Centers for Medicare & Medicaid Services (CMS)
Healthcare Common Procedure Coding System (HCPCS)
Public Meeting Summary Report
Drugs, Biologicals, and Radiopharmaceuticals
Wednesday, May 5, 2010

Introduction and Overview

Approximately 40 people attended. The agenda included 6 items.

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

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 makes 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.hhs.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.hhs.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.hhs.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.hhs.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.hhs.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
Wednesday, May 5, 2010 9:00 am – 12:00 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's preliminary coding decision is provided. An overview of Medicare pricing/payment, methodology is also attached to this agenda. 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# 10.006
Request to establish 3 codes for cryopreserved human skin, trade name: TheraSkin. Applicant's suggested language: QXXX1 CRYOPRESERVED HUMAN SKIN, THERASKIN, EQUAL TO OR LESS THAN 24 SQ. CM; QXXX2 CRYOPRESERVED HUMAN SKIN, THERASKIN, GREATER THAN 24 SQ. CM. BUT EQUAL TO OR LESS THAN 48 SQ. CM.; QXXX3 CRYOPRESERVED HUMAN SKIN, THERASKIN, GREATER THAN 48 SQ. CM.

Primary Speaker: Dr. Adam Landsman of Beth Israel Deaconess Medical Center

AGENDA ITEM #2
Attachment# 10.040
Request to establish a Level II HCPCS J code for Hyalomatrix® PA. Applicant's recommended language: "skin substitute, Hyalomatrix PA, per sq cm".

No Primary Speaker

AGENDA ITEM #3
Attachment# 10.050
Request to
1) Revise the verbiage of existing code Q4111 which currently reads; "SKIN SUBSTITUTE, GAMMAGRAFT, PER SQUARE CENTIMETER" to instead read: Allograft, human skin irradiated, GammaGraft, per square centimeter" to "better reflect the composition of the material" and thereby accurately reflect that GammaGraft is a human skin allograft and not an engineered skin substitute.
And Revise the verbiage of codes Q4112, Q4113 and Q4115 to help make a distinction between traditional (cadaver-derived) allograft material and materials that have been "engineered: to "replicate the performance of allograft skin" and in that sense, are not allografts, but are "skin substitutes".

2) Revise the verbiage of code Q4112, ALLOGRAFT, SKIN SUBSTITUTE, CYMETRA, INJECTABLE, 1CC, by omitting the word "Allograft";

3) Revise the verbiage of code Q4113 ALLOGRAFT, SUBSTITUTE, GRAFTJACKET EXPRESS, PER 1 CC, by omitting the word "Allograft";

4) Revise the verbiage of code Q4115 SKIN SUBSTITUTE, HUMAN SKIN FRESH OR FROZEN, ALLOSKIN, PER SQUARE CENTIMETER, by omitting the term "skin substitute". Note that in this code series, the applicant suggest leaving the verbiage of code Q4114 INTEGRA FLOWABLE WOUND MATRIX, INJECTABLE, 1 CC as is.

Primary Speaker: Dr. Ernest Manders of Promethean LifeSciences, Inc.

AGENDA ITEM #4
Attachment# 10.072
Request to establish a code for a reconstructive tissue matrix, trade name: Strattice™. Applicant's suggested language: "Tissue, Strattice, per square centimeter".

Primary Speaker: Dr. Ronald Silverman of University of Maryland School of Medicine

AGENDA ITEM #5
Attachment# 10.075
Request to establish a code for Conexa Reconstructive Tissue Matrix, Trade Name: Conexa Reconstructive Tissue Matrix (Generic: Surgical Mesh). Applicant's suggested language: Qxxxx Skin substitute, Conexa, per square centimeter

Primary Speaker: Dr. Robert Nowinski of Ohio State University

AGENDA ITEM #6
Attachment# 10.061
Request to establish a code for UBM (urinary bladder matrix), trade name: MatriStem® MicroMatrix™. Applicant's suggested language: "'Skin substitue, matriStem MicroMatrix, 3 mg per square centimeter".

Attachment# 10.062

Request to establish a code for UBM (urinary bladder matrix), trade name: MatriStem® Wound Sheet. Applicant's suggested language: "Skin substitute, MatriStem Wound Matrix, per Square Centimeter".

Attachment# 10.063

Request to establish a single code to identify UBM (urinary bladder matrix) surgical matrix devices, trade names: MatriStem® Surgical Matrix RS (2-layer); MatriStem® Plastic Surgery Matrix (4-layer); and MatriStem® Plastic Surgery Matrix XS (6-layer).

Attachment# 10.064

Request to establish a code for UBM (urinary bladder matrix), trade name: MatriStem® Burn Matrix. Applicant's suggested language: "Skin substitute, MatriStem Burn Matrix, per square centimeter".

Primary Speaker: Dr. Howard Kimmel of Case Western Reserve University School of Medicine

HCPCS Public Meeting Agenda Item #1
May 5, 2010

Attachment# 10.006

Topic/Issue:

Request to establish 3 codes for cryopreserved human skin, trade name: TheraSkin. Applicant's suggested language: QXXX1 CRYOPRESERVED HUMAN SKIN, THERASKIN, EQUAL TO OR LESS THAN 24 SQ. CM; QXXX2 CRYOPRESERVED HUMAN SKIN, THERASKIN, GREATER THAN 24 SQ. CM. BUT EQUAL TO OR LESS THAN 48 SQ. CM; QXXX3 CRYOPRESERVED HUMAN SKIN, THERASKIN, GREATER THAN 48 SQ. CM.

Background/Discussion:

According to the applicant, TheraSkin is cryopreserved human skin procured from consented and screened tissue donors that is used to provide a physiological and mechanical barrier that reduces environmental contamination and assists in the promotion of granulation tissue and epithelialization. The finished allograft is between 0.2 to 0.5 mm in thickness and contains both human epidermis and dermis tissues. The product is provided in a meshed form at a 1:1.5 ratio. TheraSkin contains: 1) both collagen and elastin which provide structural support and resilience, 2) a compliment of growth factors to assist healing, 3) multiple cytokines that assist in epithelialization and modulate the proliferation and differentiation of epithelium, and 4) structures that allow phagocytosis of bacteria without requirement of antibody production. TheraSkin is most commonly used in the treatment of partial and full-thickness wounds including chronic wounds, pressure ulcers, diabetic foot ulcers, venous stasis ulcers and burns. TheraSkin is generally applied like an autograft, insuring that the dressing is in close contact with the wound surface and that shear is minimized. Clinical experience supports up to five weekly to bi-weekly applications of cryopreserved human skin allograft to close the wound to the point of treatment with non-biologic wound dressings or to prepare the wound bed for autograft. According to the requester, there is no existing code to describe TheraSkin; and the creation of multiple HCPCS for TheraSkin will help to ensure that providers can utilize the most appropriately sized product to cover a particular wound, minimize wastage, and ultimately reduce costs to patients, providers, and payors.

CMS HCPCS Preliminary Decision:

Establish Qxxxx THERASKIN, PER SQUARE CENTIMETER

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker agreed with the Workgroup's preliminary decision and urged CMS to finalize its decision. The speaker also requested an expedited release of the proposed "Q" code to allow access to coding. According to the speaker, there is significant cost savings with use of this product.

HCPCS Public Meeting Agenda Item #2
May 5, 2010

Attachment# 10.040

Topic/Issue:

Request to establish a Level II HCPCS J code for Hyalomatrix® PA. Applicant's recommended language: "skin substitute, Hyalomatrix PA, per sq cm".

Background/Discussion:

According to the requester, Hyalomatrix® PA is a bilayered, sterile, flexible, and conformable non-woven pad entirely composed of HYAFF 11, a benzyl ester of hyaluronic acid. The hyaluronic acid is derived from bacterial fermentation. The HYAFF 11 serves as a scaffold to allow cell colonization and capillary growth. On the back layer of the HYAFF 11 is a semipermeable silicone membrane that does not contact the patient and controls water vapor loss. Hyalomatrix PA is applied directly to a wound. After two to three weeks the silicone layer is removed, but the HYAFF II layer is mostly or completely absorbed into the underlying tissue, and the underlying tissue typically has healed or has become ready for grafting. Hyalomatrix® PA is packaged in several different sizes: 5 cm x 5 cm sold separately and in boxes of 5 and 10 (in individual pouches); 10 cm x 10 cm sold separately; and 10 cm x 20 cm sold separately.

CMS HCPCS Preliminary Decision:

Establish Qxxxx HYALOMATRIX, PER SQUARE CENTIMETER

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item. Written comments were submitted by the applicant in support of the preliminary coding decision.

HCPCS Public Meeting Agenda Item #3
May 5, 2010

Attachment# 10.050

Topic/Issue:

Request to:
1) Revise the verbiage of existing code Q4111 which currently reads; "SKIN SUBSTITUTE, GAMMAGRAFT, PER SQUARE CENTIMETER" to instead read: Allograft, human skin irradiated, GammaGraft, per square centimeter" to "better reflect the composition of the material" and thereby accurately reflect that GammaGraft is a human skin allograft and not an engineered skin substitute; and
Revise the verbiage of codes Q4112, Q4113 and Q4115 to help make a distinction between traditional (cadaver-derived) allograft material and materials that have been "engineered: to "replicate the performance of allograft skin" and in that sense, are not allografts, but are "skin substitutes".

2) Revise the verbiage of code Q4112, ALLOGRAFT, SKIN SUBSTITUTE, CYMETRA, INJECTABLE, 1CC, by omitting the word "Allograft";

3) Revise the verbiage of code Q4113 ALLOGRAFT, SUBSTITUTE, GRAFTJACKET EXPRESS, PER 1 CC, by omitting the word "Allograft"; and

4) Revise the verbiage of code Q4115 SKIN SUBSTITUTE, HUMAN SKIN FRESH OR FROZEN, ALLOSKIN, PER SQUARE CENTIMETER, by omitting the term "skin substitute". Note that in this code series, the applicant suggests leaving the verbiage of code Q4114 INTEGRA FLOWABLE WOUND MATRIX, INJECTABLE, 1 CC as is.

Background/Discussion:

According to the requester, for years, cadaver derived allograft skin has been the gold standard in the treatment of wounds and burns. For this reason, all bioengineered grafts have attempted to replicate the performance of allograft skin, and in this sense are "skin substitutes," whereas GammaGraft is human skin allograft. However, due to the inconsistent language in the code descriptors, some allografts (i.e. GammaGraft) are mislabeled as "skin substitutes." Allografts differ in structure, tissue origin, and in some cases, differ from bioengineered "skin substitutes" in terms of how they are approved by the FDA. Both GammaGraft (Q4111) and materials described by Q4115, Alloskin, are human cadaver skin that has simply been preserved. They are regulated by the FDA as human tissue for transplantation and not devices. Other products regulated under the same regulations do not retain the original structure of the donor skin and in fact, still other products are of bovine or porcine origin and may or may not be combined with synthetic materials. According to the requester, application of the terms "allograft" and "skin substitute" in coding is "not consistent with their use in the clinical community". As such, they should not be characterized by the code descriptors as an allograft. The applicant requests that

products labeled as "allograft" in the descriptors be instead labeled as "skin substitutes", in addition to changing the Q4111 and Q4115 to descriptors to specify "allograft".

CMS HCPCS Preliminary Decision:

Revise existing code Q4101 which currently reads: “SKIN SUBSTITUTE, APLIGRAF, PER SQUARE CENTIMETER” to instead read: “APLIGRAF, PER SQUARE CENTIMETER
Revise existing code Q4102 which currently reads: “SKIN SUBSTITUTE, OASIS WOUND MATRIX, PER SQUARE CENTIMETER” to instead read: “OASIS WOUND MATRIX, PER SQUARE CENTIMETER”
Revise existing code Q4103 which currently reads: “SKIN SUBSTITUTE, OASIS BURN MATRIX, PER SQUARE CENTIMETER” to instead read: “OASIS BURN MATRIX, PER SQUARE CENTIMETER”
Revise existing code Q4104 which currently reads: “SKIN SUBSTITUTE, INTEGRA BILAYER MATRIX WOUND DRESSING (BMWD), PER SQUARE CENTIMETER” to instead read: “INTEGRA BILAYER MATRIX WOUND DRESSING (BMWD), PER SQUARE CENTIMETER”
Revise existing code Q4105 which currently reads: “SKIN SUBSTITUTE, INTEGRA DERMAL REGENERATION TEMPLATE (DRT), PER SQUARE CENTIMETER” to instead read: “INTEGRA REGENERATION TEMPLATE (DRT), PER SQUARE CENTIMETER”
Revise existing code Q4106 which currently reads: “SKIN SUBSTITUTE, DERMAGRAFT, PER SQUARE CENTIMETER” to instead read: “DERMAGRAFT, PER SQUARE CENTIMETER”
Revise existing code Q4107 which currently reads: “SKIN SUBSTITUTE, GRAFTJACKET, PER SQUARE CENTIMETER” to instead read: “GRAFTJACKET, PER SQUARE CENTIMETER”
Revise existing code Q4108 which currently reads: “SKIN SUBSTITUTE, INTEGRA MATRIX, PER SQUARE CENTIMETER” to instead read: “INTEGRA MATRIX, PER SQUARE CENTIMETER”
Revise existing code Q4109 which currently reads: “SKIN SUBSTITUTE, TISSUEMEND, PER SQUARE CENTIMETER” to instead read:”TISSUEMEND, PER SQUARE CENTIMETER”
Revise existing code Q4110 which currently reads: “SKIN SUBSTITUTE, PRIMATRIX, PER SQUARE CENTIMETER” to instead read: “PRIMATRIX, PER SQUARE CENTIMETER”
Revise existing code Q4111 which currently reads: “SKIN SUBSTITUTE, GAMMAGRAFT, PER SQUARE CENTIMETER” to instead read: “GAMMAGRAFT, PER SQUARE CENTIMETER”
Revise existing code Q4112 which currently reads: “ALLOGRAFT, CYMETRA, INJECTABLE, 1 CC” to instead read: “CYMETRA, INJECTABLE, 1 CC”
Revise existing code Q4113 which currently reads: “ALLOGRAFT, GRAFTJACKET EXPRESS, INJECTABLE, 1 CC” to instead read: “GRAFTJACKET EXPRESS, INJECTABLE, 1 CC”
Revise existing code Q4115 which currently reads: “SKIN SUBSTITUTE, ALLOSKIN, PER SQUARE CENTIMETER” to instead read: “ALLOSKIN, PER SQUARE CENTIMETER”
Revise existing code Q4116 which currently reads: “SKIN SUBSTITUTE, ALLODERM, PER SQUARE CENTIMETER” to instead read: “ALLODERM, PER SQUARE CENTIMETER”

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker thanked the Workgroup for its preliminary decision and urged CMS to finalize the decision.

HCPCS Public Meeting Agenda Item #4
May 5, 2010

Attachment# 10.072

Topic/Issue:

Request to establish a code for a reconstructive tissue matrix, trade name: Strattice™. Applicant's suggested language: "Tissue, Strattice, per square centimeter".

Background/Discussion:

According to the requester, Strattice® is a reconstructive tissue matrix (surgical mesh) that supports tissue regeneration. It is derived from porcine dermis and undergoes non-damaging proprietary processing that removes cells and significantly reduces the key component believed to play a major role in the xenogeneic rejection response. Strattice® is used by surgeons as a surgically implanted soft tissue patch to reinforce a patient's soft tissue where weakness exists, and for the surgical repair of damaged or ruptured soft tissue, such as in hernia repair, open abdominal repairs and in breast reconstruction, post mastectomy. Strattice® is available to surgeons in 2 versions: pliable and firm, in various sizes: Pliable: 5 cm x 16 cm and 8 cm x 16 cm, and Firm: 6 cm x 16 cm, 10 cm x 16 cm, 16 cm x 20 cm, 20 cm x 20 cm, and 20 cm x 25 cm. Once implanted, Strattice promotes rapid revascularization [cell repopulation and white cell migration] and provides for strong repair of the patients damaged tissue.

CMS HCPCS Preliminary Decision:

No insurer (i.e., Medicare, Medicaid, Private Insurance Sector) identified a national program operating need to establish a code to identify this product in the physician office setting. For reporting under the Medicare hospital OPPS and ASC payment systems, report C1781 "MESH (IMPLANTABLE)." Refer to the latest list of device category C codes for further information on the appropriate use of this C code, which can be found on this CMS website: **http://www.cms.hhs.gov/HospitalOutpatientPPS/04_passthrough_payment.asp#TopOfPage**

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with the Workgroup's preliminary decision and reiterated the original request to establish a code for this product. According to the speaker, establishing a code for this product is consistent with the coding of other biologic tissue products. The speaker also stated that use of the JC (SKIN SUBSTITUTE USED AS A GRAFT) and JD (SKIN SUBSTITUTE NOT USED AS A GRAFT) modifiers would aid in greater accuracy, coding specificity and claim processing for facilities and insurers when Strattice® is used.

HCPCS Public Meeting Agenda Item #5
May 5, 2010

Attachment# 10.075

Topic/Issue:

Request to establish a code for Conexa Reconstructive Tissue Matrix, Trade Name: Conexa Reconstructive Tissue Matrix (Generic: Surgical Mesh). Applicant's suggested language: Qxxxx Skin substitute, Conexa, per square centimeter

Background/Discussion:

According to the Requester, Conexa Reconstructive Tissue Matrix is an implantable orthopedic tissue graft used to reinforce orthopedic soft tissue repairs. It is made from porcine dermis processed to remove porcine cells and other cross-species contaminants, and sterilized. The Conexa Reconstructive Tissue Matrix is intended for the reinforcement of soft tissue repaired by sutures or suture anchors during tendon repair surgery and reinforcement for rotator cuff, patellar, Achilles, biceps, quadriceps, or other tendons. Other indications for use include the repair of body wall defects which require the use of reinforcing or bridging material to obtain the desired surgical outcome. The Requester claims that Conexa supports a regenerative mechanism of action, instead of a "repair" mechanism of action (i.e. scar tissue formation). With repair mechanisms of action, the body will attempt to repair the graft site with scar tissue, resulting in weaker, less functional surgical outcomes. By providing an intact, undamaged, sterile extracellular matrix, Conexa acts as a host-friendly biologic scaffold that supports attachment of the body's natural tissue regeneration mechanism to produce new tendon tissue and rapid population of new capillaries to provide blood flow and needed nutrition. Conexa also provides mechanical load sharing and reduces the stress on the repair site thereby reducing the chance of a re-tear or sub-optimal repair outcome. Conexa is supplied in a range of sizes from 2x4 cm to 5x10 cm. The size is selected by the surgeon depending on the repair size to be reinforced and may be cut or shaped as needed. Conexa is supplied in a terminally sterile pouch contained in an outer box. There is one Conexa unit per box. According to the requester, only GraftJacket (currently coded as Q4107) and Conexa have been validated in primate animal models in published peer-review tissue engineering literature to support a regenerative mechanism of action.

CMS HCPCS Preliminary Decision:

No insurer (i.e., Medicare, Medicaid, Private Insurance Sector) identified a national program operating need to establish a code to identify this product in the physician office setting since this item is a surgical supply and not separately reportable. If this item is used in the hospital outpatient and ambulatory care settings, refer to the Medicare hospital OPPS website for further information on how to submit applications for pass-through consideration as an implantable device or as a biological under the hospital OPPS:
http://www.cms.hhs.gov/HospitalOutpatientPPS/04_passthrough_payment.asp#TopOfPage

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with the Workgroup's preliminary decision and reiterated the original request to establish a code for this product. According to the speaker, Conexa is not a "surgical mesh," but is a "tissue graft" that can be used for surgical and orthopedic indications. The speaker also stated that a new code would provide several benefits: 1) consistency and consensus from CMS Administrators; 2) ability to appropriately report services and detail electronically; 3) tracking and identification of product use, indication, cost, and other relevant detail; and 4) appropriate use of existing code sets and methodologies.

HCPCS Public Meeting Agenda Item #6
May 5, 2010

Attachment# 10.061

Topic/Issue:

Request to establish a code for UBM (urinary bladder matrix), trade name: MatriStem® MicroMatrix™. Applicant's suggested language: "'Skin Substitute, MatriStem MicroMatrix, 3 mg per Square Centimeter".

Background/Discussion:

According to the requester, MatriStem MicroMatrix is a porcine-derived, naturally occurring non cross-linked, completely resorbable, acellular extracellular matrix derived from specific layers of porcine urinary bladder. MatriStem MicroMatrix is made from the same material as the MartiStem Wound Sheet (see 10.062), but in a micronized particle (powder) form. In this form, it is easier to apply when the wound has an irregular shape, under-mining edges or tunneling, or when shifting may cause the wound to lose contact with the dressing. The lyophilized micronized particles are applied topically to the surface of the wound to maintain and support a healing environment for wound management. MatriStem contains a unique epithelial basement membrane which is known to be composed of several types of collagen, adhesion proteins, glycoproteins, and other elements of an extracellular matrix which all act synergistically in supporting natural tissue healing. MatriStem triggers abundant new blood vessel formation and recruits numerous cell types to the site of the injury or wound. During the healing process, the device is degraded and completely resorbed, leaving new tissue where scar tissue would normally be expected. It is indicated for the management of wounds including: partial and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds, trauma wounds, and draining wounds. MatriStem MicroMatrix is supplied as 20 mg (5 ea) per box; 30 mg (5 ea.) per box; 60 mg (5 ea.) per box; 100 mg (1 ea.) per box; and 200 mg (1 ea.) per box. According to the requester, existing codes do not adequately describe this product because of its unique combination of bioactive properties, especially its bimodal characteristic: one surface consists of an intact basement membrane which is especially conducive to epithelial and endothelial cell attachment, proliferation, and differentiation and is ideal for epithelial cell growth in many applications, which results in a more natural regeneration with little, if any, scar tissue formation.

CMS HCPCS Preliminary Decision:

Establish Qxxxx MATRISTEM MICROMATRIX, 1 MG

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker supported the Workgroup's preliminary decision to establish a code for MatriStem MicroMatrix as well as the proposed code language and dosage descriptor.

HCPCS Public Meeting Agenda Item #6
May 5, 2010

Attachment# 10.062

Topic/Issue:

Request to establish a code for UBM (urinary bladder matrix), trade name: MatriStem® Wound Sheet. Applicant's suggested language: "Skin substitute, MatriStem Wound Matrix, per Square Centimeter".

Background/Discussion:

According to the requester, MatriStem is a porcine-derived, naturally occurring lyophilized extracellular matrix that maintains and supports a healing environment for wound management. MatriStem Wound Sheets are manufactured in multiple sizes of single layer lyophilized sheet configurations that are applied topically to the surface of the wound. MatriStem contains a unique epithelial basement membrane which is known to be composed of serveral types of collagen, adhesion proteins, glycoproteins, and other elements of an extracellular matrix which all act synergistically in supporting natural tissue healing. MatriStem triggers abundant new blood vessel formation and recruits numberous cell types to the site of the injury or wound. During the healing process, the device is degraded and completely resorbed, leaving new tissue where scar tissue would normally be expected. It is indicated for the management of wounds including: partial and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds, trauma wounds, and draining wounds. MatriStem wound sheets are supplies as: 3 cm x 3.5 cm (box of 5); 3 cm x 7 cm (box of 5); 7 cm x 10 cm (1 ea); 10 cm x 15 cm (box of 5); 10 cm x 15 cm (1 ea). According to the requester, existing codes do not adequately describe this product because of its unique combination of bioactive properties, especially its bimodal characteristic: one surface consists of an intact basement membrane which is especially conducive to epithelial and endothelial cell attachment, proliferation, and differentiation and is ideal for epithelial cell growth in many applications, which results in a more natural regeneration with little, if any, scar tissue formation.

CMS HCPCS Preliminary Decision:

Establish Qxxxx MATRISTEM WOUND MATRIX, PER SQUARE CENTIMETER

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker supported the Workgroup’s preliminary decision to establish a code for MatriStem Wound Sheet as well as the proposed code language and dosage descriptor.

HCPCS Public Meeting Agenda Item #6
May 5, 2010

Attachment# 10.063

Topic/Issue:

Request to establish a single code to identify UBM (urinary bladder matrix) surgical matrix devices, trade names: MatriStem® Surgical Matrix RS (2-layer); MatriStem® Plastic Surgery Matrix (4-layer); and MatriStem® Plastic Surgery Matrix XS (6-layer).
Applicant's suggested language: "Skin substitute, MatriStem Surgical Matrix, per square centimeter".

Background/Discussion:

According to the requester, MatriStem Surgical Matrix is a porcine-derived, naturally occurring dehydrated extracellular matrix that maintains and supports a healing environment for wound management. MatriStem surgical devices are manufactured in various sizes of multi-layer dehydrated dry sheet configurations. When applied to a wound, these devices changes the healing response, resulting in remodeled, functional, site specific tissue. MatriStem contains a unique epithelial basement membrane which is known to be composed of several types of collagen, adhesion proteins, glycoproteins, and other elements of an extracellular matrix which all act synergistically in supporting natural tissue healing. MatriStem triggers abundant new blood vessel formation and recruits numerous cell types to the site of the injury or wound. During the healing process, the device is degraded and completely resorbed, leaving new tissue where scar tissue would normally be expected. It is indicated for implantation to reinforce soft tissues. MatriStem® Surgical Matrix products are supplied as follows: surgical Matrix RS as (box of 5) 1.5 cm discs, 1 ea. 2cm x 4 cm, 1 ea. 2cm x 4 cm, 1 ea. 5 cm x 5 cm, 1 ea. 7 cm x 10 cm, 1 ea. 6 cm x 15 cm, 1 ea. 10 cm x 15 cm; Plastic Surgery Matrix as (box of 5) 1.5 cm discs, 1 ea. 4 cm x 12 cm, 1 ea. 6 cm x 15 cm, 1 ea. 7 cm x 10 cm, 1 ea. 10 cm x 15 cm; Plastic Surgery Matrix XS as 1 ea. 4 cm x 12 cm, 1 ea. 6 cm x 15 cm, 1 ea. 7 cm x 10 cm and 1 ea. 10 cm x 15 cm. According to the requester, existing codes do not adequately describe this product because of its unique combination of bioactive properties, especially its bimodal characteristic: one surface consists of an intact basement membrane which is especially conducive to epithelial and endothelial cell attachment, proliferation, and differentiation and is ideal for epithelial cell growth in many applications, which results in a more natural regeneration with little, if any, scar tissue formation.

CMS HCPCS Preliminary Decision:

No insurer (i.e., Medicare, Medicaid, Private Insurance Sector) identified a national program operating need to establish a code to identify this product in the physician office setting. For reporting under the Medicare hospital OPPS and ASC payment systems, report C1781 "MESH (IMPLANTABLE)." Refer to the latest list of device category C codes for further information on the appropriate use of this C code, which can be found on this CMS website: **http://www.cms.hhs.gov/HospitalOutpatientPPS/04_passthrough_payment.asp#TopOfPage**

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with the Workgroup's preliminary decision to use a "C" code and stated that this product is identical to Graft Jacket and Integra DRT, which are products that are currently described by existing "Q" codes. The speaker further stated that these products are used in the same manner as other products described by existing "Q" codes. Specifically, these products are used to debride wound, secure device to wound, and act as appropriate dressings.

HCPCS Public Meeting Agenda Item #6
May 5, 2010

Attachment# 10.064

Topic/Issue:

Request to establish a code for UBM (urinary bladder matrix), trade name: MatriStem® Burn Matrix. Applicant's suggested language: "Skin substitute, MatriStem Burn Matrix, per square centimeter".

Background/Discussion:

According to the requester, MatriStem Burn Matrix is a porcine-derived, naturally occurring dehydrated extracellular matrix that maintains and supports a healing environment for wound management. MatriStem Burn Matrix is manufactured in multi-layer lyophilized (freeze-dried) sheet configurations. When applied to a wound, these devices changes the healing response, resulting in remodeled, functional, site specific tissue. MatriStem contains a unique epithelial basement membrane which is known to be composed of several types of collagen, adhesion proteins, glycoproteins, and other elements of an extracellular matrix which all act synergistically in supporting natural tissue healing. MatriStem triggers abundant new blood vessel formation and recruits numerous cell types to the site of the injury or wound. During the healing process, the device is degraded and completely resorbed, leaving new tissue where scar tissue would normally be expected. It is indicated for the management of wounds including: partial and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds, trauma wounds, and draining wounds. MatriStem® Burn Matrix is supplied as: 7 cm x 10 cm fenestrated wound sheet, 1 ea; and 7 cm x 10 cm meshed wound sheet, 1 ea.; 3 cm x 3.5 cm (5/box) and (10/box); 3 cm x 7 cm (5/box and 10/box); 7 cm x 10 cm (1 ea. and 5/box); and 10 cm x 15 cm (1 ea. and 5/box). According to the requester, this product has a significant therapeutic distinction over similar products in that it offers the following characteristics: 1) naturally occurring, non-cross-linked extracellular matrix; 2) completely resorbable; 3) acellular; 3) contains multiple naturally occurring growth factors; 4) bimodal surface characteristic; 5) may reduce scar tissue formation; 6) antimicrobial properties; 7) lyophilized; and 8) indicated in a complete range of wounds. Existing code Q4100 does not adequately describe this product because it is an unlisted code and 3rd party payers only reimburse for specific Q codes.

CMS HCPCS Preliminary Decision:

Establish Qxxxx MATRISTEM BURN MATRIX, PER SQUARE CENTIMETER

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker supported the Workgroup's preliminary decision to establish a code for MatriStem Burn Matrix as well as the proposed code language and dosage descriptor.

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

Currently, Medicare pays 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.

Medicare also pays 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.

The pharmacy will also receive 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.

Currently, Medicare pays 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, Medicare pays 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 calendar year 2010, this fee is $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/Downloads/BvsDCoverage_07.27.05.pdf

http://www.cms.hhs.gov/Pharmacy/Downloads/partsbdcoverageissues.pdf