Centers for Medicare & Medicaid Services (CMS)
Healthcare Common Procedure Coding System (HCPCS)
Public Meeting Summary Report
Drugs, Biologicals, and Radiopharmaceuticals
Tuesday, May 8, 2013

Introduction and Overview

Approximately 100 people attended. The agenda included 31items.

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 8, 2013 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# 13.035
Request to establish a single new HCPCS code to identify a dehydrated human amnion membrane allograft to be marketed under two different Trade Names: AmnioExCel™ and BioDExCel™. Applicant's suggested language: "AmnioExCel™ and BioDExCel™ per $cm^{2"}$.

Attachment# 13.036
Request to establish a new Level II HCPCS code to identify a dehydrated human amnion allograft, Trade Name: BioDfence DryFlex™. Applicant's suggested langauge: QXXXX "BioDfence DryFlex™ per cm^2".

Attachment# 13.037
Request to establish a single new Level II HCPCS code to identify an injectable form of viable human multipotential placental allograft marketed under two Trade Names: AmnioMatrix™ and BioDMatrixTM. Applicant's suggested language: "AmnioMatrix™ and BioDMatrix", per cc".

Attachment# 13.038
Request to establish a new Level II HCPCS code to identify a dehydrated human amnion allograft, Trade Name: BioDfence™. Applicant's suggested language: "BioDfence, per cm^2".

No Primary Speaker

AGENDA ITEM #2
Attachment# 13.048
Request to establish a new Level II HCPCS code to identify a biological tissue allograft, Trade Name: Alloskin™ AC. Applicant's suggested language: Q41XX "AlloSkin™ AC per cm^2".

No Primary Speaker

AGENDA ITEM #3
Attachment# 13.034
Request to establish a new Level II HCPCS code to identify a biologic tissue matrix, Trade Name: XCM Biologic™. Applicants' suggested language: QXXXX XCM Biologic™ Tissue Matrix.

Primary Speaker: Scott Goldman of Kensey Nash Corporation

AGENDA ITEM #4
Attachment# 13.032
Request to establish a new Level II HCPCS code to identify an acellular dermal matrix derived from human cadaver skin. Trade Name: Repriza®. Applicant's suggested langauge: Q41XX "Repriza, per square cm".

No Primary Speaker

AGENDA ITEM #5
Attachment# 13.043
Request to establish a new Level II HCPCS code to identify a dry human amniotic allograft membrane, Trade Name: AminoClear®. Applicant's suggested language: QXXXX "AmnioClear, per square centimeter".

No Primary Speaker

AGENDA ITEM #6
Attachment# 13.044
Request to establish 3 new Level II HCPCS codes: one to identify each of three vial sizes containing an injectable micronized powder dehydrated human amniotic membrane allograft, Trade Name: EpiFix®: Applicant's suggested language: QXXX1 "EpiFix® Injectable, 0.5 cc reconstituted vial"; QXXX2 "EpiFix® Injectable, 1.25 cc, reconstituted vial"; and QXXX3 "EpiFix® Injectable, 2.0 cc reconstituted vial".

Primary Speaker: Dr. Don Fetterolf of MiMedx Group, Inc.

AGENDA ITEM #7
Attachment# 13.003
Request to establish a HCPCS Level II code to identify an acellular dermal matrix, Trade Name: TenSIX™. Applicant's suggested language: "QXXXX TenSIX™ Acellular Dermal Matrix, per square centimeter".

No Primary Speaker

AGENDA ITEM #8
Attachment# 13.025
Request to establish a new Level II HCPCS code to identify a wound dressing made from equine pericardium, Trade Name: BriDGE Extracellular Collagen Matrix Wound Dressing. Applicant suggests that the code language identify the product by its brand name, and use a unit descriptor of "per square centimeter".

Primary Speaker: Jerry Mezger of Harbor MedTech

AGENDA ITEM #9
Attachment# 13.027
Request to establish a new Level II HCPCS code to identify a non-implantable biological skin graft substitute, Trade name: NEOX™. Applicant's suggested language: QXXXX NEOX 1k, per square centimeter:

Primary Speaker: Aaron Smith of Amniox Medical

AGENDA ITEM #10
Attachment# 13.002
Request to revise the descriptor of existing code S0189 which currently reads "Testosterone Pellet, 75 mg" to instead read "Testosterone Pellet (Testopel), 75 mg.

Primary Speaker: Charlie Tobler of Actient Pharmaceuticals, LLC

AGENDA ITEM #11
Attachment# 13.011
Request to establish a new Level II HCPCS code to identify tbo-filgrastim Injection for subcutaneous use. Applicant's suggested language: "J2XXX Injection, tbo-filgrastim, 5 mcg".

No Primary Speaker

AGENDA ITEM #12
Attachment# 13.012
Request to establish a new Level II HCPCS code to identify omacetaxine mepesuccinate for injection, Trade Name: SYNRIBO™. Applicant's suggested language J9XXX "injection, omacetaxine mepesuccinate, 0.25 mg".

No Primary Speaker

AGENDA ITEM #13
Attachment# 13.040
Request to establish a new Level II HCPCS code to identify an "intrauterine contraceptive system with unique dosage and indication", Trade Name: Skyla. Applicant's suggested language: "JXXXX Levonorgestrel-releasing intrauterine contraceptive system, 13.5mg".

No Primary Speaker

AGENDA ITEM #14
Attachment# 13.004
Request to establish a new Level II HCPCS code to identify vincristine sulfate liposome injection for intravenous infusion, Trade Name Marqibo®. Applicant's suggested language: "vincristine sulfate liposome injection, 5 mg".

No Primary Speaker

AGENDA ITEM #15
Attachment# 13.014
Request to establish a new Level II HCPCS code to identify Ziv-Aflibercept for injection. Trade Name: ZALTRAP®. Applicant's suggested language: J9XXX Injection, Ziv-Aflibercept, 10 MG.

Primary Speaker: Susan Kornetsky of Sanofi

AGENDA ITEM #16
Attachment# 13.020
Request to establish a new HCPCS code to identify Trastuzumab Emtansine, Trade Name: KADCYLA™. Applicant's suggested language: "Injection, Trastuzumab Emtansine, 1 mg."

Primary Speaker: Stephanie Dyson of Genentech

AGENDA ITEM #17
Attachment# 13.021
Request to establish a new Level II HCPCS code to describe Pertuzumab, Trade Name: PERJETA®. Applicant's suggested language: "Injection, pertuzumab, 10 mg."

Primary Speaker: Stephanie Dyson of Genetech

AGENDA ITEM #18
Attachment# 13.031
Request to establish a new Level II HCPCS code to identify pooled plasma (Human), Solvent/Detergent treated, with a billing unit of 200 mL. Trade name: OCTAPLAS®. Applicant's suggested language: "Injection, pooled plasma (human), solvent/detergent treated (Octaplas), 200 mL"

Primary Speaker: Stanley Ammons of Octapharma USA, Inc.

AGENDA ITEM #19
Attachment# 13.018
Request to establish a new Level II HCPCS code to identify carafilzomab, Trade Name: Kyprolis™. Applicant's suggested language: J9XXX "Injection, carfilzomib, 1mg".

No Primary Speaker

AGENDA ITEM #20
Attachment# 13.046
Third request since 2011 to establish a new Level II HCPCS J code for Physician's office use to identify a topical anesthetic patch containing lidocaine 70mg/tetracaine 70mg, and with a Controlled Heat-Assisted Drug Delivery(CHADD®) device. Trade name: Synera.

No Primary Speaker

AGENDA ITEM #21
Attachment# 13.005
Request to establish a new Level II HCPCS code to identify taliglucerase alfa, Trade Name: Elelyso. Applicant's suggested language: "Injection, taliglucerase alfa, 100 units".

No Primary Speaker

AGENDA ITEM #22
Attachment# 13.006
Request to establish a HCPCS Level II code to identify Sodium Chloride Injection, USP, 0.9% prefilled syringes. Applicant's suggested language: JXXXX Sodium Chloride Injection, USP, 0.9% per ml".

No Primary Speaker

AGENDA ITEM #23
Attachment# 13.033
Request to establish a new Level II HCPCS code to identify Loxapine inhalation powder for oral inhalation, Trade Name ADASUVE®. Applicant's suggested language: "Lozapine, inhalation powder, 10mg."

Primary Speaker: Dr. Kay Jewell of SMT, Inc.

AGENDA ITEM #24
Attachment# 13.022
Request to establish a new Level II HCPCS code to identify Once-Monthly Aripiprazole for Extended Release Injectable Suspension, Trade Name: Abilify Maintena™. Applicant's suggested language: JXXXX "Injection, Aripiprazole Suspension Extended Release, 1 mg".

No Primary Speaker

AGENDA ITEM #25
Attachment# 13.045
Request to establish a new Level II HCPCS code to identify Ocriplasmin intravitreal injection, Trade Name: Jetrea®. Applicant's suggested language: JXXXX, Ocriplasmin Intravitreal Injection, per 0.125mg".

Primary Speaker: Dr. Dhaval Desai of ThromboGenics, Inc.

AGENDA ITEM #26
Attachment# 13.024
Request to establish a new Level II HCPCS code to identify Immune Globulin, Intravenous [Human}, Trade Name: BIVIGAM™. Applicant's suggested language: JXXXX "Injection, immune globulin (Bivigam), intravenous, non-lyophilized (e.g., liquid), 500 mg.

No Primary Speaker

AGENDA ITEM #27
Attachment# 13.028
Request to establish a Level II HCPCS code to identify Teduglutide [rDNA origin] for subcutaneous administration only, Trade Name: GATTEX®. Applicant's suggested language: "(teduglutide [rDNA origin]) for injection".

No Primary Speaker

AGENDA ITEM #28
Attachment#13.015
Requesting new code for gadoterate meglumine (DOTAREM)

No Primary Speaker

AGENDA ITEM #29
Attachment# 13.029
Request to revise the dose descriptor of existing code J0152 from 30 mg to 1 mg. In other words, revise existing code J0152 which currently reads: "Injection, Adenosine for Diagnostic

use, 30 mg (not to be used to report any adenosine phosphate compounds; instead use A9270)"; to instead read: "Injection, adenosine for diagnostic use, 1 mg (not to be used to report any adenosine phosphate compounds; instead use A9270).

No Primary Speaker

AGENDA ITEM #30
Attachment# 13.049
Request to establish a new Level II HCPCS code to identify Technetium Tc 99m Tilmanocept Injection, Brand Name: Lymphoseek®. Applicant's suggested language: "TechnetiumTC 99m Tilmanocept, Diagnostic, per study dose".

Primary Speaker: Dr. Paul Radensky of McDermott Will & Emery, LLP

AGENDA ITEM #31
Attachment# 13.047
Request to revise existing Level II HCPCS code J7507 which currently reads: "Tacrolimus, oral, per 1 mg." to instead read: "Tacrolimus, immediate release, oral, per 1 mg"; in order to set up a distinction between Prograf® and an extended release version of Tacrolimus (which is awaiting FDA clearance).

No Primary Speaker

HCPCS Public Meeting Agenda Item #1
May 8, 2013

Attachment# 13.035
Topic/Issue:

Request to establish a single new HCPCS code to identify a dehydrated human amnion membrane allograft to be marketed under two different Trade Names: AmnioExCel™ and BioDExCel™. Applicant's suggested language: "AmnioExCel™ and BioDExCel™ per $cm^{2"}$.

Background/Discussion:

According to the requester, AmnioExCel™ (also marketed under trade name BioDExCel™) is a dehydrated human amnion membrane allograft composed of an epithelial layer and a stromal layer specifically processed for repair or replacement of lost or damaged dermal tissue. The product contains collagen and extracellular substrates to include growth factors, connective proteins, and cytokines that support and promote angiogenesis, tissue granulation and epithelialization for the repair and replacement of injured tissue. The collagen in the allograft provides an extracellular matrix which acts as a natural scaffold for cellular attachment and a structural tissue matrix that facilitates cell migration and proliferation. The natural composition of the amniotic membrane extracellular matrix is preserved without cross-linkage, thereby providing improved graft incorporation by the body. Usage includes, but is not limited to, allograft application to wounds including traumatic injuries, burns or surgical wounds; complex, chronic and acute wounds, such as diabetic ulcers, venous and arterial ulcers, pressure ulcers or cutaneous ulcers; wounds with exposed tendon, muscle, bone or other vital structures and other soft tissue defects. Both AmnioExCel™ and BioDExCel™ are sterilely packaged for single use and each product is available in the same 5 sizes: 1.5 x 2 cm; 2 x 3 cm; 2 x 6 cm; 4 x 4 cm; and 4 x 8 cm.

Preliminary Decision:

Establish Q41XX: AmnioExCel, per square centimeter. Effective 1/1/2014.

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item #1

May 8, 2013

Attachment# 13.036

Topic/Issue:

Request to establish a new Level II HCPCS code to identify a dehydrated human amnion allograft, Trade Name: BioDfence DryFlex™. Applicant's suggested langauge: QXXXX "BioDfence DryFlex™ per cm^2".

Background/Discussion:

According to the requester, BioDfence DryFlex™ is a human placental-derived amniotic tissue based allograft composed of an epithelial layer and a stromal layer specifically processed for the repair and replacement of lost or damaged dermal tissue or the prohibition of adhesion formation. This allograft contains collagens and extracellular substrates to include growth factors, connective proteins, and cytokines that preserve planes of tissue while inhibiting incorporation of the vital structure(s) into the overlying developing tissue. The collagen acts as a scaffold for cellular attachment and a structural tissue matrix that facilitates cell migration and proliferation. While this product was initially used in the acute care inpatient setting in connection with neurosurgical, orthopedic and spine surgical procedures, physicians and surgeons are now consistently reporting positive outcomes in individual wound care cases. The dehydrated (and the hydrated) human amnion allografts are intended for the repair or replacement of lost or damaged dermal tissue. Usage includes, but is not limited to, allograft application to wounds including: traumatic injuries, burns Mohs procedures or surgical wounds; complex chronic and acute wounds, such as diabetic ulcers venous and arterial leg ulcers, pressure ulcers or cutaneous ulcers; wounds with exposed vital structures, e.g., tendon, bone, blood vessels; and other soft tissue defects. The product also provides adhesion barrier properties when necessary. BioDfence DryFlex is packaged for single use in 5 sizes: 1.5 x 2cm; 2 x 3 cm; 2 x 6 cm; 4 x 4 cm; and 4 x 8 cm. Wound applications in non-hospitalized care settings have commonly not been reimbursed since there were no assigned codes to specifically identify the products. The differences between BioDfence Dryflex™ and BioDfence (see application 13.038) are as follows: BioDfence DryFlex is dehydrated, making it a better choice for use with instrumentation. BioDfence is hydrated, which may not be needed, which may make it easier to use for procedures such as on corneal defects. Both products have a cross-linked basement membrane which is not penetrable and becomes a biologic barrier. It is placed over exposed vital structures, such as nerves, blood vessels or other tissues to protect them and keep them intact.

Preliminary Decision:

Establish Q41XX: BioDfence DryFlex, per square centimeter. Effective 1/1/2014.

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item #1

May 8, 2013

Attachment# 13.037
Topic/Issue:

Request to establish a single new Level II HCPCS code to identify an injectable form of viable human multipotential placental allograft marketed under two Trade Names: AmnioMatrix™ and BioDMatrixTM. Applicant's suggested language: "AmnioMatrix™ and BioDMatrix", per cc".

Background/Discussion:

According to the requester, AmnioMatrix and BioDMatrix are a viable human multipotential placental allografts composed of morselized amniotic membrane and amniotic fluid components recovered from the same human donor. The amniotic membrane is separated from the placenta and morselized into particulate form, then combined with amniotic fluid components to form the allograft. The processing method is intended to preserve the structural properties of the collagen; growth factors; inherent cellular materials and matrix present in the tissue to create a micro-scaffold to be used to aid in the wound healing process. AmnioMatrix (also to be marketed under the trade name BioDMatrix™) is intended for the treatment of wounds, including but not limited to surgical wounds, burns or traumatic injury; and chronic and acute wound conditions. The allograft is also used to augment the local treatment of soft tissue defects for the supportive treatment of wound-associated bone defects. The product may be mixed with normal saline for application to surgical sites and open, complex or chronic wounds or mixed with the recipient's blood to fill soft tissue defects and wound-associated bone defects. AmnoMatrix™ is cryopreserved and supplied in injectable form in sterile vials. It is available in 4 sizes: small (0.25 cc); medium (0.50 cc); large (1.0 cc); and extra-large (3.0 cc).

According to the requester, no existing code describes a human placental-derived allograft composed of a homogenate of morselized amniotic membrane and amniotic fluid components that provides a viable multipotential placental allograft for homologous application.

Preliminary Decision:

Establish Q41XX, AmnioMatrix or BioDMatrix, injectable, 1 cc.

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item #1
May 8, 2013

Attachment# 13.038
Topic/Issue:

Request to establish a new Level II HCPCS code to identify a dehydrated human amnion allograft, Trade Name: BioDfence™. Applicant's suggested language: "BioDfence, per cm^2".

Background/Discussion:

According to the requester, BioDfence™ is a human placental-derived amniotic tissue based allograft composed of an epithelial layer and a stromal layer specifically processed for the repair and replacement of lost or damaged dermal tissue or the prohibition of adhesion formation. This allograft contains collagens and extracellular substrates to include growth factors, connective proteins, and cytokines that preserve planes of tissue while inhibiting incorporation of the vital structure(s) into the overlying developing tissue. The collagen acts as a scaffold for cellular attachment and a structural tissue matrix that facilitates cell migration and proliferation. While this product was initially used in the acute care inpatient setting in connection with neurosurgical, orthopedic and spine surgical procedures; physicians and surgeons are now consistently reporting positive outcomes in individual wound care cases. The dehydrated (and the hydrated) human amnion allografts are intended for the repair or replacement of lost or damaged dermal tissue. Usage includes, but is not limited to, allograft application to wounds including: traumatic injuries, burns, Mohs procedures or surgical wounds; complex chronic and acute wounds, such as diabetic ulcers venous and arterial leg ulcers, pressure ulcers or cutaneous ulcers; wounds with exposed vital structures, e.g., tendon, bone, blood vessels; and other soft tissue defects. The product also provides adhesion barrier properties when necessary. BioDfence is packaged for single use in 7 sizes: 1.5 x 2cm; 2 x 3 cm; 2 x 6 cm; 4 x 4 cm; 4 x 8 cm; 10 x 10 cm; and 15 x 15 cm. Wound applications in non-hospitalized care settings have commonly not been reimbursed since there were no assigned codes to specifically identify the products. According to the requester, the differences between BioDfence™ and BioDfence Dryflex (see application 13.036) are as follows: BioDfence DryFlex is dehydrated, making it less sticky, and a better choice for use with instrumentation. BioDfence is hydrated, which makes it a bit sticky and glue may not be needed, which may make it easier to use for procedures such as on corneal defects. Both BioDfence DryFlex and BioDfence have a cross-linked basement membrane which is not penetrable and becomes a biologic barrier. It is placed over exposed vital structures, such as nerves, blood vessels or other tissues to protect them and keep them intact.

Preliminary Decision:

Establish Q41XX, BioDfence, per square centimeter. Effective 1/1/2014.

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item #2

May 8, 2013

Attachment# 13.048

Topic/Issue:

Request to establish a new Level II HCPCS code to identify a biological tissue allograft, Trade Name: Alloskin™ AC. Applicant's suggested language: Q41XX "AlloSkin™ AC per cm^2".

Background/Discussion:

According to the requester Alloskin™ is a 1:1 meshed, biological cadaveric dermis, which is decellularized and further processed to provide an acellular tissue allograft. Alloskin™ AC allograft is a natural skin replacement that can be used as a scaffold for regeneration of tissue through revascularization and remodeling into the host tissue to achieve wound closure of partial or full-thickness wounds due to tissue loss from burns, trauma and chronic wounds, such as venous and arterial ulcers, diabetic foot ulcers and pressure ulcers.

Alloskin™ AC tissue allograft is surgically applied and secured to the skin by the anchoring method chosen by the surgeon (sutures, staples, adhesive glue, etc.). Alloskin ™ AC is supplied 4cmx4cm/16cm2 and 5cmx5cm/25cm2.

There is no current HCPCS code to define Alloskin™ AC. However there is a similar human cadaver acellular product GRAFTJACKET, per square cm which is assigned Q4107. Alloskin(TM AC is processed differently than the mentioned product. After epidermal layer is removed by chemical delamination, the resulting dermal product is low-dose, e-beam irradiated to preserve the graft in a shelf-stable format. E-beam sterilization is considered a gentler method of sterilization than gamma irradiation for delicate collagen matrices. The suggested new language is: Q41XX Alloskin™ AC per $cm^{2.}$

Preliminary Decision:

Establish Q41XX, AlloSkin AC, per square centimeter. Effective 1/1/2014

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item #3
May 8, 2013

Attachment# 13.034
Topic/Issue:

Request to establish a new Level II HCPCS code to identify a sterile, non-crosslinked, 3-D biologic tissue matrix derived from porcine dermis, Trade Name: XCM Biologic™. Applicants' suggested language: QXXXX XCM Biologic™ Tissue Matrix, per square centimeter.

Background/Discussion:

According to the requester, XCM Biologic Tissue Matrix is a sterile, non-cross-linked 3-D matrix derived from porcine dermis. It provides a support structure for cellular migration and as such the matrix is incorporated into the surrounding tissue. It is "indicated for use in general surgical procedures for the reinforcement and repair of soft tissue where weakness exists including, but not limited to: defect of the thoracic wall, suture line reinforcement, and muscle flap reinforcement; urogynecological surgical reinforcement including but not limited to, rectal and vaginal prolapse, reconstruction of the pelvic floor, hernia repair; soft tissue reconstructive procedures including plastic and reconstructive surgical application, and for reinforcement of the soft tissues, which are repaired by suture or suture anchors, including but not limited to, rotator cuff, patellar, Achilles, biceps, quadriceps and other tendons." XCM Biologic Tissue Matrix is supplied sterile (hydrated) in a foil liner pouch. It does not require refrigeration, or any preparation before use. According to the requester, Medicare and private payers administer coverage policies for xenografts used in general surgical and wound care application on a brand-name basis, and therefore these skin substitutes must be issued a brand-name specific HCPCS code in order to be eligible for claims submission and reimbursement."

Preliminary Decision:

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

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, similar products to XCM Biologic with comparable indications have been granted HCPCS codes. The speaker requested that a code be developed in alignment with the precedence set for granting Q-codes to similar tissue forms; and in order to accommodate reporting and tracking of this item.

HCPCS Public Meeting Agenda Item #4
May 8, 2013

Attachment# 13.032
Topic/Issue:

Request to establish a new Level II HCPCS code to identify an acellular dermal matrix derived from human cadaver skin. Trade Name: Repriza®. Applicant's suggested langauge: Q41XX "Repriza, per square cm".

Background/Discussion:

According to the requester, Repriza is a biologic graft intended for use in a single application. It is used as a skin substitute in the treatment of various types of wounds including burns, chronic ulcers, and surgical wounds. In addition to its use as a skin substitute, Repriza may also be used as an implant during plastic and reconstructive surgeries wherever an acellular dermal matrix may be used. For example, it may be used to support implants in a defined pocket such as in breast reconstruction, and abdominal wall reconstruction procedures. The quantity and size of product used varies based upon surgical application, individual patient circumstances, and the dimensions of the wound or surgical site. It is available in standard sizes with custom sizes and thicknesses available upon request. Repriza is used in the same indications and the same manner as both Alloderm and Graft Jacket. However, there is a significant difference in cost of the materials. In addition, Repriza is sterile, hydrated and ready to use on opening its package without soaking or washing and it may be stored at ambient temperature. It has no “sidedness”, so either side may be approximated to tissues of the wound or burn. Since the coding nomenclature for skin substitutes is product specific, Repriza should be assigned its own unique code consistent with the code structure for other skin substitutes.

Preliminary Decision:

Revise existing code Q4111 which currently reads: "Gammagraft, per square centimeter"; to instead read: "Gammagraft or Repriza, per square centimeter".

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item. However, the manufacturer submitted written comments disagreeing with the preliminary decision on the basis of structural differences between Gammagraft and Repriza, and reiterating the original request for a unique code for Repriza.

HCPCS Public Meeting Agenda Item #5
May 8, 2013

Attachment# 13.043
Topic/Issue:

Request to establish a new Level II HCPCS code to identify a dry human amniotic allograft membrane, Trade Name: AmnioClear®. Applicant's suggested language: QXXXX "AmnioClear, per square centimeter".

Background/Discussion:

According to the requester AmnioClear® is a human tissue allograft made of donated amniotic membrane derived from the inner lining of the placenta. AmnioClear® can be used as a covering for full-thickness skin wounds, damaged membranes, and as a burn dressing. The AmnioClear membrane delivers the unique functionality of the amnion to wound sites, including anti-inflammatory function and unique anti-microbial, anti-viral and anti-bacterial capabilities. The AmnioClear allograft is minimally processed to remove cells from the membrane while retaining the structural properties of the extracellular matrix. The resulting decellularized and dehydrated allograft is aseptically packaged in sterilized, hermetically sealed foil and Tyvek pouches and stored at ambient temperature until ready for use. When ready for use, the allograft is aseptically trimmed to appropriate size, applied or grafted to wound site. The allograft may be rehydrated with saline or naturally rehydrated in situ with body fluids.

Preliminary Decision:

Establish new code Q41XX AmnioClear, per square centimeter. Effective 1/1/2014

Summary of Primary Speaker Comments at the Public Meeting:

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

HCPCS Public Meeting Agenda Item #6
May 8, 2013

Attachment# 13.044
Topic/Issue:

Request to establish 3 new Level II HCPCS codes: one to identify each of three vial sizes containing an injectable micronized powder dehydrated human amniotic membrane allograft, Trade Name: EpiFix®: Applicant's suggested language: QXXX1 "EpiFix® Injectable, 0.5 cc reconstituted vial"; QXXX2 "EpiFix® Injectable, 1.25 cc, reconstituted vial"; and QXXX3 "EpiFix® Injectable, 2.0 cc reconstituted vial".

Background/Discussion:

According to the requester EpiFix® Injectable is a minimally manipulated, dehydrated, non-viable cellular amniotic membrane allograft that preserves and delivers multiple extracellular matrix proteins, growth factors, cytokines and other specialty proteins present in amniotic tissue to help regenerate soft tissue.

EpiFix® Injectable is used in the treatment and management of chronic wounds. Usage includes injectable applications for neuropathic ulcers, venous stasis ulcers, post traumatic ulcers, post-surgical ulcers and pressure ulcers. It is particularly suited to deeply creviced, irregularly shaped or tunneling wounds. EpiFix® Injectable is used for wound treatment, when it is necessary to replace or repair lost or damaged human collagen tissue.

EpiFix® Injectable can be injected in the wound site and hydrated as needed, or mixed with a fixed amount of normal saline solution to prepare a suspension for injection into the wound or areas of chronic inflammation. The size of the dosing used is determined based upon the size of the wound defect.

EpiFix® Injectable vials contain processed, dehydrated, sterilized amniotic membrane tissue grafts to be reconstituted to 0.5cc, 1.25cc and 2.0cc amounts.

Preliminary Decision:

Establish Q41XX: Micronized Dehydrated Human Amniotic Membrane Allograft, Injectable, 1mg. Effective 1/1/2014. This code adequately describes the identical product in all three vial sizes that are the subject of this application.

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker agreed with the workgroup for its preliminary decision to establish a Q code but requested that the Brand Name EpiFix® be added to the code descriptor and also to expand the descriptor to specify the exact composition of the material. EpiFix is a unique material and without specification might encourage generic or therapeutic substitution with

alternative or relative products that do not have the rigorous production processes or final biological characteristics of EpiFix. The speaker also asked that the term “injectable” be omitted from the code descriptor so that the code could also be used to report the powder itself (not in a liquid suspension).

HCPCS Public Meeting Agenda Item #7
May 8, 2013

Attachment# 13.003
Topic/Issue:

Request to establish a HCPCS Level II code to identify an acellular dermal matrix, Trade Name: TenSIX™. Applicant's suggested language: "QXXXX TenSIX™ Acellular Dermal Matrix, per square centimeter".

Background/Discussion:

According to the applicant, TenSIX is an acellular dermal matrix derived from aseptically processed cadaveric human skin tissue that is terminally sterilized. It is made from human donor skin, which undergoes a process that removes the epidermis and dermal cells, thereby creating an acellular dermis. "Human cadaveric dermal tissue" is referred to as acellular dermal allograft.

TenSIX acts as a scaffold to facilitate angiogenesis and migration of growth factors that stimulate cell migration. Once rehydrated, the allograft can be applied topically to the wound and secured in the preferred manner of choice by the physician. Typically this is accomplished by the suturing or stapling the allograft to the skin surrounding the wound.

TenSIX allograft tissue is to be used for the repair or replacement of damaged or inadequate integumental tissue or for the other homologous of human integument. Most notably, it will be used for wounds resulting from chronic diabetic foot ulcers.

There is no unique HCPCS code for this product.

Preliminary Decision:

Establish Q41XX "TenSIX, per square centimeter". Effective 1/1/2014

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item #8
May 8, 2013

Attachment# 13.025
Topic/Issue:

Request to establish a new Level II HCPCS code to identify a wound dressing made from equine pericardium, Trade Name: BriDGE Extracellular Collagen Matrix Wound Dressing. Applicant suggests that the code language identify the product by its brand name, and use a unit descriptor of "per square centimeter".

Background/Discussion:

According to the applicant, Architect™ ECM is a "medical device comprised almost entirely of type I collagen that has been stabilized and sterilized for ease of use and enhance durability as a wound dressing. It is made from equine pericardium and utilized a patented collagen stabilizing technology called "BriDGE" that supports rapid healing by: not promoting an inflammatory response; serving as a temporary matrix that provides a platform for cell migration; helping to optimize the wound-healing environment; and facilitating cellular activity. The applicant comments that a new code is warranted because Architect™, when cleared by the FDA, "will become the only equine pericardium sourced ECM wound dressing available on the US market since the withdrawal of Synovis' Unite Biomatrix in June, 2012." According to the applicant, "since HCPCS codes for wound dressings are product and brand-specific, a new code is needed for Architect™ ECM".

Preliminary Decision:

Establish Q41XX, Architect Extracellular Matrix, per square centimeter. Effective 1/1/2014

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 8, 2013

Attachment# 13.027
Topic/Issue:

Request to establish a new Level II HCPCS code to identify a non-implantable biological skin graft substitute, Trade name: NEOX™. Applicant's suggested language: QXXXX NEOX 1k, per square centimeter:

Background/Discussion:

According to the requester NEOX™ 1k is a non-implantable biological skin graft substitute comprised of human amniotic membrane retrieved from electively donated umbilical cords.

NEOX™ 1k is used as a wound covering in chronic non-healing dermal wounds, such as diabetic ulcers, to modulate inflammation and encourage healing. It is supplied as a single-use graft in four different sizes: 1.5 x 1.5 cm; 2.5 x 2.5 cm; 4.0 x 3.0 cm; 6.0 x 3.0 cm. NEOX™ 1k 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:

A national program operating need to establish a code was not identified by Medicare, Medicaid and the Private Insurance sector. CMS recommends that the applicant review the whether CMS' Pass-through coding process is appropriate for this product which is integral to a surgical procedure.

Summary of Primary Speaker Comments at the Public Meeting:

The applicant disagreed with CMS' preliminary decision not to establish a HCPCS code. NEOX was initially used for wound and surgical indication. Similar to other products with established "Q" codes. The preliminary decision seems to proceed on a misunderstanding about NEOX, and it fails to treat this product as six other similarly situated products in this year's HCPCS cycle. NEOX currently is marketed and sold only for use as a skin substitute. The speaker is recommended a "Q" code.

HCPCS Public Meeting Agenda Item #10
May 8, 2013

Attachment# 13.002
Topic/Issue:

Request to revise the descriptor of existing code S0189 which currently reads "Testosterone Pellet, 75 mg" to instead read "Testosterone Pellet (Testopel), 75 mg.

Background/Discussion:

According to the requester, existing code S0189 adequately describes the only FDA approved testosterone pellet product (Testopel). However, pharmacies are engaging in compounding to produce testosterone pellets that are being sold to physicians. The proposed revision to the descriptor of code S0189 (specifying Testopel by brand name within the code), is needed in order to ensure that this code is used to bill only for a Food and Drug Administration (FDA) approved final product, and not a compounded testosterone pellet product.

Preliminary Decision:

A national program operating need was not identified by Medicare, Medicaid or the Private Insurance sector to revise the descriptor of HCPCS code S0189.

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with CMS' preliminary decision not to revise the descriptor of HCPCS code S0189 to specify Testopel by Brand Name. The speaker believes the descriptor for HCPCS code S0189 is broad enough to include compounds. Compounded testosterone pellets present issues in terms of lack of safety and lack of sterility. The speaker reiterated the original request to add the brand name Testopel to existing code S0189. According to the speaker, this would promote patient safety with regard to implanted testosterone pellets. The speaker commented that the code revision is necessary to facilitate the billing guidance of CMS and other payers, and suggested use of "a miscellaneous code for compounds if we think the pharmacy is safe."

HCPCS Public Meeting Agenda Item #11
May 8, 2013

Attachment# 13.011
Topic/Issue:

Request to establish a new Level II HCPCS code to identify tbo-filgrastim Injection for subcutaneous use. Applicant's suggested language: "J2XXX Injection, tbo-filgrastim, 5 mcg".

Background/Discussion:

According to the requester, tbo-filgrastim is a leukocyte growth factor indicated for the reduction in the duration of severe neutropenia in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia. The dosage is weight-dependent, at 5mcg/kg per day, administered as a subcutaneous injection by a healthcare professional. Tbo-filgrastim is administered no earlier than 24 hours following myelosuppressive chemotherapy, and discontinued within 24 hours prior to chemotherapy. Tbo-filgrastim is a human granulocyte colony-stimulating factor (G-CSF) produced by recombinant DNA technology. Tbo-filgrastim binds to G-CSF receptors and stimulates proliferation of neutrophils. G-CFS is known to stimulate differentiation commitment and some end-cell functional activation, which increases neutrophil counts and activity. Tbo-filgrastim is supplied in single-use prefilled syringes with two strengths: 300 mcg/0.5 mL injection in single use prefilled syringe and 480 mcg/0.8 mL injection in single use prefilled syringe. The provider will monitor the patient's complete blood count (CBC) prior chemotherapy, and twice per week until recovery.

Preliminary Decision:

Establish JXXXX "Injection, tbo-filgrastim, 5 micrograms". Effective 1/1/2014

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item, however; the applicant submitted written comments in agreement with the recommended coding action and coding text.

HCPCS Public Meeting Agenda Item #12
May 8, 2013

Attachment# 13.012
Topic/Issue:

Request to establish a new Level II HCPCS code to identify omacetaxine mepesuccinate for injection, Trade Name: SYNRIBO™. Applicant's suggested language J9XXX "injection, omacetaxine mepesuccinate, 0.25 mg".

Background/Discussion:

According to the requester, SYNRIBO™ is a protein synthesis inhibitor and is independent of direct BCR-Abl binding. It is FDA approved for the treatment of adult patients with chronic or accelerated phase chronic myeloid leukemia (CML) with resistance and/or intolerance to two or more tyrosine kinase inhibitors (TKIs). This indication is based upon response rate. There are no trials verifying an improvement in disease-related symptoms or increased survival with SYNRIBO™.

SYNRIBO ™ is supplied in single-use vials containing 3.5 mg of lyophilized powder that requires reconstitution with 1 ml of 0.9% sodium chloride Injection. Once reconstituted, the drug is administered via subcutaneous injection twice daily. SYNRIBO™ will be furnished "incident-to" a physician's service. The dosing regimen is dependent upon whether a patient is in an induction or maintenance treatment phase:

INDUCTION: A dose of 1.25 mg/m^2 is administered by subcutaneous injection twice daily for 14 consecutive days of a 28-day cycle. The cycle should be repeated every 28 days until the patient achieves hematologic response.

MAINTENANCE: A dose of 1.25 mg/m^2 is administered by subcutaneous injection twice daily for 7 consecutive days of a 28-day cycle. Treatment should continue as long as the patient is clinically benefiting from therapy.

SYNRIBO™ is a first-in-class cephalotaxine, and there are no similar products on the market.

Preliminary Decision:

Establish J9XXX Omacetaxine Mepesuccinate 0.01 mg. Effective 1/1/2014

HCPCS code C9297 "Injection, Omacetaxine Mepesuccinate 0.01 mg" is available for assignment by insurers until such time as a J code would be established.

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item, however; the applicant submitted written comments in agreement with the recommended coding action and coding text.

HCPCS Public Meeting Agenda Item #13

May 8, 2013

Attachment# 13.040

Topic/Issue:

Request to establish a new Level II HCPCS code to identify an "intrauterine contraceptive system with unique dosage and indication", Trade Name: Skyla. Applicant's suggested language: "JXXXX Levonorgestrel-releasing intrauterine contraceptive system, 13.5mg".

Background/Discussion:

According to the requester Skyla™ (levonorgestrel-releasing intrauterine system) is an intrauterine contraceptive indicated to prevent pregnancy for up to three years. Studies of Skyla and similar Intrauterine System (IUS) prototypes have suggested several mechanisms that prevent pregnancy; thickening of cervical mucus preventing passage of sperm into the uterus; inhibition of sperm capacitation or survival; and alteration of the endometrium.

Skyla is placed in within the uterine cavity by a healthcare professional. Skyla contains 13.5 mg of levonorgestrel released at a progressively decreasing rate over 3 years. It must be removed by the end of the third year and can be replaced at the time of removal with a new Skyla if needed. Skyla is supplied in a carton of one sterile unit, which includes one Skyla contained within an inserter. Skyla consists of a T-shaped polyethylene frame (T-body) with a steroid reservoir (hormone elastomer core) around the vertical stem. A ring composed of 99.95% pure silver is located at the top of the vertical stem close to the horizontal arms and is visible by ultrasound. The T-body has a loop at one end of the vertical stem and two horizontal arms at the other end.

Preliminary Decision:

1. Newly established code Q0090 Levonorgestrel-Releasing Intrauterine Contraceptive System (SKYLA), 13.5 mg, effective 7/1/2013, describes the product that is the subject of this application.

2. Discontinue Q0090 effective 12/31/2013.

3. Establish JXXXX Levonorgestrel-Releasing Intrauterine Contraceptive System (SKYLA), 13.5 mg. Effective 1/1/2014

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item #14
May 8, 2013

Attachment# 13.004
Topic/Issue:

Request to establish a new Level II HCPCS code to identify vincristine sulfate liposome injection for intravenous infusion, Trade Name Marqibo®. Applicant's suggested language: "vincristine sulfate liposome injection, 5 mg".

Background/Discussion:

According to the requester, Marqibo is the only sphinogomyelin-cholesterol liposome formulation of vincristine sulfate. It is the first and only drug approved in the U.S. indicated to treat adult patients with Philadelphia chromosome-negative (Ph-) acute lymphoblastic leukemia (ALL) in second or greater relapse or whose disease has progressed following two or more anti-leukemia therapies. Despite achievement of an initial remission, the vast majority of adults with Ph- ALL will relapse, or are refractory to conventional treatments. Marqibo provides an important salvage therapy for these patients. The novel liposomal formulation of Marqibo differs from conventional, non-liposomal vincristine in indication, formulation, patient dosing, drug delivery, and in the resulting patient clinical outcomes.

The recommended dose of Marqibo is 2.25 mg/m^2 intravenously over 1 hour every 7 days. Marqibo is prepared from components of the Marqibo Kit (contents which are detailed in the Level II HCPCS application). After preparation, each single-dose vial of Marqibo contains 5 mg/31mL (0.16 mg/mL) vincristine sulfate, 500 mg mannitol, 73.5 sphingomyelin, 29.5 mg cholesterol, 36 mg sodium citrate, 38 mg citric acid, 355 mg sodium phosphate, and 225 mg sodium chloride.

Currently, there are no Level II codes to describe a liposomal formulation of vincristine sulfate. The applicant requests that CMS issue a unique Level II HCPCS code to distinguish the liposomal formulation from the non-liposomal formulation of vincristine sulfate.

Preliminary Decision:

Establish J93XX "Injection, Vincristine Sulfate Liposome, 1 mg". Effective 1/1/14

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item #15
May 8, 2013

Attachment# 13.014
Topic/Issue:

Request to establish a new Level II HCPCS code to identify Ziv-Aflibercept for injection. Trade Name: ZALTRAP®. Applicant's suggested language: J9XXX Injection, Ziv-Aflibercept, 10 MG.

Background/Discussion:

According to the requester ZALTRAP® is a recombinant fusion protein consisting of Vascular Endothelial Growth Factor (VEGF)-binding portions from the extracellular domains of human VEGF Receptors 1 and 2 fused to the Fc portion of the human lgG1. ZALTRAP® is approved in combination with 5-fluorouracil, leucovorin, irinotecan-(FOLFIRI) in patients with metastatic colorectal cancer (mCRC) that is resistant to or has progressed following an oxaliplatin-containing regimen.

ZALTRAP® is supplied in single-use vials of 100mg per 4mL (25mg per mL) and 200mg per 8 mL (25mg per mL) and requires dilution before administration. ZALTRAP® is required to be diluted with 0.9% sodium chloride, USP or 5% dextrose solution for injection, USP to achieve a final concentration of 0.6-8mg/mL before administration as an intravenous infusion. Dosage is 4mg/kg as an intravenous infusion over 1 hour every 2 weeks. ZALTRAP® is a hyperosmolar solution. ZALTRAP® is formulated for administration only as an intravenous infusion after dilution. ZALTRAP® or diluted ZALTRAP® should not be administered by any other route.

Preliminary Decision:

Establish J9XXX Injection, Ziv-Aflibercept, 1 mg. Effective 1/1/2014

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 #16
May 8, 2013

Attachment# 13.020
Topic/Issue:

Request to establish a new HCPCS code to identify Trastuzumab Emtansine, Trade Name: KADCYLA™. Applicant's suggested language: "Injection, Trastuzumab Emtansine, 1 mg."
Background/Discussion:

According to the requester, Trastuzumab Emtansine is a HER2-targeted antibody-drug conjugate (ADC) which contains the humanized anti-HER2 IgG1, trastuzumab, covalently linked to the microtubule inhibitory drug DM1 (a maytansine derivative) via the stable thioether linker MCC (4-[N-maleimidomethyl] cyclohexane-1-carbolylate). Conjugation of DM1 to trastuzumab confers selectivity of the cytotoxic agent for HER2-overexpressing tumor cells, thereby increasing intracellular delivery of DM1 directly to malignant cells. Upon binding to HER2, KADCYLA undergoes receptor-mediated internalization and subsequent lysosomal degradation, resulting in intracellular release of DM1-containing cytotoxic catabolites. KADCYLA has the mechanisms of action of both trastuzumab and DM1. KADCYLA, as a single agent, is indicated for the treatment of patients with HER2-positive, unrespectable locally advanced or metastatic breast cancer who have received prior treatment with trastuzumab and a taxane. KADCYLA is supplied as a preservative-free lyophilized powder in a 100 mg or 160 mg single use vial, one vial per carton. The recommended dose of KADCYLA is 3.6 mg/kg given as an intravenous infusion every 3 weeks (21-day cycle) until disease progression or unacceptable toxicity

Preliminary Decision:

Establish JXXXX Injection, Ado-trastuzumab Emtansine, 1 mg. Effective 1/1/2014

Summary of Primary Speaker Comments at the Public Meeting:

The applicant agrees with CMS' preliminary decision to establish a code, and with the proposed code language.

HCPCS Public Meeting Agenda Item #17
May 8, 2013

Attachment# 13.021
Topic/Issue:

Request to establish a new Level II HCPCS code to describe Pertuzumab, Trade Name: PERJETA®. Applicant's suggested language: "Injection, pertuzumab, 10 mg."

Background/Discussion:

According to the requester, PERJETA is a recombinant monoclonal antibody indicated for use in combination with trastuzumab and docetaxel for the treatment of patients with HER2-positive metastatic breast cancer who have not received prior anti-HER2 therapy or chemotherapy for metastatic disease. PERJETA is supplied in a single-use vial of 420 mg per 14 mL (30 mg/mL). The initial dose of PERJETA is 840 mg administered as a 60-minute intravenous infusion, followed every 3 weeks thereafter by 420 mg administered as a 30 to 60-minute intravenous infusion. When administered with PERJETA, the recommended initial dose of trastuzumab is 8 mg/kg administered as a 90-minute intravenous infusion, followed every 3 weeks thereafter by a dose of 6 mg/kg administered as an intravenous infusion over 30 to 90 minutes. When administered with PERJETA, the recommended initial dose of docetaxel is 75 mg/m^2 administered as an intravenous infusion. The dose may be escalated to 100 mg/m^2 administered every 3 weeks if the initial dose is well tolerated.

Preliminary Decision:

Establish JXXXX Injection, Pertuzumab, 1 mg. Effective 1/1/2014

Summary of Primary Speaker Comments at the Public Meeting:

The applicant agreed with the preliminary decision to establish a J code for Perjeta, but suggested that the dose descriptor read "10 mg", rather than the proposed "1 mg", to avoid potential billing errors.

HCPCS Public Meeting Agenda Item #18
May 8, 2013

Attachment# 13.031
Topic/Issue:

Request to establish a new Level II HCPCS code to identify pooled plasma (Human), Solvent/Detergent treated, with a billing unit of 200 mL. Trade name: OCTAPLAS®. Applicant's suggested language: "Injection, pooled plasma (human), solvent/detergent treated (Octaplas), 200 mL"

Background/Discussion:

According to the requester, Octaplas® is a sterile, pyrogen free, frozen solution of solvent/detergent (S/D) treated pooled human plasma, which replaces human plasma proteins. Octaplas® is a biological product, not a blood product, and it will be indicated for: (1) replacement of multiple coagulation factors in patients with acquired deficiencies due to liver disease or undergoing cardiac surgery or liver transplant, and (2) transfusion or plasma exchange in patients with thrombotic thrombocytopenic purpura (TTP). Each lot of Octaplas® is manufactured from pooled plasma of a single ABO blood group (A, B, AB, or O). Octaplas® will be the only FDA licensed (as a biological) solvent/detergent (S/D) treated, pooled human plasma available in the U.S.

Octaplas® may be used intravenously for transfusions or for plasma exchange. Initially it should be infused at 10 to 15 mL Octaplas® per kilogram body weight. If hemostasis is not achieved, use higher doses. A patient's dose should be based on desired clinical response. Patients responses should be monitored, including measurement of activated partial thromboplastin time (aPTT), prothrombin time (PT), and/or specific coagulation factors. In transfusion or plasma exchange in patients with TTP, Octaplas® completely replaces plasma volume removed during plasmapheresis with Octaplas®. Generally, 1 to 1.5 plasma volumes corresponds to 40 to 60 milliliters per kg. It is supplied in polyvinyl chloride blood bags containing 200 mL frozen solution. A separate code for Octaplas ® with a billing unit of 200mL will enhance access to this life-saving drug.

Preliminary Decision:

Existing code P9023 "Plasma, Pooled Multiple Donor, Solvent/Detergent Treated, Frozen, Each Unit" adequately describes the product that is the subject of this application.

Summary of Primary Speaker Comments at the Public Meeting:

The applicant disagreed with CMS' preliminary decision stating that: 1) Octaplas was approved by the FDA as a biological product and should be added as such; 2) does not fit within the CMS definition of "blood and blood products" such that a "P" code is inappropriate for the product;

and Octaplas does not fit within the FDA definition of blood or blood component. The speaker reiterated the original request to establish a “J” code for Octaplas.

HCPCS Public Meeting Agenda Item #19
May 8, 2013

Attachment# 13.018
Topic/Issue:

Request to establish a new Level II HCPCS code to identify carfilzomab, Trade Name: Kyprolis™. Applicant's suggested language: J9XXX "Injection, carfilzomib, 1mg".

Background/Discussion:

According to the requester KRYPROLIS™ is a tetrapeptide epoxyketone proteasome inhibitor that selectively and irreversibly binds to the N-terminal threonine-containing active sites of the 20S proteasome, the proteolytic core particle within 26s proteasome. It is indicated for the treatment of patients with multiple myeloma who have received at least 2 prior therapies, including bortezomib and an immunomodulatory agent, and have demonstrated disease progression on or within 60 days of completion of the last therapy.

KYPROLIS™ is administered intravenously over 2 to 10 minutes, on two consecutive days each week for three weeks (Days 1, 2, 8, 9, 15 and 16), followed by a 12-day rest period (Days 17 to 28). Each 28-day period is considered one treatment cycle. In Cycle 1, KYPROLIS™ is administered at a dose of 20 mg/m^2. If tolerated in Cycle 1, the dose should be escalated to 27 mg/m^2 beginning in Cycle 2, and continued at 27 mg/m^2 in subsequent cycles.

KYPROLIS™ is supplied as an individually cartoned single-use vial containing a dose of 60 mg of carfilzomib.

There is no existing coded that describes KYPROLIS™.

Preliminary Decision:

Establish J9XXX Injection, Carfilzomab, 1 mg. Effective 1/1/2014

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item #20
May 8, 2013

Attachment# 13.046
Topic/Issue:

Third request since 2011 to establish a new Level II HCPCS J code for Physician's office use to identify a topical anesthetic patch containing lidocaine 70mg/tetracaine 70mg, with a Controlled Heat-Assisted Drug Delivery(CHADD®) device. Trade name: Synera.

Background/Discussion:

According to the requester, SYNERA is a topical anesthetic patch with a novel, controlled heat-assisted drug delivery device (CHADD®) that enhances the delivery of local anesthetics, a eutectic mixture of lidocaine and tetracaine. It is indicated for use on intact skin to provide local dermal analgesia for superficial venous access and superficial dermatological procedures such as excision, electrodessication and shave biopsies. Synera is supplied as individual packets containing one patch, or as a box of 10 individually packaged patches. The requester comments that, while there is currently a C code for hospital outpatient use, there is no corresponding J code for physician office/clinic use, and "health plans that receive miscellaneous (NOC) J-code claims submissions must spend additional time and money adjudicating claims".

Preliminary Decision:

Existing code C9285 "Lidicaine 7 mg/Tetracaine 70 mg, per patch" adequately describes the product that is the subject of this request, and is available for assignment by insurers if they deem appropriate. A national program operating need to establish a HCPCS Level II "J" code for Physician's office use was not identified by Medicare, Medicaid or the Private Insurance sector. When this product is used in a physician's office, it is included in the practice expense, and therefore separate billing would be redundant.

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item #21
May 8, 2013

Attachment# 13.005
Topic/Issue:

Request to establish a new Level II HCPCS code to identify taliglucerase alfa, Trade Name: Elelyso. Applicant's suggested language: "Injection, taliglucerase alfa, 100 units".

Background/Discussion:

According to the requester Taligucerase alfa is a hydrolytic lysosomal glucocerebroside-specific enzyme for intravenous infusion, is a recombinant active form of the lysosmal enzyme, beta-glucocerebrosidase. ELEYSO catalyzes the hydrolysis of glucocerebroside to glucose and ceramide. It is indicated for long-term enzyme replacement therapy (ERT) for adults with a confirmed diagnosis of Type 1 Gaucher disease. The recommended dose is 60 units per kg of patient body weight once every two weeks as a 60-120 minute intravenous infusion. ELEYSO is supplied as a lyophilized powder in 200 unit single use vials. The requester comments that there are no other taliglucerase alfa products approved in the United States. The reqester suggests that the 100 unit descriptor be awarded to maintain consistency with the descriptor of the recently issued C code for taliglucerase alfa: C9294 (Injection, taliglucerase alfa, 100 units).

Preliminary Decision:

Establish JXXXX "Injection, Taliglucerace alfa, 10 units". Effective 1/1/2014

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item #22
May 8, 2013

Attachment# 13.006
Topic/Issue:

Request to establish a HCPCS Level II code to identify Sodium Chloride Injection, USP, 0.9% prefilled syringes. Applicant's suggested language: JXXXX Sodium Chloride Injection, USP, 0.9% per ml".

Background/Discussion:

According to the requester Sodium Chloride Injection, USP, 0.9% prefilled syringes are used for diluting or dissolving drugs for intravenous, intramuscular or subcutaneous injection. It is also used as a flush syringe to maintain the patency of indwelling intravenous access devices (IVADs).

Medifil's sodium chloride injection, USP, 0.9% is packaged in a clear plastic hypodermic syringe. There are two syringe sizes (6mL and 12mL), intended for single use and subsequent disposal. The fill volumes for the 6 mL syringe are: 1mL, 2mL, 2.5mL, 3mL, and 5mL. The fill for the 12mL syringes are 3mL, 5mL, and 10mL. The filled 6mL and 12mL syringes are packaged individually in plastic pouches and 60 syringes are packaged into each dispenser.

Currently this product does not have a J-Code and must be billed utilizing J3490. The use of a "not otherwise classified" code (J3490) results in manual claims processing, which causes inordinate delays in claims and payment processing, errors in determining an accurate payment rate, and a high frequency of "pending" and "denial" rates for an approved medical therapy. Also codes J7030, J7040 and J7050 which are used for normal saline infusion describe products that 250 mL or larger. A4216 describes products that are 10mL and doesn't adequately allow for billing of a prefilled syringe. A J code would alleviate these problems.

Preliminary Decision:

Existing code A4216, Sterile water, saline and/or dextrose, diluent/flush, 10 ml 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 #23
May 8, 2013

Attachment# 13.033
Topic/Issue:

Request to establish a new Level II HCPCS code to identify Loxapine inhalation powder for oral inhalation, Trade Name ADASUVE®. Applicant's suggested language: "Lozapine, inhalation powder, 10mg."

Background/Discussion:

According to the requester, loxapine inhalation powder for oral inhalation (ADASUVE®) is a typical antipsychotic: "Physicians will prescribe ADASUVE® for patients in healthcare settings participating in the REMS, which would include emergency departments (general hospitals), psychiatric emergency departments, and inpatient psychiatric settings. It is indicated for the rapid management of acute agitation in persons with schizophrenia or bipolar 1 disorder." The mechanism of action of loxapine in the treatment of agitation associated with schizophrenia is unknown. Use of loxapine is limited to health care facilities enrolled in the Risk Evaluation and Mitigation Strategy "REMS". ADASUVE must be administered only by a healthcare professional, consistent with the REMS. It is administered by oral inhalation only. Only 1 dose should be administered within a 24-hour period. ADASUVE is supplied in a single-use, disposable inhaler containing 10 mg of loxapine base. It is a drug-device combination product that provides rapid systemic delivery by inhalation of a thermally-generated aerosol of loxapine. To dose, patients take a single breath through the mouthpiece. The applicant comments that there are no existing HCPCS "J" codes specifically for loxapine, and the two "Not Otherwise Classified" codes for inhalation drugs indicate inhalation through DME, whereas the single-use inhaler system used with ADUSIVE is not DME.

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 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. According to the speaker, the FDA label requires that Adasuve be administered by a healthcare professional and it is only available in facilities that have met REMS requirement. Adasuve is used in the ED and inpatient setting for the treatment of agitation in persons with bipolar disorder and schizophrenia. Also according to the applicant, not all patients that receive Adasuve are admitted via the E.R., and a HCPCS "J" code is needed to bill payers for Adasuve administration for those who were not admitted.

HCPCS Public Meeting Agenda Item #24
May 8, 2013

Attachment# 13.022
Topic/Issue:

Request to establish a new Level II HCPCS code to identify Once-Monthly Aripiprazole for Extended Release Injectable Suspension, Trade Name: Abilify Maintena™. Applicant's suggested language: JXXXX "Injection, Aripiprazole Suspension Extended Release, 1 mg".

Background/Discussion:

According to the requester ABILIFY MAINTENA™ is a once-monthly atypical antipsychotic intramuscular injection for the treatment of schizophrenia in adults.

The mechanism of action of aripiprazole in the treatment of schizophrenia is unknown. However, the efficacy of aripiprazole may be mediated through a combination of partial agonist activity at D2 and 5-HT1A receptors and antagonist activity at 5-HT2A receptors. ABILIFY MAINTENA™ is believed to be a partial agonist at the D2 receptor, while other antipsychotics are believed to be antagonist at the D2 receptor. Aripiprazole' s relatively low affinity for muscarinic, cholinergic, and histaminergic receptors may be translated into its clinical profile, including low potential for cognitive impairment and wright gain that is lower than in other antipsychotics. Neither aripiprazole oral nor short-acting injectable aripiprazole (J0400 *injectable, aripiprazole, intramuscular, 0.25 mg*) are interchangeable with ABILIFY MAINTENA™.

ABILIFY MAINTENA™ is available in 400 mg and 300 mg vials and is provided as a lyophilized powder for reconstitution. The lyophilized powder is packaged as kits, with diluent and syringes included. The recommended starting and maintenance dose of ABILIFY MAINTENA™ is 400 mg monthly. After the first ABILIFY MAINTENA™ injection, continue treatment with oral aripiprazole or other oral antipsychotic for 14 consecutive days to maintain therapeutic antipsychotic concentration during initiation of therapy.

Preliminary Decision:

Establish JXXXX Injection, Aripiprazole, Extended Release, 1 mg. Effective 1/1/2014

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item, however; the applicant submitted written comments in agreement with CMS' workgroup preliminary decision.

HCPCS Public Meeting Agenda Item #25
May 8, 2013

Attachment# 13.045
Topic/Issue:

Request to establish a new Level II HCPCS code to identify Ocriplasmin intravitreal injection, Trade Name: Jetrea®. Applicant's suggested language: JXXXX, Ocriplasmin Intravitreal Injection, per 0.125mg".

Background/Discussion:

According to the requester JETREA® has proteolytic activity against protein components of the vitreous body and the vitreoretinal interface (VRI) (eg. Laminin, fibronectin and collagen), thereby dissolving the protein matrix responsible for the vitreomacular adhesion, (VMA). It is the first and only pharmacologic/biologic option approved for the treatment of symptomatic VMA. VMA occurs when the area of remaining vitreous attachment is in the macula. It can progress to symptomatic VMA. Patients with symptomatic VMA can present with visual distortion, decreased visual activity, and/or central vision loss. Previously, surgical vitrectomy has been the only intervention available for the treatment of symptomatic VMA.

JETREA® comes in a single-use vials (one vial per eye)containing JETREA 0.5 mg in 0.2mL solution for intravitreal injection to the affected eye once as a single dose. A dilution process with 0.2 mL of sterile, preservative-free saline is required for administration of JETREA

Preliminary Decision:

Establish JXXXX: Injection, Ocriplasmin, 0.125mg. Effective 1/1/2014

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker made a brief comment agreeing with CMS' preliminary decision.

HCPCS Public Meeting Agenda Item #26
May 8, 2013

Attachment# 13.024
Topic/Issue:

Request to establish a new Level II HCPCS code to identify Immune Globulin, Intravenous [Human], Trade Name: BIVIGAM™. Applicant's suggested language: JXXXX "Injection, immune globulin (Bivigam), intravenous, non-lyophilized (e.g., liquid), 500 mg."

Background/Discussion:

According to the requester, BIVIGAM is a purified, sterile, ready-to-use preparation of concentrated human immunoglobulin G (lgG) antibodies. BIVIGAM™ is a replacement therapy indicated for the treatment of primary humoral immunodeficiency (PI), including, but not limited to the humoral immune defect in common variable immunodeficiency (CVID); X-linked agammaglobulinemia; congenital agammaglobulinemia; Wiskott-Aldrich syndrome; and severe combined immunodeficiences. BIVIGAM™ is supplied as a 10% liquid lgG solution in vials containing either 5g in 50 mL solution or 10g in 100 mL solution, in cartons of 10 individually packaged vials of 50 mL solution or cartons of 10 individually packaged vials of 100 mL solution. Dosage for PI is 300 to 800 mg/kg via IV infusion every 3 to 4 weeks. For patients at risk of renal dysfunction or thrombotic events, administer at the minimum infusion rate practicable. The requester comments that there is no existing code that specifically describes BIVIGAM™.

Preliminary Decision:

Establish JXXXX Injection, Immune Globulin (Bivigam), 500 mg. Effective 1/1/2014

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item #27
May 8, 2013

Attachment# 13.028
Topic/Issue:

Request to establish a Level II HCPCS code to identify Teduglutide [rDNA origin] for subcutaneous administration only, Trade Name: GATTEX®. Applicant's suggested language: "(teduglutide [rDNA origin]) for injection".

Background/Discussion:

According to the requester, the active ingredient in GATTEX (teduglutide [rDNAorigin]) is a 33 amino acid glucagon-like peptide-2 (GLP-2) analog manufactured using a strain of Eschericia coli modified by recombinant DNA technology. This analog is known to increase intestinal and portal blood flow, and inhibit gastric acid secretion. It has been developed to improve intestinal absorption and reduce dependence on parenteral support. It is indicated for the treatment of adult patients with Short Bowel Syndrome (SBS) who are dependent on parenteral support. GATTEX for injection is supplied in single-use vials containing 5 mg of teduglutide as a lyophilized powder to be reconstituted with 0.5 mL Sterile Water for injection. Upon reconstitution with the 0.5 mL Sterile Water provided in the prefilled syringe, and according to the applicant, a maximum of 0.38 mL of the reconstituted solution which contains 3.8 mg of teduglutide can be withdrawn from the vial for dosing. GATTEX should be used within 3 hours after reconstitution. The recommended daily dose of GATTEX is 0.05 mg/kg body weight administered by subcutaneous injection once daily.

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 Gattex.

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item #28
May 8, 2013

Attachment#13.015
Topic/Issue:

Request to establish a new level II HCPCS code to identify Gadoterate Meglumine (DOTAREM).

Background/Discussion:

According to the requester, Dotarem® is a paramagnetic extracellular, ionic, macrocyclic MRI contrast agent. It is indicated for intravenous use with magnetic resonance imaging (MRI) in brain (intracranial), spine and associated tissues in adults and pediatric patients (from neonates to 1 years of age) to detect and visualize areas with disruption of the blood brain barrier (BBB) and/or abnormal vascularity. According to the requester, a distinct HCPCS code is necessary to facilitate proper billing and tracking of Dotarem. Each vial or pre-filled syringe contains the active ingredient gadoteric acid. For pediatric use, the safety and efficacy of Dotarem at a single dose of 0.1 mmoll/kg have been established in children from neonates to 17 years of age. No dosage adjustment is necessary in this population. For geriatric use no dosage adjustment is necessary. For renal impairment no dosage adjustment is recommended. The dosing guidelines for adults and children (neonates and older), the recommended dose of Dotarem is 0.2 mL/kg (0.1 mmol/kg) body weight administered as an intravenous bolus injection, manually or by power injector, at a flow rate of approximately 2 mL/second for adults and 1-2 mL/second for children. Dotarem is supplied in 1. 5 mL, 10 mL, 15 mL or 20 mL glass vials 2 and in 10 mL, 15 mL or 20 mL glass prefilled syringe.

Preliminary Decision:

Establish A95XX "Injection, Gadoterate Meglumine, 0.1 mL", effective 1/1/2014.

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item #29
May 8, 2013

Attachment# 13.029
Topic/Issue:

Request to revise the dose descriptor of existing code J0152 from 30 mg to 1 mg. In other words, revise existing code J0152 which currently reads: "Injection, Adenosine for Diagnostic use, 30 mg (not to be used to report any adenosine phosphate compounds; instead use A9270)"; to instead read: "Injection, adenosine for diagnostic use, 1 mg (not to be used to report any adenosine phosphate compounds; instead use A9270).

Background/Discussion:

According to the applicant, this request to revise the dose descriptor of HCPCS code J0152 from 30 mg to 1 mg is being made because the dose of Adenosine associated with the treatment of any given patient may not be 30 mg, or even a multiple of 30 mg. The requested revision would enable exact reporting of the dosage used with each patient. Adenoscan (approved for intravenous infusion only), is indicated as an adjunct to thallium-201 myocardial perfusion scintigraphy in patients unable to exercise adequately. Adenoscan is supplied as 20 mL and 30 mL vials of sterile solution in normal saline, packaged as 60 mg/20 mL (3mg/mL) single-dose vials, packaged individually in packs of (10) 20 mL vials per carton; and 90 mg/30 mL (3mg/mL) single-dose vials, packaged individually in packs of (10) 30 mL vials per carton. Adenoscan should be given as a continuous peripheral intravenous infusion. The recommended intravenous dose for adults is 140 mcg/kg/min infused for 6 minutes (total dose of 0.84 mg/kg).

Preliminary Decision:

Discontinue existing code J0152 "Injection, Adenosine For Diagnostic Use, 30 mg (not to be used to report any Adenosine Phosphate Compounds; Instead use A9270), effective 12/31/13.

Establish new code JXXXX to read: "Injection, Adenosine For Diagnostic Use, 1 mg (not to be used to report any Adenosine Phosphate Compounds; Instead use A9270), effective 1/1/14.

Existing code J0150 "Injection, Adenosine for Therapeutic Use, 6 mg (not to be used to report any Adenosine Phosphate Compounds; Instead use A9270)" is available for assignment to report Adenosine for therapeutic use.

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item #30

May 8, 2013

Attachment# 13.049

Topic/Issue:

Request to establish a new Level II HCPCS code to identify Technetium Tc 99m Tilmanocept Injection, Brand Name: Lymphoseek®. Applicant's suggested language: "TechnetiumTC 99m Tilmanocept, Diagnostic, per study dose".

Background/Discussion:

According to the requester, Technetium TC 99m Tilmanocept Injection is a first-in-class receptor-targeted lymphatic mapping agent indicated for lymphatic mapping with a hand-held gamma counter to assist in the localization of lymph nodes, draining a primary tumor site in patients with breast cancer or melanoma. Tilmanocept transits and accumulates in lymphatic tissue by selectively and tightly binding to mannose binding receptors located within tumor-draining lymph nodes. It is specifically designed to assist in the staging of breast cancer and melanoma. It is injected intradermally, subcutaneously, subareolarly or peritumorally. Lymphoseek® is primarily distributed in unit-dose syringes with a recommended dosage of 0.5 milliCuries equivalent to 50 micrograms as a mass dose. The recommended dose is 0.5 mCi (18.5 MBq), this comprises 50 mcg of Tilmanocept, administered at least 15 minutes prior to initiation of intraoperative lymphatic mapping. There are currently no HCPCS codes which describe Technetium Tc 99m Timanocept.

Preliminary Decision:

A national program operating need to establish a HCPCS Level II code to identify Technetium TC 99m Tilmanocept was not identified by Medicare, Medicaid or the Private Insurance Sector. CMS recommends that the applicant consider whether it may be appropriate to submit an application to CMS' Pass-Through coding process.

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with CMS' preliminary decision. According to the speaker it is necessary that Tc 99m tilmanocept receive an "A" code. The speaker stated all other diagnostic radiopharmaceuticals have A-codes, including technetium sulfur colloid, the agent historically used for lymph node mapping. Not to adopt a radiopharmaceutical "A" code will lead to confusion. Technetium Tc99m tilmanocept will be used outside the hospital setting.

HCPCS Public Meeting Agenda Item #31
May 8, 2013

Attachment# 13.047

Topic/Issue:

Request to revise existing Level II HCPCS code J7507 which currently reads: "Tacrolimus, oral, per 1 mg." to instead read: "Tacrolimus, immediate release, oral, per 1 mg"; in order to set up a distinction between Prograf® and an extended release version of Tacrolimus (which is awaiting FDA clearance).

Background/Discussion:

According to the requester, existing code J7507 "Tacrolimus, Oral, Per 1 mg" describes Tacrolimus capsules (Prograf® and its generic equivalents) immediate release immunosuppressant's, which are administered twice daily, to prevent the rejection of transplanted kidneys in adult patients, and to prevent the rejection of transplanted livers in adult male patients.

Tacrolimus extended release is anticipated to have FDA clearance for different indications than Prograf® and its generic equivalents. Specifically, Prograf® and its generic equivalents are indicated for kidney, liver, and heart transplant patients. However for Tacrolimus extended release, FDA clearance is being sought only for adult male liver and adult kidney transplant patients. Furthermore, tacrolimus extended release contains Ethylcellulose, a new, proprietary excipient which is not in Prograf®, and which makes once-daily dosing possible by releasing tacrolimus gradually, over time.

The requester suggests revising existing code J7507 to specify an immediate release formulation, so that this code could not be used to bill for extended release tacrolimus, once it is FDA cleared and marketed. A separate HCPCS code application for extended release Tacrolimus would be submitted to CMS once it is FDA cleared.

Preliminary Decision:

A national program operating need to revise existing code J7507 was not identified by Medicare, Medicaid or the Private Insurance sector.

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

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 hereafter 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 - Injectable or intravenous drugs as well as non-injectable or non-intravenous drugs are administered incident-to a physician's service. Under the “incident-to” provision, the physician must incur a cost for the drug, and must 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 - DME drugs are administered through a covered item of DME, such as a nebulizer or pump; and
- Drugs covered by statute - Drugs specifically covered by statute include 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.

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. The statutory term, average wholesale price (AWP), 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 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 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

Dispensing Fees

During calendar year (CY) 2010, Medicare paid an initial dispensing fee of $57.00 to a pharmacy for the initial 30-day period of inhalation drugs furnished through DME regardless of the number of shipments or drugs dispensed during that time and regardless of the number of pharmacies used by a beneficiary during that time. This dispensing fee is a one-time fee applicable only to beneficiaries who are using inhalation drugs for the first time as Medicare beneficiaries.

During CY 2010, Medicare also paid a dispensing fee of $33.00 to a pharmacy for a 30-day period of inhalation drugs furnished through DME regardless of the number of shipments or drugs dispensed during that time and regardless of the number of pharmacies used by a beneficiary during that time. This dispensing fee will be paid for a 30-day period of inhalation drugs, except in those circumstances where an initial 30-day dispensing fee is applicable instead.

During CY 2010, the pharmacy also received a dispensing fee of $66.00 for each dispensed 90-day period of inhalation drugs furnished through DME regardless of the number of shipments or drugs dispensed during that time and regardless of the number of pharmacies used by a beneficiary during that time.

Supplying Fees

For 2005, Medicare provided a supplying fee of $24 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. The pharmacy also received a supplying fee of $50 for the initial supplied prescription of the above-mentioned drugs during the 1st month following the beneficiary's transplant.

During CY 2010, Medicare paid a supplying fee of $24.00 for the first prescription of immunosuppressive, oral anti-cancer, or oral anti-emetic drugs supplied to a beneficiary during a 30-day period. Each pharmacy that supplies the

above-mentioned drugs to a beneficiary during a 30-day period will be eligible for one $24 fee in that 30-day period. The pharmacy will be limited to one $24 fee per 30-day period even if the pharmacy supplies more than one category of the above-mentioned drugs (for example, an oral anti-cancer drug and an oral anti-emetic drug) to a beneficiary.

Additionally, during CY 2010, Medicare paid a supplying fee of $16.00 to a pharmacy for each subsequent prescription, after the first one, of immunosuppressive, oral anti-cancer, or oral anti-emetic drugs supplied to a beneficiary during a 30-day period. Medicare pays the supplying fee for each prescription, including prescriptions for different strengths of the same drug supplied on the same day (for example, prescriptions for 100mg tablets and 5 mg tablets).

Furnishing Fees

In 2005, Medicare began 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. In each year, the prior year's fee is increased by the percentage increase in the consumer price index for medical care for the 12-month period ending June of the previous year. For CY 2010, this fee was $0.17 per unit.

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.

Please see the following Web links for additional information regarding Part versus Part D coverage:

http://www.cms.hhs.gov/PrescriptionDrugCovContra

http://www.cms.hhs.gov/Pharmacy

Contact Information

Anne Hauswald, Acting Director
Division of Ambulatory Services (DAS)
Hospital and Ambulatory Policy Group (HAPG)
Center for Medicare (CM)
Centers for Medicare and Medicaid Services (CMS)
Phone: (410)786-4546
E-Mail: anne-e-tayloe.hauswald@cms.hhs.gov