Centers for Medicare & Medicaid Services (CMS)
Level II Healthcare Common Procedure Coding System (HCPCS)
Application Summary, 2015-2016 Coding Cycle for Items Discussed at the Drugs, Biologicals, and Radiopharmaceuticals HCPCS Public Meeting
Thursday, May 7, 2015

Introduction and Overview

Approximately 75 people attended. The agenda included 22 items.

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

Marge Watchorn, 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
Thursday, May 7, 2015 12:00 pm (noon) – 5:00 pm
CMS Auditorium
7500 Security Boulevard
Baltimore (Woodlawn), Maryland 21244-1850

11:15 a.m. Arrival and sign-in

12:00 p.m. (noon) 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# 15.021
Request to establish a new Level II HCPCS code to identify Zarxio, a biosimilar to the reference drug Filgrastim. Applicant's suggested language: "JXXXX Injection, Filgrastim, Zarxio 1 mcg"

Primary Speaker: Brian Hare of Sandoz Biopharmaceuticals

AGENDA ITEM #2
Attachment# 15.037
Second request to establish a new Level II HCPCS code to identify Low-nitrogen 1% Polidocanol injectable foam, Trade Name: Varithena. Applicant's suggested language: "JXXXX Low Nitrogen 1% Polidocanol Injectable foam: Sterile canister, 1 ml."

Primary Speaker: Dr. Robert Diamond of BTG International

AGENDA ITEM #3
Attachement#15.040
Request to establish a new Level II HCPCS code to identify Albuterol Sulfate Inhalation Solution, 0.5% concentrate. Applicant's suggested language: "Albuterol, Inhalation Solution, fda-approved final product, non-compounded, administered through DME, concentrated form, unit dose, 0.5 mg (Albuterol non-comp unit)."

Primary Speaker: Lou Kennedy of Nephron Pharmaceuticals Corporation

AGENDA ITEM #4
Attachment# 15.024
Second request to establish a new Level II HCPCS code to identify loxapine, Trade Name: Adusuve. Applicant's suggested language: "JXXXX Loxapine, inhalation powder, 10 mg."

Primary Speaker: Dr. Horacio Capote of Dent Neurologic Institute

AGENDA ITEM #5
Attachment# 15.008
Request to establish a unique Level II HCPCS code to identify Flutemetamol F18 Injection, Trade Name: Vizamyl.

Primary Speaker: Meredith Johnson of GE Healthcare

AGENDA ITEM #6
Attachment# 15.047
Second request to establish a unique Level II HCPCS code to identify florbetaben F 18, Trade Name: Neuraceq. Applicant's suggested language: "AXXXX Injection, florbetapen F 18, diagnostic, per study dose, up to 8.1 millicuries".

Primary Speaker: Susan de Santi of Piramal Imaging

AGENDA ITEM #7
Attachment#15.033
Request to establish a unique Level II HCPCS code to identify phenylephrine and ketorolac injection 1%/0.3%., Trade Name: Omidria. Applicant's suggested language: "JXXXX - injection, phenylephrine and ketorolac 1% / 0.3%, 4 mL vial"

Primary Speaker: Dr. Gregory Demopulos of Omeros Corporation

AGENDA ITEM #8
Attachment# 15.065
Request to establish a unique Level II HCPCS code to identify an injectable flowable allograft, Trade Name: AmnioClear® LTC. Applicant's suggested language: J73XX - AmnioClear LTC, per ml.

Primary Speaker: Robin Young of Liventa Bioscience

AGENDA ITEM #9
Attachment#15.011
Request to establish a unique Level II HCPCS code to identify an extracellular collagen matrix surgical mesh derived from porcine dermis, Trade Name: Fortiva. Applicant's suggested language: QXXXX - Fortiva, per square centimeter

Attachment#15.054
Request to establish a new Level II HCPCS code to identify Tutopatch™ bovine pericardium. Applicant's suggested language: QXXXX - Tutopatch, per square centimeter

Attachment#15.055

Request to establish a new Level II HCPCS code to identify Tutomesh™ bovine pericardium. Applicant's suggested language: QXXXX - Tutomesh, per square centimeter

Attachment#15.056

Request to establish a new Level II HCPCS code to identify Cortiva™, allograft dermis. Applicant's suggested language: QXXXX - Cortiva, per square centimeter

Attachment#15.057

Request to establish a new Level II HCPCS code to identify Cortiva™, 1 mm allograft dermis. Applicant's suggested language: QXXXX - Cortiva, 1 mm, per square.

No Primary Speaker

AGENDA ITEM #10
Attachment# 15.049
Request to establish a new Level II HCPCS code to identify a porcine-derived, non-cross linked, cellular dermal matrix surgical mesh, Trade Name HPTM. Applicant's suggested language: Q41XX - HPTM, per square centimeter.

Primary Speaker: Cheri Ritter of Lifecell

AGENDA ITEM #11
Attachment# 15.048
Repeat request to establish a unique Level II HCPCS Q-code to identify a porcine-derived collagen matrix, Trade Name: Ologen® Applicant's suggested language: QXXXX- Ologen® Collagen Matrix, per unit.

Primary Speaker: Dr. Angelo Tanna of Northwestern University

AGENDA ITEM #12
Attachment# 15.062
Second request to establish a new Level II HCPCS code to identify a bovine collagen acellular dermal matrix, Trade Name: Helicoll™. Applicant's suggested language: Q41XX - Helicoll™ Acellular Dermal Matrix, per square centimeter.

Primary Speaker: Subramanian Gunasekaran of Encoll

AGENDA ITEM #13
Attachment# 15.064
Request to establish a unique Level II HCPCS Q-code to identify a matrix skin substitute, Trade Name: Keramatrix®. Applicant's suggested language: Q41xx - keramatrix®, per square centimeter.

Primary Speaker: Rob Kelly of Keraplast Technologies, LLC

AGENDA ITEM #14
Attachment# 15.058
Repeat request to establish a unique Level II HCPCS code to identify INTEGRA® Meshed Bilayer Wound Matrix. Applicant's suggested language: Integra Meshed Bilayer Wound Matrix, per sq cm.

Primary Speaker: Stuart Langbein of Hogan Lovells

AGENDA ITEM #15
Attachment# 15.043
Request to establish a new Level II HCPCS code to identify bio-ConneKt Wound Matrix. Applicant's suggested language: Q41XX - Bio-ConneKt Wound Matrix, per square centimeter

No Primary Speaker

AGENDA ITEM #16
Attachment# 15.053
Request to expand the Q41XX code series in order to distinguish coded products based on size and other product characteristics. Specifically, to create a coding distinction between Epifix products that measure more than 20 square centimeters vs. all other (smaller) sizes. Applicant's suggested language: Revise existing code Q4131 which currently reads "EpiFix, per square centimeter"; to instead read "Human dehydrated amniotic membrane allograft, EpiFIx®, *for sizes up to 20 square centimeters*, per square centimeter"; and Establish a new code: QXXXX - Human dehydrated amniotic membrane allograft, EpiFix® for *sizes 20 square centimeters and above*, per square centimeter.

Primary Speaker: Deborah Dean of MiMedx Group, Inc.

AGENDA ITEM #17
Attachment# 15.045
Request to establish a unique Level II HCPCS code to identify an osteochondral allograft, Trade Name: Cartiform®. Applicant's suggested language: JXXXX - 1 centimeter squared, Cryopreserved Viable Osteochondral Allograft

Primary Speaker: Dr. Philip Davidson of Heiden Davidson Orthopedics

AGENDA ITEM #18
Attachment# 15.059
Request to establish two new Level II HCPCS codes to identify injectable liquid placental tissue matrix: one to identify a cryopreserved version of the product, AmnioGen –C; and another to identify an ambient version, AmnioGen-A.

Attachment# 15.060
Request to establish two new Level II HCPCS codes to identify an amniotic membrane allograft: one to identify a 45 micron thick version, AmnioGen-45; and another to identify a 200 micron thick version, AmnioGen-200.

No Primary Speaker

AGENDA ITEM #19
Attachment# 15.052
Request to establish a unique Level II HCPCS code to identify a porcine-derived, non-crosslinked acellular wound matrix, Trade Name: MIRODERM. Applicant's suggested language: Q41XX - MIRODERM, per square centimeter.

No Primary Speaker

AGENDA ITEM #20
Attachment# 15.063
Request to establish a unique Level II HCPCS code to identify a human placental connective tissue matrix, Trade Name Plurivest. Applicant's suggested language: Plurivest™, per square centimeter.

No Primary Speaker

AGENDA ITEM #21
Attachment# 15.050
Request to establish a unique Level II HCPCS code to identify a human amniotic tissue allograft, Trade Names: AmnioPro™ Membrane, WoundEx™, BioRenew™ and BioSkin™. Applicant's suggested language: Q41XX - AmnioPro Membrane, per cm

No Primary Speaker

AGENDA ITEM #22

Attachment# 15.051

Request to establish a unique Level II HCPCS code to identify a human placental tissue matrix allograft, Trade Names: AmnioPro™ Flow, BioSkin Flow, BioRenew Flow and WoundEx Flow. Applicant's suggested language: Q41XX - AmnioPro Flow, per cc

No Primary Speaker

HCPCS Public Meeting Agenda Item #1

May 7, 2015

Attachment# 15.021

Topic/Issue:

Request to establish a new Level II HCPCS code to identify Zarxio, a biosimilar to the reference drug Filgrastim. Applicant's suggested language: "JXXXX Injection, Filgrastim, Zarxio 1 mcg"

Background/Discussion:

Sandoz, Incorporated, submitted a request to establish a code to identify Zarxio. According to the requester, Zarxio is a biosimilar product with the same indications included in the reference product, Filgrastim. According to the requester, Zarxio is indicated for the treatment of Neutropenia, a condition where the body makes too few neutrophils, a type of white blood cell. This condition is sometimes induced by drugs used to treat cancer. Zarxio is indicated to: 1) decrease the incidence of infection in patients with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with a fever; 2) reduce the duration of neutrophil recovery and the duration of fever following induction or consolidation chemotherapy treatment of adults with Acute Myeloid Leukemia (AML); 3) reduce the duration of neutropenia and neutropenia-related clinical squeal; 4) mobilize hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis; and 5) reduce the incidence and duration of sequelae of neutropenia in symptomatic patients with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia.

Filgrastim is a human granulocyte colony stimulating factor (G-CSF). Zarxio is produced by Escherichia coli bacteria that have been inserted in the human G-CSF gene. G-CSF regulates the production of neutrophils within the bone marrow and affects neutrophil progenitor proliferation, differentiation, and selected end-cell functional activation.

Zarxio is supplied as single-dose prefilled syringes containing 300mcg/.5mL or 480mcg/.8mL of filgrastim. Packages are dispensed in packs of 1 or 10. It is administered via subcutaneous or intravenous injection. Recommended starting dosage is 5 mcg/kg/day for patients with cancer receiving myelosuppressive chemotherapy or induction and/or consolidation chemotherapy for AML, and for patients with cyclic idiopathic neutropenia; 6 mcg/kg/day for patients with congenital neutropenia; and 10 mcg/kg/day for patients with cancer undergoing bone marrow transplantation.

The applicant states that a new code is warranted and makes the following claims: no existing HCPCS codes describe Zarxio; biosimilar products "must be separated", via HCPCS coding; and biosimilar products should be considered single source drugs and as such, receive unique codes.

Preliminary Decision:

Establish new code Q5101 Injection, Filgrastim (G-CSF), Biosimilar, 1 microgram. Effective 7/1/15.

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker offered comments at CMS' HCPCS Public Meeting in support of our preliminary decision to establish a code, and requested that a new J code be established effective 1/1/16 that would replace code Q5101 and include language that would distinguish zarxio from other biosimilars.

Final Decision:

Establish new code Q5101 Injection, Filgrastim (G-CSF), Biosimilar, 1 microgram. Effective 7/1/15.

Revise Code J1442 which currently reads "Injection, filgrastim (g-csf)" to instead read "Injection, filgrastim (g-csf) 1 microgram, excluding biosimiliars".

HCPCS Public Meeting Agenda Item #2

May 7, 2015

Attachment# 15.037

Topic/Issue:
Second request to establish a new Level II HCPCS code to identify Low-nitrogen 1% Polidocanol injectable foam, Trade Name: Varithena. Applicant's suggested language: "JXXXX Low Nitrogen 1% Polidocanol Injectable foam: Sterile canister, 1 ml."

Background/Discussion:
Provensis Ltd., submitted a request for a new HCPCS code to identify Varithena. According to the requester, Varithena is a drug-device combination low-nitroben 1% Polidocanol sclerosant, used for the treatment of incompetent great saphenous veins, accessory saphenous veins and visible varicosities of the great saphenous vein (GSV) system above and below the knee. The foam is generated from a proprietary canister system and is composed of a gas and liquid phase. The foam displaces blood from the target vein and the polidocanol within the foam scleroses the endothelium. Varithena is intended for intravenous injection using ultrasound guidance, administered via a single cannula into the lumen of the target incompetent trunk vein or by direct injection into varicosities. The hydrophobic pole of the polidocanol molecule attaches to the lipid cell membrane of the venous enfothelium and vasospasm. Following exposure to polidocanol, the interior surface of the vein becomes thrombogenic, which leads to thrombus formation and venous occlusion. The occluded vein is eventually replaced by fibrous connective tissue. Polidocanol is deactivated upon contact with blood, thus limiting the sclerosant action to the endothelium near the site of injection.

Varithena is supplied in a Tyvek pouch containing two sterile, connected 303 mL aluminum alloy canisters, one containing polidocanol solution and one containing pressurized oxygen at approximately 5.4 bar absolute. The connector joins the two canisters and allows activation of the product. Upon activation, the multi-use canister generates 45 ml of usable foam. Up to 5mL can be used per injection and no more than 15 mL should be used per session.

The applicant claims that a new code is warranted for the following reasons: 1) no existing code describes Varithena; 2) due to "poor J coding", claims cannot be timely processed and physicians or patients are not paid in a timely manner, (patients have to sign an ABN due to "inadequate J-coding"; 3) neither CPT codes nor miscellaneous J codes allow "optimal dosing", or tracking of clinical outcomes.

Preliminary Decision:
Level II HCPCS is not the appropriate coding jurisdiction for this product. The miscellaneous CPT code used to report the physician's office procedure includes all items used, including the Varithena. Separate coding and billing for Varithena using a "J" code or any other Level II HCPCS code is duplicative and inappropriate. Having patients sign an ABN for a product that is included in the CPT is also inappropriate.

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with CMS' preliminary decision, commenting that Varithena is a single source drug and as such should be uniquely coded; and that some insurers are paying for Varithena when an unlisted code is reported together with CPT 37799. The speaker reiterated the original request to establish a code.

Final Decision:

The CMS HCPCS Workgroup reconvened to consider input provided and upheld its decision not to establish a Level II HCPCS code. Level II HCPCS is not the appropriate coding jurisdiction for this product. The miscellaneous CPT code used to report the physician's office procedure includes all items used, including the Varithena. Separate coding and billing for Varithena using a "J" code or any other Level II HCPCS code is duplicative and inappropriate. In addition, having patients sign an ABN for a product that is included in the CPT is also inappropriate.

HCPCS Public Meeting Agenda Item #3

May 7, 2015

Attachment# 15.040

Topic/Issue:

Request to establish a new Level II HCPCS code to identify Albuterol Sulfate Inhalation Solution, 0.5% concentrate. Applicant's suggested language: "Albuterol, Inhalation Solution, fda-approved final product, non-compounded, administered through DME, concentrated form, unit dose, 0.5 mg (Albuterol non-comp unit)."

Background/Discussion:

Nephron Pharmaceuticals Corporation requested a new HCPCS code to identify for Albuterol Sulfate Inhalation Solution, .5% concentrate. According to the requester, the drug is indicated for the relief of bronchospasm in patients 12 years of age and older with reversible obstructive airway disease and acute attacks of bronchospasm. Albuterol stimulates adenyl clyclas, the enzyme that catalyzes the formation of cyclic-3', 5'-adenosine monophosphate (cyclic AMP) from adenosine triphosphate (ATP) in beta-adrenergic cells. The cyclic AMP thus formed mediates the cellular responses. Increased cyclic AMP levels are associated with relaxation of bronchial smooth muscle and inhibition of release of mediators of immediate hypersensitivity from cells, especially from mast cells.

The typical dosage for adults and pediatric patients 12 years of age and older is 2.5 mg (one unit-of-use vial) administered 3 to 4 times daily by nebulization. Albuterol Sulfate Inhalation Solution is supplied in sterile, "unit-of-use" vials of 0.5 mL each, supplied in individual foil pouches; 30 pouches in one package.

The applicant claims that there is no existing code to identify a concentrated form *in unit dose packaging*, as such, a new code is warranted.

Preliminary Decision:

Existing code J7611 "Albuterol, Inhalation Solution, FDA-approved final product, non-compounded, administered through DME, concentrated form, 1 mg", adequately describes the product that is the subject of this request.

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with CMS preliminary decision. The speaker stated that the product combines the best of a concentrated formula, provided in a packaging configuration desired by hospitals and home care providers. The requested code reflects appropriate billing for this cost effective treatment option, while supporting post-discharge compliance and continuity of care initiatives. The speaker reiterated the request for a new code, but modified that request to specify a different dose descriptor.

Final Decision:

Existing code J7611 “Albuterol, Inhalation Solution, FDA-approved final product, non-compounded, administered through DME, concentrated form, 1 mg”, adequately describes the product that is the subject of this request

HCPCS Public Meeting Agenda Item #4

May 7, 2015

Attachment# 15.024

Topic/Issue:

Second request to establish a new Level II HCPCS code to identify loxapine, Trade Name: Adasuve. Applicant's suggested language: "JXXXX Loxapine, inhalation powder, 10 mg."

Background/Discussion:

Teva Pharmaceuticals requests a new Level II HCPCS code to identify for loxapine. According to the requester, loxapine is an atypical antipsychotic drug supplied as a powder for oral inhalation, indicated for the acute treatment of agitation associated with schizophrenia or bipolar I disorder in adults. "Psychomotor agitation" is defined in DSM-IV as "excessive motor activity associated with a feeling of inner tension." Patients experiencing agitation often manifest behaviors that interfere with their care (e.g., threatening behaviors; escalation or urgently distressing behavior; self-exhausting behavior), leading clinicians to use a rapidly absorbed antipsychotic medication to achieve immediate control of the agitation. To limit the risk of serious side effects such as bronchospasm, use of Adasuve must only be used in healthcare facilities enrolled in the Adasuve Risk Evaluation and Mitigation Strategy (REMS) Program that have immediate (on-site) access to equipment and personnel trained to manage acute bronchospasm, including advanced airway management (intubation and mechanical ventilation). Adasuve is administered in a single breath inhalation via a single-use, disposable, handheld inhaler that contains the drug. Patients are instructed to hold the inhaler away from their mouth and exhale fully, then put the mouthpiece of the inhaler between their lips, close their lips and inhale with a single steady, deep breath, remove the mouthpiece and hold their breath for up to 10 seconds.

The applicant comments that a new code is warranted because there are no existing "J" codes to describe this formulation and delivery method of loxapine.

Preliminary Decision:

A national program operating need was not identified by Medicare, Medicaid or Private Insurers to establish another Level II HCPCS code to identify Adasuve. Existing code C9497 "Loxapine, inhalation powder, 10 mg" 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 not to establish a HCPCS code. The speaker stated the agency mischaracterized the mode of administration as self-administration; whereas the FDA approved label clearly states that the therapy is to only be administered by a healthcare professional. There are free standing physician clinics, such as the Dent Neurologic institute, that use ADASUVE and are eligible for "incident to" billing such that a J code is the proper code to use.

Final Decision:

The CMS HCPCS Workgroup reconvened to consider all input provided and upheld its decision.

The request to establish a new Level II HCPCS code to identify this self-administered drug has not been approved. Existing code C9497”Loxapine, Inhaler Powder, 10 mg” describes ADASUVE, and is available for assignment by insurers if they deem appropriate, if the product is used in a hospital outpatient setting.

HCPCS Public Meeting Agenda Item #5

May 7, 2015

Attachment# 15.008

Topic/Issue:
Request to establish a unique Level II HCPCS code to identify Flutemetamol F18 Injection, Trade Name: Vizamyl.

Background/Discussion:
GE Healthcare submitted a request to establish a new Level II HCPCS code to identify Flutemetamol F18 Injection (Vizamyl). According to the requester, Vizamyl is a radioactive diagnostic agent indicated for Positron Emission Tomography (PET) imaging of the brain to estimate Beta Amyloid neuritic plaque density in adult patients with cognitive impairment who are being evaluated for Alzheimer's disease (AD), or other causes of cognitive decline. A negative Viazmyl scan indicates sparse to no neurotic plaques, and is inconsistent with a neuropathological diagnosis of AD at the time of image acquisition. A negative scan reduces the likelihood that a patient's cognitive impairment is a result of AD. A positive Vizamyl scan indicates moderate to frequent amyloid neuritic plaques; neuropathological examination has shown this amount of neuritic plaque is present in patients with AD, but may also be present in patients with other types of neurologic conditions, as well as older people with normal cognition. Vizamyl is an adjunct to other diagnostic evaluations. There are, however; some limitations of use. A positive Vizamyl scan does not establish a diagnosis of AD or other cognitive disorder.

Recommended dose is 185 megabecquerels (MBq) [5 millicuries (mCi)]; maximum mass dose 20 micrograms] in a maximum dose volume of 10 mL, administered as a single intravenous bolus within 40 seconds, followed by an intravenous flush of 0.9% sterile sodium chloride injection. It is supplied in a 10 mL or a 30 mL multi-dose vial with 1 -10 mL and 1-30 mL fill volume respectively. Each vial is enclosed in a radiation shield. The total concentration is 150 MBq/mL (4.05 mCi/mL) of flutemetamol F 18 at reference date and time.

The applicant comments that a new code is warranted because no existing HCPCS code accurately describes this product.

Preliminary Decision:
Existing code A9599 "Radiopharmaceutical, diagnostic, for beta-amyloid positron emission tomography (PET) imaging, per study dose" adequately describes the product that is the subject of this request.

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with CMS preliminary decision. The speaker stated there is no HCPCS code that accurately denotes this product that is used in Positron Emission Tomography (PET) imaging. According to the speaker, historically radiopharmaceuticals have been assigned specific codes.

Final Decision:

The CMS HCPCS Workgroup reconvened to consider all input provided and upheld its decision.

Existing code A9599 “Radiopharmaceutical, diagnostic, for beta-amyloid positron emission tomography (PET) imaging, per study dose” adequately describes the product that is the subject of this request, including use in CMS' coverage with Evidence Development (CED) study.

HCPCS Public Meeting Agenda Item #6

May 7, 2015

Attachment# 15.047

Topic/Issue:

Second request to establish a unique Level II HCPCS code to identify florbetaben F 18, Trade Name: Neuraceq. Applicant's suggested language: "AXXXX Injection, florbetapen F 18, diagnostic, per study dose, up to 8.1 millicuries".

Background/Discussion:

Piramal Pharma, Inc., submitted a request for a new code to identify Neuraceq (florbetaben F 18). According to the applicant, Neuraceq is a radioactive diagnostic agent indicated for Positron Emission Tomography (PET) imaging of the brain to estimate β-amyloid neuritic plaque density in adult patients with cognitive impairment who are being evaluated for AD and other causes of cognitive decline. Florbetaben binds to β-amyloid plaques in the brain. This produces a position signal that is detected by a PET scanner.

Neuraceq is administered by intravenous injection. Recommended dosage is a single IV bolus of 300 MBq of Neuraceq followed 45-130 minutes afterwards by brain PET imaging for 15-20 minutes in duration. Neuraceq is supplied in 30 mL multi-dose vials containing 50 to 5000 MBq/mL (1.4 to 135 mCi/mL) florbetaben F 18 at EOS. At time of administration, 300 MBq (8.1 mCi_ are contained in up to 10 mL of solution for injection.

The applicant claims that there is a significant therapeutic distinction between Amyvid and Vizamil – and Neuraceq. All three of these products have different dosages; there is also a difference between the mean effective radiation dose of Neuraceq and Vizamyl and the mean effective radiation dose of Amyvid. The applicant claims that, as per prior CMS HCPCS coding determination, existing code A9599, *Radiopharmaceutical, diagnostic, for beta-amyloid positron emission tomography (pet) imaging , per study dose* does not accurately describe Neuraceq, because the descriptor is not specific to the active ingredient, florbetaben F 18.

Preliminary Decision:

Existing code A9599 "Radiopharmaceutical, diagnostic, for beta-amyloid positron emission tomography (PET) imaging, per study dose" adequately describes the product that is the subject of this request.

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with CMS's preliminary decision, stating that historically, radiopharmaceuticals that were approved by the FDA under original new drug applications have all received unique product specific codes, and suggested separate and unique HCPCS code for each beta-amyloid imaging agent.

Final Decision:

The CMS HCPCS Workgroup reconvened to consider input provided at the public meeting and CMS upheld its original decision.

Existing code A9599 “Radiopharmaceutical, diagnostic, for beta-amyloid positron emission tomography (PET) imaging, per study dose” adequately describes the product that is the subject of this request.

HCPCS Public Meeting Agenda Item #7

May 7, 2015

Attachment# 15.033

Topic/Issue:
Request to establish a unique Level II HCPCS code to identify phenylephrine and ketorolac injection 1%/0.3%., Trade Name: Omidria. Applicant's suggested language: "JXXXX - injection, phenylephrine and ketorolac 1% / 0.3%, 4 mL vial"

Background/Discussion:
Omeros Corporation submitted a request for a code to identify Omidria. According to the requester, Omidria is a preservative-free, bisulfite-free, sodium citrate-buffered, sterile drug solution that is added to standard irrigation solution and is used during cataract surgery or other IOL replacement procedures. It contains 10.16 mg/mL (1%w/v) of phenylephrine and 2.88 mg/mL (0.3% w/v) of ketorolac in a single-patient-use vial. Omidria is indicated for maintaining pupil size by preventing intraoperative miosis and for reducing postoperative ocular pain. Omidria is currently indicated for use in adults during refractive lens exchange (RLE). Omidria must be diluted prior to intraocular use. For administration to patients undergoing cataract surgery or intraocular lens replacement, 4 mL of Omidria is diluted in 500 mL of ophthalmic irrigation solution, to be used as needed for the surgical procedure. Safety and efficacy of Omidria in pediatric patients has not been established. Omidria is supplied as a sterile solution concentrate in a clear, 5-mL single-patient-use vial containing 4 mL of sterile solution. Omidria is supplied in a multi-pack containing four single-patient-use vials: NDC 62225-600-04 or ten single-patient-use vials: NDC 62225-6001.

According to the applicant, there are no existing HCPCS codes that accurately describe Omidria.

Preliminary 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 Omidria, which is included in surgical the procedure. Existing code C9447 "Injection, Phenylephrine and Ketorolac, 4 ml vial", 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, stating that many private insurance plans will not recognize the existing HCPCS code C9447 when claims are filed for the use of Omidria in cataract surgery or other lens replacement procedures. Also, Medicare and private insurers do not recognize C9447 when Omidria is used in a physician's office. According to the speaker, Omidria can improve outcomes and reduce complications in cataract surgery and other IOL replacement procedures. The speaker stated that these procedures are very common among both Medicare and non-Medicare patients and reiterated the original request for a unique code to identify Omidria.

Final Decision:

The CMS HCPCS Workgroup reconvened to consider input and upheld its decision.

The request to establish a new Level II HCPCS code to identify Omidria has not been approved because this product is an integral part of a surgical procedure. Payment for that service includes payment for Omidria, if it is used. Existing code C9447 "Injection, Phenylephrine and ketorolac, 4ml vial," is available for assignment for insurers if they deem appropriate to report use of Omidria in a hospital outpatient setting.

HCPCS Public Meeting Agenda Item #8

May 7, 2015

Attachment# 15.065

Topic/Issue:

Request to establish a unique Level II HCPCS code to identify an injectable flowable allograft, Trade Name: AmnioClear® LTC. Applicant's suggested language: J73XX - AmnioClear LTC, per ml.

Background/Discussion:

Liventa Bioscience requests a new code for AmnioClear. According to the requester, AmnioClear LTC (loose connective tissue) is minimally processed amniotic tissue. It is an injectable flowable allograft reduces knee pain and inflammation while also increasing the knee range of motion, lubrication and shock absorption by supplementing the existing knee synovial fluid with human allograft. It is intended for use in supplementing synovial fluid in articulating joints. The typical dose for viscosupplementation of the knee is 4 mL. The typical patient-candidate presents with musculoskeletal joint pain often caused by osteoarthritis. The requester claims that AmnioClear LTC "is very similar to the viscosupplement products for which HCPCS codes have been established (J7321 to J7327) and therefore should be treated as a drug or biological. .
The typical dose for injection into the knee as a viscosupplement is 4ml. A 2ml injection may be appropriate for smaller patients. AmnioClear LCT comes in 1ml, 2ml, and 4ml vial sizes.

The requester comments that a new code in the J73XX seectin is warranted because there is currently no code that describes the human tissue-based viscosupplement product by the brand-name AmnioClear LCT, while there are numerous brand-specific codes for viscosupplement products.

Preliminary Decision:

A national program operating need was not identified by Medicare, Medicaid or Private Insurance sector to establish a HCPCS code to identify AmnioClear®LCT. This product is not FDA cleared for the indication specified in the code application.

Summary of Primary Speaker Comments at the Public Meeting:

The applicant disagreed with CMS preliminary decision, stating that AmnioClear LCT is a viscosupplement derived from human amniotic fluid and therefore is regulated by the FDA as a HCT/P human tissue. Furthermore, as an HCT/P, AmnioClear LCT does not receive a specific indication from the FDA nor does it require specific approval, clearance or license, and like other 361 HCT/P products can, per FDA regulations (21 CFR Part 1270), be marketed without pre-market approval. The primary speaker reiterated their request for a new unique code in the sodium hyaluronate code series.

Final Decision:

The CMS HCPCS Workgroup reconvened to consider your input and upheld its decision not to establish a code. This request to establish a Level II HCPCS code to identify AmnioClear LTC has not been approved because this product does not have the FDA clearance that is required for the indication specified in the code application, and as such, this application is incomplete.

HCPCS Public Meeting Agenda Item #9

May 7, 2015

Attachment# 15.011

Topic/Issue:

Request to establish a unique Level II HCPCS code to identify an extracellular collagen matrix surgical mesh derived from porcine dermis, Trade Name: Fortiva. Applicant's suggested language: QXXXX - Fortiva, per square centimeter

Background/Discussion:

RTI Surgical dba RTI Biologics, Inc., submitted a request to establish a new HCPCS code to identify Fortiva, a porcine-derived extracellular collagen matrix. Fortiva is intended for use as a soft tissue patch to reinforce soft tissue where weakness exists and for the surgical repair of damaged or ruptured soft tissue membranes. Indications for use include the repair of hernias and/or body wall defects which require the use of reinforcing or bridging material to obtain he desired surgical outcome. According to the requester, Fortiva performs as a scaffold that allows for neovascularization and permits the replacement of the porcine dermis with the patient's tissue. The matrix is derived from porcine dermis and preserved using a multi-step sterilization process which includes terminal sterilization by gamma irradiation. Fortiva is provided hydrated and is ready for immediate use without additional preparation. As a surgical mesh, Fortiva is hydrated and stored at 10-30 degrees Celsius. The typical patient population is persons over age 18 who present with soft tissue repair needs.

The requester claims that there are no existing codes that describe Fortiva. A code is needed in order to process claims and track costs. Miscellaneous skin substitute code Q4100 is currently being used to identify this product on claims.

Preliminary Decision:

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

Summary of Primary Speaker Comments at the Public Meeting:

CMS received no comments at CMS' HCPCS Public Meeting regarding this application.

Final Decision:

CMS upheld its decision not to establish a code. This request to establish a Level II HCPCS code to separately identify Fortiva has not been approved because this product is an integral part of a surgical procedure and payment for that service includes payment for Fortiva, if it is used.

HCPCS Public Meeting Agenda Item #9

May 7, 2015

Attachment# 15.054

Topic/Issue:

Request to establish a new Level II HCPCS code to identify Tutopatch™ bovine pericardium. Applicant's suggested language: QXXXX - Tutopatch, per square centimeter

Background/Discussion:

RTI Surgical dba RTI Biologics, Inc., submitted a request for a new code to identify Tutopatch (Bovine Pericardium). Tutopatch is indicated for use in general and plastic surgery applications. It is intended for repair of pericardial structures and for use in surgical repair of soft tissue deficiencies which include: defects of the abdominal and thoracic wall, gastric banding, muscle flap reinforcement, rectal and vaginal prolapse, reconstruction of the pelvic floor, and hernias (including diaphragmatic, femoral, incisional, inguinal, lumbar, paracolostomy, scrotal and umbilical hernias). Tutopatch is preserved by the Tutoplast process, whereby low-dose gamma irradiation is applied terminally to the product to achieve a sterility assurance level of 10^{-6}, while preserving structural integrity. This process retains the original three-dimensional collagen structure responsible for the multidirectional, mechanical properties of tissue. The typical patient population is persons over the age of 18 who present with soft tissue repair needs.

The requester claims that there are no existing codes that describe Tutopatch. A code is needed in order to process claims and track costs. Currently, miscellaneous skin substitute code Q4100 is being used to identify this product on claims.

Preliminary Decision:

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

Summary of Primary Speaker Comments at the Public Meeting:

Written comments were provided in disagreement with CMS' preliminary HCPCS coding decision.

Final Decision:

This request to establish a Level II HCPCS code to separately identify Tutopatch has not be approved because this product would be used as an integral part of a surgical procedure, and payment for that service includes payment for Tutupatch, if it is used.

HCPCS Public Meeting Agenda Item #9

May 7, 2015

Attachment# 15.055

Topic/Issue:

Request to establish a new Level II HCPCS code to identify Tutomesh™ bovine pericardium. Applicant's suggested language: QXXXX - Tutomesh, per square centimeter

Background/Discussion:

RTI Surgical, dba RTI Biologics, Inc., requests a new code to identify Tutomesh, a fenestrated version of bovine pericardium tissue. According to the requester, Tutomesh is preserved by the Tutoplast process, whereby low-dose gamma irradiation is applied terminally to the product to achieve a sterility assurance level of 10^{-6}, while preserving structural integrity. Tutomesh is used in general and plastic surgery applications. It is a biological scaffold intended to be replaced by newly formed connective tissue through remodeling. Tutomesh bovine pericardium is intended for use to reinforce soft tissue where weakness exists in general and plastic surgery applications and is indicated f or repair of pericardial structures and for use for surgical repair of soft tissue deficiencies including gastric banding muscle flap reinforcement, repair of rectal prolapse using an abdominal approach, reconstruction of the pelvic floor using an abdominal approach, and hernias. The typical patient population is adults over the age of 18 who present with soft tissue repair needs.

The requester claims that there are no existing codes that describe Tutomesh. A code is needed in order to process claims and track costs. Currently, miscellaneous skin substitute code Q4100 is being used to identify this product on claims.

Preliminary Decision:

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

Summary of Primary Speaker Comments at the Public Meeting:

CMS received no comments at CMS' HCPCS Public Meeting regarding this application.

Final Decision:

CMS upheld its decision not to establish a code. This request to establish a Level II HCPCS code to identify Tutomesh has not been approved because this product would be used as an integral part of the surgical procedure, and payment for that service includes payment for Tutomesh, if it is used.

HCPCS Public Meeting Agenda Item #9

May 7, 2015

Attachment# 15.056

Topic/Issue:

Request to establish a new Level II HCPCS code to identify Cortiva™, allograft dermis. Applicant's suggested language: QXXXX - Cortiva, per square centimeter

Background/Discussion:

RTI Surgical, dba RTI Biologic, Inc., submitted a request for a new HCPCS code to identify Cortiva (allograft dermis). Cortiva is a sterile, dehydrated dermis from donated human tissue. It is preserved by the Tutoplast process, whereby low-dose gamma irradiation is applied terminally to the product to achieve a sterility assurance level of 10^{-6}, while preserving structural integrity. Cortiva is an implant regulated as a 361 human cell and tissue product (HCT/P) and restricted to homologous use for the repair, replacement, reconstruction or augmentation of soft tissue, including supplemental support and reinforcement of soft tissue in hernia repair.

The requester claims that there are no existing codes that describe Cortiva. A code is needed in order to process claims and track costs. Currently, miscellaneous skin substitute code Q4100 is being used to identify this product on claims.

Preliminary Decision:

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

Summary of Primary Speaker Comments at the Public Meeting:

CMS received no comments at CMS' HCPCS Public Meeting regarding this application.

Final Decision:

CMS upheld its decision not to establish a code. This request to establish a Level II HCPCS code to identify Cortiva has not been approved because this product would be used as an integral part of the surgical procedure, and payment for that service includes payment for Cortiva, if it is used.

HCPCS Public Meeting Agenda Item #9

May 7, 2015

Attachment# 15.057

Topic/Issue:

Request to establish a new Level II HCPCS code to identify Cortiva™, 1 mm allograft dermis. Applicant's suggested language: QXXXX - Cortiva, 1 mm, per square.

Background/Discussion:

RTI Surgical, dba RTI Biologic, Inc., submitted a request for a new HCPCS code to identify Cortiva 1mm (allograft dermis). Cortiva, 1mm is a sterile, dehydrated dermis from donated human tissue. It is preserved by the Tutoplast process, whereby low-dose gamma irradiation is applied terminally to the product to achieve a sterility assurance level of 10^{-6}, while preserving structural integrity. Cortiva, 1mm is an implant regulated as a 361 human cell and tissue product (HCT/P) and restricted to homologous use for the repair, replacement, reconstruction or augmentation of soft tissue, including supplemental support and reinforcement of soft tissue in hernia repair.

The requester claims that there are no existing codes that describe Cortiva, 1mm. A code is needed in order to process claims and track costs. Currently, miscellaneous skin substitute code Q4100 is being used to identify this product on claims.

Preliminary Decision:

A national program operating need was not identified by Medicare, Medicaid or the Private Insurance sector to establish a HCPCS code to separately identify Cortiva, 1mm, which is included as part of the surgical procedure.

Summary of Primary Speaker Comments at the Public Meeting:

CMS received no comments at CMS' HCPCS Public Meeting regarding this application.

Final Decision:

CMS upheld its decision not to establish a code. This request to establish a Level II HCPCS code to identify Cortiva I mm allograft dermis has not been approved because this product would be used as an integral part of the surgical procedure, and payment for that service includes payment for Cortiva allograft dermis, if it is used.

HCPCS Public Meeting Agenda Item #10

May 7, 2015

Attachment# 15.049

Topic/Issue:

Request to establish a new Level II HCPCS code to identify a porcine-derived, non-cross linked, cellular dermal matrix surgical mesh, Trade Name HPTM. Applicant's suggested language: Q41XX - HPTM, per square centimeter.

Background/Discussion:

LifeCell Corporation requests the creation of a new HCPCS code to identify HPTM, a sterile, porcine derived, non-cross linked biologic, acellular tissue matrix surgical mesh. HPTM is intended for use as a soft tissue patch to reinforce soft tissue where weakness exists and for the surgical repair of damaged or ruptured soft tissue membranes which require the use of reinforcing or bridging material to obtain the desired surgical outcome. The implant is intended for reinforcement of soft tissue in plastic and reconstructive surgery. Once applied by a surgeon, HPTM supports revascularization, cell repopulation and white cell migration while providing mechanical support. The surgeon determines the most appropriate size and shape of HPTM to use on the patient. Each package contains one piece of HPTM, an outer carton, an outer foil package containing a sterile inner foil pouch with HPTM.

The requester comments that a new code is necessary in order to provide for greater coding accuracy and utilization documentation for providers and insurers when billing for the use of this product.

Preliminary Decision:

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

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with CMS preliminary decision. The speaker commented that accurate and complete claims reporting is dependent upon the availability of brand specific codes, and that inconsistency and possible arbitrary granting of Q codes creates confusion for facilities. According to the speaker, in many cases, commercial payers have policies based on brand name products. The speaker reiterated the lack of a specific code for HPTM would lead to inaccurate documentation and tracking of product use; potential errors in total cost of care calculations; and confusion when determining appropriate code selection.

Final Decision:

The CMS HCPCS Workgroup reconvened to reconsider this application together with all input provided. CMS upheld its decision not to establish a code. This request to establish a Level II HCPCS code to separately identify HPTM has not been approved because this product would be used as an integral part of a surgical procedure, and payment for that service includes payment for HPTM, if it is used.

HCPCS Public Meeting Agenda Item #11

May 7, 2015

Attachment# 15.048

Topic/Issue:

Repeat request to establish a unique Level II HCPCS Q-code to identify a porcine-derived collagen matrix, Trade Name: Ologen®

Applicant's suggested language: QXXXX- Ologen® Collagen Matrix, per unit.

Background/Discussion:

A request was submitted on behalf of Aeon Astron Europe BV, for a HCPCS code to identify Ologen Collagen Matrix. According to the requester, Ologen Collagen Matrix 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 collaten Matrix. It is configured to support and mudultate wound healing in connective and epithelial ocular tissue, and is used exclusively in ophthalmic surgery procedures such as glaucoma filtering surgery, primarily in the trabeculectomy surgical procedure.

The requester claims that there is a "significant therapeutic distinction" between Ologen and other collagen matrices, in that none of the other matrices are indicated by the FDA for ophthalmic surgery.

Preliminary Decision:

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

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with CMS preliminary decision stating that existing HCPCS codes for collagen matrices do not accurately describe Ologen CM as they are primarily wound-dressings. The speaker also stated various clinical trials and case series report Ologen CM is as effective as mitomycin-C as an adjunctive treatment in glaucoma surgery. Ologen CM is only used for glaucoma surgery. According to the speaker a HCPCS code for Ologen CM could potentially alleviate reimbursement issues and allow for accurate tracking of utilization of this product. The speaker recommended a new code.

Final Decision:

The CMS HCPCS Workgroup reconvened to consider your input and upheld its decision not to establish a code. This request to establish a Level II HCPCS code to separately identify Ologen has not been approved because this product would be used as an integral part of a surgical procedure, and payment for that service includes payment for Ologen, if it is used.

HCPCS Public Meeting Agenda Item #12

May 7, 2015

Attachment# 15.062

Topic/Issue:
Second request to establish a new Level II HCPCS code to identify a bovine collagen acellular dermal matrix, Trade Name: Helicoll™.

Applicant's suggested language: Q41XX - Helicoll™ Accellular Dermal Matrix, per square centimeter.

Background/Discussion:

EnColl Corporation requests a HCPCS code to identify Helicoll, a bovine collagen acellular dermal matrix. Helicoll is a semi-occlusive, self-adhering and sterilized Type- 1 collagen sheet for wound treatments, second degree burns, and chronic ulcers. It is indicated for use as a topical collagen wound dressing, and topical wound management including partial and full-thickness wounds, pressure ulcers, venous ulcers, chronic vascular ulcers, diabetic ulcers, trauma wounds (abrasions, lacerations, second-degree burns, skin tears, and for surgical wounds, donor sites/grafts, post-Mohs' surgery, post-laser surgery, podiatric, wound dehiscence).

Biodegradable collagen dressings are derived from animal tissues; they maintain a moist environment that promotes healing and the formation of granulation tissue. Helicoll is individually packaged and intended as a single application for an individual patient. Product should be trimmed to size prior to contact with the patient. It is supplied in a multiple sizes ranging from 2x2 to 6x26 square *inches*.

The requester comments that prior assignment to codes A6021 and A6023 are inadequate to describe Helicoll, because Encoll revised its description of the product to refer to it as a Bioengineered Acellular Construct, or a Biological Skin Substitute, or as an Acellular Dermal Replacement Matrix, and "the product is not used anymore as a collagen dressing, but as a bioengineered skin substitute," and is more appropriately coded in the Q41XX code series.

Preliminary Decision:
Use existing 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"; or A6023 "Collagen dressing, sterile, size more than 48 sq. in., each," based on size, 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 commenting that unlike a wound dressing, Helicoll stimulates tissue regeneration in chronic wounds. Helicoll is recognized as a skin substitute by the FDA and AHRQ. It is marketed as a skin substitute and sold primarily to hospitals for inpatient and outpatient use. And you asked CMS to reconsider the request to establish a unique Q code.

Final Decision:

The CMS HCPCS Workgroup reconvened to reconsider this application together with all input provided. CMS revised its decision. The following modification has been made to the HCPCS Level II standard, national code set:

Establish Q4164 “Helicoll, per square centimeter”, effective 1/1/16

HCPCS Public Meeting Agenda Item #13

May 7, 2015

Attachment# 15.064

Topic/Issue:

Request to establish a unique Level II HCPCS Q-code to identify a matrix skin substitute, Trade Name: Keramatrix®. Applicant's suggested language: Q41xx - keramatrix®, per square centimeter.

Background/Discussion:

Keraplast Technologies, LLC, submitted a request for a HCPCS code to identify Keramatrix, an open-cell wound dressing comprised of freeze-dried acellular, animal-derived keratin protein. Keramatrix provides a biocompatible cell-growth substrate or scaffold for growth of new tissue in three dimensions and is resorbed into the developing tissue. When a wound occurs, the epithelium is lost and thus the keratin based skin structure is also lost; keramatrix substitutes the outer layer of the skin by introducing a replacement keratin-based structure. When placed in the wound bed it provides a cell-growth-friendly structure for tissue regeneration and maintains moist wound healing environment. Through interaction with enzymes in the healing wound, keramatrix is degraded to a gel which is resorbed. Keramatrix is indicated for the patient population with the following types of chronic wounds: pressure ulcers, venous stasis ulcers, ulcers caused by mixed vascular etiologies, diabetic ulcers and donor sites and grafts. It is supplied in various sizes.

The requester claims a significant therapeutic distinction between Keramatrix and "Standard Care" wound products, based on Keramatrix' combination of moist wound healing, growth-friendly structure and resorption into the wound, causing minimal disturbance to developing tissue.

The requester comments that, because HCPCS identifiers for skin substitutes are brand-specific, existing codes do not adequately describe Keramatrix.

Preliminary Decision:

Establish QXXXX, Keramatrix, per square centimeter.

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.

Final Decision:

The CMS HCPCS Workgroup reconvened to consider your input and upheld its decision. The following modification has been made to the HCPCS Level II standard, national code set:

Establish Q4165, Keramatrix, per square centimeter.

HCPCS Public Meeting Agenda Item #14

May 7, 2015

Attachment# 15.058

Topic/Issue:

Repeat request to establish a unique Level II HCPCS code to identify INTEGRA® Meshed Bilayer Wound Matrix. Applicant's suggested language: Integra Meshed Bilayer Wound Matrix, per sq cm.

Background/Discussion:

Integra LifeSciences Corporation submitted a request to establish a new permanent code to identify Integra Meshed Bilayer Wound Matrix (Collagen-Glycosaminoglycan Matrix-Meshed), and to differentiate it from the non-meshed version of the identical product. According to the requester, Integra Meshed Bilayer Wound Matrix is an advanced wound care device comprised of a porous matrix of cross-linked bovine tendon collagen and glycosaminoglycan with a polysiloxane (silicone) layer. Integra Meshed Bilayer Wound Matrix is intended for the management of wounds including: partial and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, surgical wounds, trauma wounds and draining wounds. The meshed bilayer matrix allows draining of wound exudate and provides a flexible adherent covering for the wound surface.

Integra Meshed Bilayer Wound Matrix is packaged in sterile, single-use, double peel packages containing phosphate buffer. It is available in 4 sizes: 500 square centimeters (8”x10” sheets), 250 square centimeters (4”x10” sheets), 125 square centimeters (4”x5” sheets), and 25 square centimeters (2”x2” sheets). The product is cut to the size of the wound size and applied immediately following wound bed preparation. It should be firmly secured using surgical staples, sutures, or other mechanical means.

The requester comments that existing code C9363 is inadequate for physician office billing, because this code is for use in the Hospital Outpatient setting (for the purpose of billing Medicare). In order to capture a separate ASP payment the Meshed product has been assigned to code Q4100 for the purpose of billing Medicare Part B, when used in the physician office setting. As such, existing code Q4104 has not been assigned for the purpose of billing Medicare.

Preliminary Decision:

Existing code Q4104 "Integra bilayer matrix wound dressing (bmwd), per square centimeter" adequately describes the product and is available for assignment by insurers, if they deem appropriate, for use in the physician’s office setting. Existing code C9363 “Skin Substitute, Integra Meshed Bilayer Wound Matrix, per square centimeter,” also adequately describes the product, and is available for assignment by insurers, if they deem appropriate, for use in the

hospital outpatient setting. For coding guidance, contact the insurer in whose jurisdiction a claim would be filed.

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with CMS preliminary decision, commenting that the preliminary decision conflicts with multiple CMS HCPCS coding principles specified in longstanding guidance issued by CMS and in the decisions that have been made with other similarly situated products; conflicts with CMS sub-regulatory guidance; and is inconsistent with past precedent. The speaker commented that consistency with the treatment of other similarly situated products demands the creation of a unique code for Integra Meshed Bilayer Wound Matrix.

Final Decision:

The CMS HCPCS Workgroup reconvened to consider all input provided and upheld its decision.

Existing code Q4104 "Integra bilayer matrix wound dressing (bmwd), per square centimeter" adequately describes the product and is available for assignment by insurers, if they deem appropriate, for use in the physician's office setting. Existing code C9363 "Skin Substitute, Integra Meshed Bilayer Wound Matrix, per square centimeter," also adequately describes the product, and is available for assignment by insurers, if they deem appropriate, for use in the hospital outpatient setting.

HCPCS Public Meeting Agenda Item #15

May 7, 2015

Attachment# 15.043

Topic/Issue:

Request to establish a new Level II HCPCS code to identify bio-ConneKt Wound Matrix. Applicant's suggested language: Q41XX - Bio-ConneKt Wound Matrix, per square centimeter

Background/Discussion:

MLM Biologics submitted a request to establish a new HCPCS code to identify Bio-ConneKt Wound Matrix. According to the requester, Bio-ConneKt is a bioengineered skin substitute derived from equine Type I collagen. Bio-ConneKt is intended for management of moderately to heavily exuding wounds, including partial and full thickness wounds, draining & tunneling wounds, pressure sores/ulcers, venous ulcers, chronic vascular ulcers, diabetic ulcers, trauma wounds, and surgical wounds. The product is placed directly into the wound site and incorporates into the wound, as the wound heals.

Bio-ConneKt is supplied in 4 different sizes: 6 cm x 7 cm, 5 cm x 5 cm, 3 cm x 3 cm, and 2 cm x 2 cm. It comes in a double pouch package and in a final outer cardboard envelope. The product is trimmed to a size slightly larger than the outline of the wound, then affixed to the wound and covered with a standard, non-adherent surgical dressing.

The requester comments that a brand-specific code is needed to identify Bio-ConneKT in order for the payers to accurately and efficiently administer claims and benefits.

Preliminary Decision:

Establish QXXXX, Bio-Connekt Wound Matrix, per square centimeter.

Summary of Primary Speaker Comments at the Public Meeting:

No public comments were offered at CMS' HCPCS Public Meeting in response to our preliminary decision.

Final Decision:

CMS upheld its decision. We are pleased to inform you that the following modification has been made to the HCPCS Level II standard, national code set:

Establish Q4161, Bio-Connekt Wound Matrix, per square centimeter

HCPCS Public Meeting Agenda Item #16

May 7, 2015

Attachment# 15.053

Topic/Issue:

Request to expand the Q41XX code series in order to distinguish coded products based on size and other product characteristics. Specifically, to create a coding distinction between Epifix products that measure more than 20 square centimeters vs. all other (smaller) sizes.

Applicant's suggested language:

Revise existing code Q4131 which currently reads "EpiFix, per square centimeter"; to instead read "Human dehydrated amniotic membrane allograft, EpiFIx®, *for sizes up to 20 square centimeters*, per square centimeter"; and

Establish a new code: QXXXX - Human dehydrated amniotic membrane allograft, EpiFix® for *sizes 20 square centimeters and above*, per square centimeter.

Background/Discussion:

MiMedx Group, Inc. submitted a request to revise existing Epifix code Q4131, by adding language that would limit its application to only product sizes up to 20 square centimeters. MiMedx Group also requests the establishment of a new code in the same series to identify Epifix in sizes 20 square centimeters and above.

EpiFix is a multi-layer biologic dehydrated human amnion/chorion membrane allograft comprised of an epithelial layer and two fibrous connective tissue layers processed from human placenta. The processed allograft contains collagen types IV, V and VII that promote cellular differentiation and adhesion. EpiFix is used in wound care where it is necessary to repair or replace lost or damaged human collagen tissue. The actions of EpiFix for wound repair include: providing a matrix for cellular migration/proliferation, promoting increased healing, it is non-immunogenic, natural biological barrier, contains essential growth factors, reduces inflammation, reduces scar tissue, has antibacterial properties and reduces the pain at the site. EpiFix allografts are placed on the wound site and hydrated as necessary. The size needed is determined based upon the size of the wound defect.

The requester claims that existing code Q4131 does is insufficient to accurately describe EpiFix, because of the wide range and variety of sizes offered, and that coding distinctions based on size will "facilitate the establishment of a lower payment rate, thus affording medical providers a more cost effective way to provide the best care to patients with larger wounds."

Preliminary Decision:

Existing code Q4131 "Epifix, per square centimeter" adequately describes the product that is the subject of your request, and permits reporting of the number of units administered, to accommodate all sizes.

Summary of Primary Speaker Comments at the Public Meeting:

The applicant disagreed with CMS' preliminary decision stating that creating a second code and ASP payment rate for larger sizes of EpiFix will allow CMS to benefit from reduced pricing on these larger sizes. The speaker also commented that, if a second code is established for larger sizes of EpiFix, sales of the larger sizes would no longer necessarily jeopardize the reimbursement rate for smaller sizes, and that many wounds are big, so a separate code is warranted.

Final Decision:

The CMS HCPCS Workgroup reconvened to consider your input and upheld its decision.

Existing code Q4131 "Epifix, per square centimeter" adequately describes the product that is the subject of your request, and permits reporting of the number of units administered, to accommodate all sizes.

HCPCS Public Meeting Agenda Item #17

May 7, 2015

Attachment# 15.045

Topic/Issue: Request to establish a unique Level II HCPCS code to identify an osteochondral allograft, Trade Name: Cartiform®. Applicant's suggested language: JXXXX - 1 centimeter squared, Cryopreserved Viable Osteochondral Allograft

Background/Discussion:

Osiris Therapeutics submitted a request to establish a HCPCS code to identify Cartiform®. According to the requester, Cartiform is a cryopreserved viable osteochondral allograft, processed from donated human osteochondral tissue. Cartiform contains all necessary components for cartilage reconstruction and tissue repair, and is the only cartilage repair product with viable chondrocytes within an intact native cartilage architecture that can be stored frozen for immediate, point-of-care use. It is used to treat articular cartilage defects for a patient population similar to those that would undergo a micro fracture, fresh-stored osteochondral allografting and/or ACI/ Carticel procedures. Cartiform is safe for patients 55 and younger with at least 6 months of symptoms, radiographic evidence of normal joint space, no evidence of inflammation or osteoarthritis, stable ligaments, adequate meniscus, no malalignment with focal, full thickness Grade 3-4 isolated lesions up to 10 cm caused by acute or repetitive trauma. The surgical technique depends on the defect location, size and physician preference. Cartiform can be implanted arthroscopically or following an arthrotomy or mini-arthrotomy to expose cartilage defect. The quantity used will vary based upon articular cartilage lesion size and physician recommendation. Cartiform is packaged as a circular disc, stored frozen, and is available in 2 sizes: 20 mm diameter disc and 10 mm diameter disc.

The requester comments that a new code is warranted for Cartiform because there are no HCPCS codes that accurately describe it.

Preliminary Decision:

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

Summary of Primary Speaker Comments at the Public Meeting:
The primary speaker disagreed with CMS' published preliminary. The speaker stated that the agency based the conclusion on the fact that Cartiform is bundled in as part of a surgical procedure. According to the speaker, this is not always the case. There are rare circumstances under the Medicare program where Cartiform is used in the physician's office and separately reimbursed. There are many commercial plans and Medicaid agencies that pay separately for Cartiform. A unique billing code is warranted at a minimum for those specific payer entities. The speaker indicated that there are no coding categories for this product that can adequately describe Cartiform and that can be used for its placement and reimbursement.

Final Decision:

The CMS HCPCS Workgroup reconvened to consider all input provided and upheld its decision not to establish a code. This request to establish a Level II HCPCS code to separately identify Cartiform has not been approved because this product is an integral part of the surgical procedure and payment for that service includes payment for Cartiform, if it is used.

HCPCS Public Meeting Agenda Item #18

May 7, 2015

Attachment# 15.059

Topic/Issue:

Request to establish two new Level II HCPCS codes to identify injectable liquid placental tissue matrix: one to identify a cryopreserved version of the product, AmnioGen –C; and another to identify an ambient version, AmnioGen-A.

Background/Discussion:

US Biologix, LLC submitted a request to establish two separate HCPCS codes to identify AmnioGen-C and AmnioGen-A injectable liquid placental tissue Matrix. According to the requester, both are amniotic membrane product in particulate form obtained fromd onated human placental tissue. Both are intended to facilitate replacement or supplement damaged or inadequate integumental tissue. They are intended to be used as a physical wound covering, a foundation for regeneration, modulate correct tissue reconstruction, and to regulate inflammation and pain. Amniotic membranes are a rich source of ExtraCellular Matrix proteins that provide the foundation for the body's tissues and organs. Both products are prepared by the physician as a suspension with normal saline for injection. Both are products are supplied as a single-dose vial, and are available in three different doses: 0.5cc, 1.0cc and 2.0cc. AmnioGen-C is cryopreserved. AmnioGen-A is ambient.

The requester comments that new codes are warranted because there are no existing codes that describe these products.

Preliminary Decision:

Establish QXXXX, AmnioGen-C and AmnioGen-A, 0.5cc.

Summary of Primary Speaker Comments at the Public Meeting:

No comments were offered at CMS' HCPCS Public Meeting in response to our published preliminary decision.

Final Decision:

CMS upheld its decision to establish a code, but modified the language from that originally proposed. The following modification has been made to the HCPCS Level II standard, national code set:

Establish code Q4162: "AmnioPro Flow, BioSkin Flow, BioRenew Flow, WoundEx Flow, AmnioGen-A, AmnioGen-C, 0.5cc.

HCPCS Public Meeting Agenda Item #18

May 7, 2015

Attachment# 15.060

Topic/Issue:

Request to establish two new Level II HCPCS codes to identify an amniotic membrane allograft: one to identify a 45 micron thick version, AmnioGen-45; and another to identify a 200 micron thick version, AmnioGen-200.

Background/Discussion:

US Biologix, LLC submitted a request to establish two separate HCPCS codes to identify AmnioGen-45 and AmnioGen-200 amniotic membrane allografts. Both products are amniotic membrane allografts derived from electively donated placental tissue. Both grafts are intended to be used as a physical wound covering, a foundation for regeneration, modulate correct tissue reconstruction, and to regulate inflammation and pain. Both are preserved through a proprietary, patented method. Both are supplied as a single-use biologic available in six different sizes: 1x1 cm, 2x2 cm, 2x4 cm, 4x4 cm, 4x6 cm and 4x8 cm. AmnioGen membrane comes in two sizes, a thin membrane (45 microns) and a thicker membrane (200 microns).

The requester comments that new codes are warranted because there are no existing codes to describe these products.

Preliminary Decision:

A national program operating need was not identified by Medicare, Medicaid or the Private Insurance sector to establish HCPCS code(s) to separately identify these products, which are included as part of the surgical procedure.

Summary of Primary Speaker Comments at the Public Meeting:

No comments were offered at CMS' HCPCS Public Meeting in response to our published preliminary decision.

Final Decision:

Establish code Q4163: AmnioPro, BioSkin, BioRenew, WoundEx, AmnioGen-45, AmnioGen-200 per square centimeter.

HCPCS Public Meeting Agenda Item #19

May 7, 2015

Attachment# 15.052

Topic/Issue:

Request to establish a unique Level II HCPCS code to identify a porcine-derived, non-crosslinked acellular wound matrix, Trade Name: MIRODERM. Applicant's suggested language: Q41XX - MIRODERM, per square centimeter.

Background/Discussion:

A request was submitted on behalf of Miromatrix Medical, Inc. to establish a new code to identify MIRODERM. According to the requester, MIRODERM, an extracellular matrix wound care product. It is a bioengineered skin substitute derived from porcine liver, processed and stored in a phosphate buffered aqueous solution. MIRODERM is indicated for the management of wounds including: partial and full-thickness wounds, pressure ulcers, venous ulcers, chronic vascular ulcers, diabetic ulcers, drainage wounds, trauma wounds and surgical wounds. It provides a scaffold to maintain and support a healing environment through constrictive remodeling. MIRODERM is supplied in 17 varying sizes, ranging from 4 sq. cm to 200 sq. cm.

According to the requester, a new for MORODERM is warranted in order for payers to accurately and efficiently administer claims and coverage policy.

Preliminary Decision:

A national program operating need was not identified by Medicare, Medicaid or the Private insurance sector to identify MIRODERM, which is included in the procedure.

Summary of Primary Speaker Comments at the Public Meeting:

CMS received no comments at CMS' HCPCS Public Meeting regarding this application.

Final Decision:

CMS upheld its decision not to establish a code. This request to establish a Level II HCPCS code to separately identify Microderm has not been approved because this product is an integral part of a surgical procedure and payment for that service includes payment for Microderm, if it is used.

HCPCS Public Meeting Agenda Item #20

May 7, 2015

Attachment# 15.063

Topic/Issue:

Request to establish a unique Level II HCPCS code to identify a human placental connective tissue matrix, Trade Name Plurivest. Applicant's suggested language: Plurivest™, per square centimeter.

Background/Discussion:

Aedicell, Inc. submitted a request to establish a new code to identify Plurivest. According to the requester, Plurivest is a human placental connective tissue matrix, available in sizes: 2x3 and 4x4 cm. Plurivest is intended to replace or supplement damaged or inadequate integument. Plurivest may be clinically indicated for patients with partial and full thickness wounds, pressure ulcers, venous ulcers, chronic vascular ulcers, diabetic ulcers, trauma wounds, drainage wounds and surgical wounds. The attachment protein, growth factor and structural aspects of the placental connective tissue matrix act as a scaffold for cell infiltration and proliferation.

The requester comments that a new HCPCS code is warranted to identify Plurivest because there is no existing code that describes it.

Preliminary Decision:

Revise existing code Q4153 which currently reads: "Dermavest, per square centimeter", to instead read: "Dermavest and Plurivest, per square centimeter". The revised code 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 and CMS received no comments at CMS' HCPCS Public Meeting regarding this application.

Final Decision:

CMS upheld its decision. The following modification has been made to the HCPCS Level II standard, national code set:

Revise existing code Q4153 which currently reads: "Dermavest, per square centimeter", to instead read: "Dermavest and Plurivest, per square centimeter". The revised code adequately describes the product that is the subject of this request.

HCPCS Public Meeting Agenda Item #21

May 7, 2015

Attachment# 15.050

Topic/Issue:

Request to establish a unique Level II HCPCS code to identify a human amniotic tissue allograft, Trade Names: AmnioPro™ Membrane, WoundEx™, BioRenew™ and BioSkin™. Applicant's suggested language: Q41XX - AmnioPro Membrane, per cm

Background/Discussion:

Human Regenerative Technologies, LLC, submitted a request to establish a new code to identify AmnioPro Membrane. According to the requester, AmnioPro membrane is a human amniotic tissue allograft, consisting of dehydrated and decellularized human amniotic membrane that has been processed with proprietary HydraTek technology. AmnioPro thin membrane is designed as a single layer wound covering for common wounds, and AmnioPro thick membrane is designed as a thicker single layer wound covering for deeper wounds where tissue bulk is required. It is intended to be used as a wound covering and is surgically applied to the skin in the treatment of chronic acute and surgical wounds. Both products are available in the following sizes: 1x1cm, 1x2cm, 2x2cm, 2x4cm, 4x4cm, 4x6cm, and 4x8cm.

The requester comments that a new HCPCS code is warranted because there are no existing codes that describe AmnioPro membrane.

Preliminary Decision:

Establish QXXXX, AmnioPro, BioSkin, BioRenew, WoundEx Membrane, per square centimeter.

Summary of Primary Speaker Comments at the Public Meeting:

No comments were offered at CMS' HCPCS Public Meeting.

Final Decision:

CMS upheld its decision to establish a new code, and revised the code text to capture additional products in the code category. The following modification has been made to the HCPCS Level II standard, national code set:

Establish code Q4163: "AmnioPro, BioSkin, BioRenew, WoundEx, AmnioGen-45, AmnioGen-200, per square centimeter."

HCPCS Public Meeting Agenda Item #22

May 7, 2015

Attachment# 15.051

Topic/Issue:

Request to establish a unique Level II HCPCS code to identify a human placental tissue matrix allograft, Trade Names: AmnioPro™ Flow, BioSkin Flow, BioRenew Flow and WoundEx Flow. Applicant's suggested language: Q41XX - AmnioPro Flow, per cc

Background/Discussion:

Human Regenerative Technologies, LLC submitted a request to establish a code to identify AmnioPro Flow. According to the requester, AmnioPro Flow is a human placental tissue matrix consisting of decellularized particulate placental connective tissue matrix intended to replace or supplement damaged or inadequate integument. AmnioPro Flow is ideal for use in difficult to reach, irregularly shaped or tunneled wounds. Typically one application is applied per wound; however it may be reapplied if necessary. AmnioPro Flow is supplied in the following sizes: 0.5cc, 1.0cc, 1.5cc, and 2.0cc vials.

According to the requester, a new HCPCS code to identify AmnioPro Flow is warranted because there are no existing codes that describe it.

Preliminary Decision:

Establish QXXXX, "AmnioPro Flow, BioSkin Flow, BioRenew Flow, WoundEx Flow, 0.5cc.

Summary of Primary Speaker Comments at the Public Meeting:

No comments were offered at CMS' HCPCS Public Meeting.

Final Decision:

CMS upheld its decision to establish a new code, and revised the code text to capture additional products in the code category. The following modification has been made to the HCPCS Level II standard, national code set:

Establish Q4162, "AmnioPro Flow, BioSkin Flow, BioRenew Flow, WoundEx Flow, AmnioGen-A, AmnioGen-C, 0.5cc.

PAYMENT FOR PART B DRUGS, BIOLOGICALS, BIOSIMILARS, 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 certain 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.

In accordance with 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. CMS has continued to review 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. Also, in accordance with revisions to section 1847A of the Social Security Act made by the Affordable Care Act, CMS will incorporate biosimilars that are approved under the abbreviated biological approval pathway into the ASP payment methodology, and will issue additional guidance as necessary.

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 . . ." Payment for radiopharmaceuticals administered in the physician's office is determined by Medicare administrative contractors (MACs).

Part B versus Part D

The implementation of Medicare Part D did 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.

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