will refer to both drugs and biologicals. Currently, covered Medicare Part B drugs generally fall into three categories:

- Drugs furnished incident-to a physician's service - These are injectable or intravenous drugs as well as non-injectable or non-intravenous drugs that are administered incident-to a physician's service. Under the “incident-to” provision, the physician must incur a cost for the drug, and must also bill for it. “Incident-to” coverage is limited to drugs that are not usually self-administered;
- Drugs administered via a covered item of durable medical equipment - These are DME drugs are administered through a covered item of DME, such as a nebulizer or a pump; and
- Drugs covered by statute - These are drugs specifically covered by statute including immunosuppressive drugs; hemophilia blood clotting factor; certain oral anti-cancer drugs; oral anti-emetic drugs; pneumococcal, influenza and hepatitis B vaccines; antigens; erythropoietin for trained home

dialysis patients; certain other drugs separately billed by end-stage renal disease (ESRD) facilities; and osteoporosis drugs.

Drugs Paid on a Cost or Prospective Payment Basis

Drugs paid on a cost or prospective payment basis that are outside of the scope of the current drug payment methodology include--drugs furnished during an inpatient hospital stay (except clotting factor); drugs paid under the outpatient prospective payment system (OPPS); drugs furnished by ESRD facilities whose payments are included in Medicare's composite rate; and drugs furnished by critical access hospitals, skilled nursing facilities (unless outside of a covered stay), comprehensive outpatient rehabilitation facilities, rural health facilities, and Federally Qualified Health Centers (FQHCs).

Part B Drug Payment Methodology

Historical Payment Methodology

Prior to January 1, 2004, payment for the majority of Medicare Part B drugs was set at 95 percent of the average wholesale price (AWP). The statutory term, average wholesale price, was not defined in law or regulation. In creating payment limits for Medicare covered drugs, Medicare relied on the list AWP which referred to the AWP published in commercial drug compendia such as Red Book, Price Alert, and Medispan.

In 2004, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) revised the drug payment methodology, reducing the payment rate for most covered Part B drugs from 95 percent of the AWP to 85 percent of the AWP.

Current Methodology

In 2005, the MMA again revised the drug payment methodology by creating a new pricing system based on a drug's Average Sales Price (ASP). Effective January 2005, Medicare pays for the majority of Part B covered drugs using a drug payment methodology based on the ASP. In accordance with section 1847A of the Social Security Act, manufacturers submit to us the ASP data for their products. These data include the manufacturer's total sales (in dollars) and number of units of a drug to all purchasers in the United States in a calendar quarter (excluding certain sales exempted by statute), with limited exceptions. The sales price is net of discounts such as volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, and rebates (other than rebates under section 1927 of the Act). The Medicare payment rate is based on 106 percent of the ASP (or for single source drugs, 106 percent of the wholesale acquisition cost (WAC), if lower), less applicable deductible and coinsurance. The WAC is defined, with respect to a drug or biological, as the manufacturer's list price for the drug or biological to wholesalers or direct

purchasers in the United States, not including prompt pay or other discounts, rebates, or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological pricing data.

After carefully examining Section 1847A of the Social Security Act, as established in the MMA, CMS has been reviewing its coding and pricing determinations to ensure that separate and appropriate payment is made for single source drugs and biologics as required by this section of the Act. In order to facilitate separate and appropriate payment, it may be necessary to create unique HCPCS level II codes for certain products. As part of this effort, we are also closely reviewing how we operationalize the terms 'single source drug,' 'multiple source drug,' and 'biological product' in the context of payment under section 1847A to identify the potential need to make any changes to our assignment of National Drug Codes (NDCs) to billing codes for payment purposes.

So that we can implement coding and pricing changes swiftly, CMS has used and will continue to use its internal process, when appropriate, for modifying the code set. Please be aware that internally generated code requests are not part of the HCPCs public meeting process.

Exceptions to ASP pricing methodology

The MMA exempted certain drugs from the ASP pricing methodology and payment for these drugs remained at 95 percent of the AWP. These drugs include:

- Vaccines – Influenza, Pneumococcal, Hepatitis B;
- Infusion drugs furnished through DME; and
- Blood and blood products (other than blood clotting factor)

Payment for Radiopharmaceuticals

The payment methodology for radiopharmaceuticals did not change under the MMA. Specifically, Section 303(h) states that "[n]othing in the amendments . . . shall be construed as changing the payment methodology . . . for radiopharmaceuticals . . ."

Dispensing/Supplying/Furnishing Fees

Medicare pays a **dispensing fee** to a pharmacy for inhalation drugs furnished through DME, a **supplying fee** to a pharmacy for each supplied prescription of immunosuppressive drugs, oral anti-cancer drugs and oral anti-emetic drugs used as part of an anti-cancer chemotherapeutic regimen, or a **furnishing fee** per unit of clotting factor to entities that furnish blood clotting factor unless the costs of furnishing the blood clotting factor are paid through another payment system.

Part B versus Part D

The implementation of Medicare Part D does not change Medicare Part B drug coverage in any way. Drugs that were covered by Medicare Part B prior to the implementation of Part D continue to be covered by Medicare Part B.

Contact Information

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