Centers for Medicare & Medicaid Services (CMS) Healthcare Common Procedure Coding System (HCPCS) Public Meeting Agenda for Drugs, Biologicals and Radiopharmaceuticals
Tuesday, May 8, 2012 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.

Attachment#12.038
Request to establish a code for a collagen wound dressing, trade name: Endoform Dermal Template and place it in the surgical dressing category. Will be discussed at the Supply and Other Public Meeting on Wednesday, May 9, 2012.

AGENDA ITEM #1
Attachment#12.014
Request to establish 4 codes for dehydrated human amniotic membrane (dHAM) allograft, based on product size. Trade name: EpiFix®. Applicant's suggested language:

Jxxx1 "Human dehydrated amniotic membrane allograft, EpiFix®, 16mm disk, per allograft"

Jxxx2 "Human dehydrated amniotic membrane allograft, EpiFix®, 2 cm x3 cm, per allograft"

Jxxx3 "Human dehydrated amniotic membrane allograft, EpiFix®, 4 cm x 4 cm, per allograft"

Jxxx4 "Human dehydrated amniotic membrane allograft, EpiFix®, 7 cm x 7 cm, per allograft".

AGENDA ITEM #2
Attachment#12.015
Request to establish a code for acellular dermal allograft, trade name: DermaSpan™ Acellular Dermal Matrix. Applicant's suggested language: Qxxxx "DermaSpan™, per square centimeter".

AGENDA ITEM #3
Attachment#12.021
Request to establish a code for acellular human dermis, trade name: InteguPly™. Applicant's suggested language: Qxxxx "Integuply, per square centimeter".

AGENDA ITEM #4
Attachment#12.029
Request to establish a code for allograft tissue cellular repair matrix, trade name: Grafix® core. Applicant's suggested language: Qxxxx "Grafix® Core, per square centimeter".

Attachment# 12.030
Request to establish a code for allograft tissue cellular repair matrix, trade name: Grafix® prime. Applicant's suggested language: Qxxxx "Grafix® prime, per square centimeter".

AGENDA ITEM #5
Attachment#12.041
Request to establish a code for a skin/dermal substitute, trade name: hMatrix.

AGENDA ITEM #6
Attachment#12.042
Request to establish a permanent HCPCS Level II Q code for Integra Meshed Bilayer Matrix and discontinue existing code C9363, which presently identifies this product.

AGENDA ITEM #7
Attachment#12.043
Request to establish a code for human skin allograft, trade name: Matrix™ HD. Applicant's suggested language: Qxxxx "Matrix HD, per square centimeter".

AGENDA ITEM #8
Attachment#12.044
Request a new code for Mediskin.

Attachment# 12.045
Request a new code for EZ Derm.

AGENDA ITEM #9
Attachment#12.046
Request to establish a code for a six-layer Porcine Urinary Bladder Matrix (UBM), trade name: MatriStem Wound Matrix PSMX. Applicant’s suggested language: “Skin substitute, MatriStem Multi-layer Wound Matrix PSMX, per square centimeter.”

Attachment# 12.047
Request to establish a code for two-layer Porcine Urinary Bladder Matrix (UBM), trade name: MatriStem Wound Matrix RS. Applicant's suggested language: "Skin substitute, MatriStem Multi-layer Wound Matrix RS, per square centimeter."

Attachment# 12.048
Request to establish a code for three-layer Porcine Urinary Bladder Matrix (UBM), trade name: MatriStem Wound Matrix PSM. Applicant's suggested language: "Skin substitute, MatriStem Multi-layer Wound Matrix PSM, per square centimeter."

AGENDA ITEM #10
Attachment#12.032
Request to establish a code for immune globulin for subcutaneous use, trade name: Gammagard Liquid. Applicant's suggested language: Jxxxx "Injection, immune globulin (Gammagard Liquid), subcutaneous, nonlyophilized, (e.g., liquid), 500 mg".

AGENDA ITEM #11
Attachment#12.035
Request to establish a code for Mometasone furoate implant, trade name: Propel™. Applicant's suggested language: Jxxxx "Mometasone furoate sinus implant, each".

AGENDA ITEM #12
Attachment#12.037
Request to establish a code for influenza virus vaccine, trade name: AGRIFLU.

AGENDA ITEM #13
Attachment#12.022
Request to establish a new unique, simplified, permanent code for Sipuleucel-T, trade name: PROVENGE®. Applicant's suggested language: Jxxxx "Sipuleucel-T, 250 mL".

AGENDA ITEM #14
Attachment#12.065
Request to discontinue code J8561 "EVEROLIMUS, ORAL, 0.25 MG" and replace it with a new code for the same product in the J7xxx series. Applicant's suggested language: J7xxx "Everolimus, Oral (Zortress), 0.25 mg".

AGENDA ITEM #15
Attachment#12.024
Request to establish a new HCPCS "J" code for lidocaine/tetracaine topical patch, trade name: Synera®. Applicant's suggested language: Jxxxx "Lidocaine 70 mg/tetracaine 70 mg, per patch".

AGENDA ITEM #16
Attachment#12.009
Request to establish a new HCPCS code for Mitosol® (ophtalmic mitomycin USP).

AGENDA ITEM #17
Attachment#12.013
Request to: 1) establish a code for Erwinia-derived asparaginase, trade name: ERWINAZE® and 2) revise the description of code J9020 which currently reads: "INJECTION, ASPARAGINASE, 10,000 UNITS" to instead read: "Injection, E.coli asparaginase, 10,000 units". Applicant's suggested language for new code: "Injection, asparaginase, per 10,000 units".

AGENDA ITEM #18
Attachment#12.033
Request to discontinue existing code J1680 "INJECTION, HUMAN FIBRINOGEN CONCENTRATE, 100MG) and replace with a temporary "Q" code for the remainder of year 2012; and establish a "J7xxx" code effective 1/1/13 to replace codes J1680 and Qxxxx so that Human Fibrinogen will be in the series with other clotting factors and the "unit" definition among the various clotting factors will be 1 mg. Applicant's suggested language: Qxxxx and Jxxxx "Injection, human fibrinogen concentrate, 1 mg".

AGENDA ITEM #19
Attachment#12.040
Request to establish a code for Aflibercept for intravitreal injection, trade name: EYLEA. Applicant's suggested language: Jxxxx "Aflibercept for intravitreal injection, 2 mg".

AGENDA ITEM #20
Attachment#12.007
Request to establish a code for belatacept, trade name: Nulojix®. The applicant submitted two different suggested code descriptors: “Injection, Belatacept, 1 mg”, and “Injection, Belatacept, 250 mg per vial”.

AGENDA ITEM #21
Attachment#12.039
Request to establish a code for brentuximab vedotin, trade name: ADCETRIS™. Applicant's suggested language: Jxxxx "Injection, brentuximab vedotin, 1 mg".

AGENDA ITEM #22
Attachment#12.026
Request to establish another HCPCS code for a new formulation of Epoprostenol for Injection, trade name: VELETRI®. Applicant's suggested language: "Injection, Epoprostenol, Saline Diluent, 1.5 mg".

AGENDA ITEM #23
Attachment#12.006
Request to establish a code for Ibuprofen for intravenous injection, trade name: Caldolor.

AGENDA ITEM #24
Attachment#12.008
Request to establish a code for bupivacaine liposome injectable suspension, trade name: Exparel.

AGENDA ITEM #25
Attachment#12.018
Request to establish a code for Centruroides (Scorpion) Immune $F(ab')_2$ (Equine) injection, trade name: Anascorp®. Applicant's suggested language: "Injection, Centruroides (Scorpion) Immune $F(ab')_2$ (Equine) Injection, 1 vial".

AGENDA ITEM #26
Attachment#12.020
Request to establish a code for methylnaltrexone bromide, trade name: Relistor. Applicant's suggested language: "Injection, methylnaltrexone bromide, up to 12 mg".

AGENDA ITEM #27
Attachment#12.027
Request to establish a code for icatibant injection, trade name: FIRAZYR®. Applicant's suggested language: Jxxxx "Injection, icatibant, 1 mg".

AGENDA ITEM #28
Attachment#12.034
Request to establish a code for clevidipine butyrate injectable emulsion for intravenous use, trade name: Cleviprex®. Applicant's suggested language: "Cleviprex Injectable Emulsion, 1 mg".

AGENDA ITEM #29
Attachment#12.028
Request to establish a permanent HCPCS code for hexaminolevulinate hydrochloride, trade name: Cysview, to replace existing code C9275. Applicant's suggested language: "Hexaminolevulinate HCl, 100mg/50mL per dose".

AGENDA ITEM #30
Attachment#12.031
Request to establish a code for pre-storage pooled, leukocyte reduced platelets. Applicant's suggested language: "Platelets, pre-storage pooled, leukocyte reduced, each unit."

AGENDA ITEM #31
Attachment# 12.023
Request to establish a code for Peginesatide Acetate, trade name to be determined. Applicant's suggested language: "Injection, peginesatide acetate, 1 mg".

AGENDA ITEM #32
Attachment# 12.038
Request to establish a code for Florbetapir F 18, trade name: AMYViD™. Applicant's suggested language: "Injection, florbetapir F 18, diagnostic, per study dose".

HCPCS Public Meeting Agenda Item #1
May 8, 2012

Attachment# 12.014

Topic/Issue:

Request to establish 4 codes for dehydrated human amniotic membrane (dHAM) allograft, based on product size. Trade name: EpiFix®. Applicant's suggested language:

Jxxx1 "Human dehydrated amniotic membrane allograft, EpiFix®, 16mm disk, per allograft"

Jxxx2 "Human dehydrated amniotic membrane allograft, EpiFix®, 2 cm x3 cm, per allograft"

Jxxx3 "Human dehydrated amniotic membrane allograft, EpiFix®, 4 cm x 4 cm, per allograft"

Jxxx4 "Human dehydrated amniotic membrane allograft, EpiFix®, 7 cm x 7 cm, per allograft".

Background/Discussion:

According to the requester, EpiFix® is a multi-layer biologic dehydrated human amniotic membrane allograft comprised of an epithelial layer and two fibrous connective tissue layers specifically processed to be used for the repair or replacement of lost or damaged dermal tissue. It is prepared from human placenta. The processed allograft contains collagen types IV, V, and VII that promote cellular differentiation and adhesion. Usage includes on lay applications for, but not limited to, neuropathic ulcers, venous stasis ulcers, post-traumatic wounds and post-surgical wounds and pressure ulcers. EpiFix® provides a matrix for cellular migration/proliferation, provides a natural biological barrier, and is non-immunogenic. It also delivers well-known essential wound healing growth factors; delivers minimally manipulated extracellular matrix (ECM) proteins; provides unique anti-inflammatory cytokines, and contains tissue inhibitors of metallo-proteinases. Each allograft is packed in a hermetically sealed double peel pouch packaging in an outer box carton. According to the requester, EpiFix® differs from other products produced from human tissue based upon the derived source of the tissue allograft and allograft contents. Only EpiFix® is composed of normal dehydrated human amniotic membrane (dHAM) and has no synthetic components. There is no existing code to describe EpiFix® because existing HCPCS codes for wound care products are product- and brand specific.

Preliminary Decision:

Establish Qxxxx EPIFIX, PER SQUARE, CENTIMETER

HCPCS Public Meeting Agenda Item #2
May 8, 2012

Attachment# 12.015

Topic/Issue:

Request to establish a code for acellular dermal allograft, trade name: DermaSpan™ Acellular Dermal Matrix. Applicant's suggested language:

Qxxxx "DermaSpan™, per square centimeter".

Background/Discussion:

According to the requester, DermaSpan™ is an acellular dermal matrix derived from aseptically processed cadaveric human allograft skin tissue. It is used for the repair or replacement of damaged or inadequate integumental tissue or for other homologous uses of human integument. The allograft acts as a scaffold to facilitate angiogenesis and migration of growth factors that stimulate cell migration. The collagen scaffold of DermaSpan™ facilitates the recellularization and revascularization of the host tissue. DermaSpan™ is applied to the patient's surgical site and secured by suturing. It may be applied for up to two applications. According to the applicant, when applied to the wound, DermaSpan™ has been shown to become vascularized and incorporated into the wound bed and to provide an effective means for wound closure. DermaSpan™ is supplied freeze-dried, with one side covered by a layer of N-Terface® membrane backing enclosed inside a Tyvek inner pouch. The allograft and inner pouch are then enclosed in a secondary outer Poly-foil pouch and sterilized. Approximate allograft dimensions, thicknesses and expiration date are indicated on the labeling. According to the requester, there are no existing codes to describe this product because the HCPCS codes for similar wound care products are product- and –brand specific.

Preliminary Decision:

Revise existing code Q4126 which currently reads: "MEMODERM, PER SQUARE CENTIMETER" to instead read: "MEMODERM, DERMASPAN, TRANZGRAFT OR INTEGUPLY, PER SQUARE CENTIMETER"

HCPCS Public Meeting Agenda Item #3
May 8, 2012

Attachment# 12.021

Topic/Issue:

Request to establish a code for acellular human dermis, trade name: InteguPly™. Applicant's suggested language: Qxxxx "Integuply, per square centimeter".

Background/Discussion:

According to the requester, Integuply™ is an acellular human dermis derived from aseptically processed human allograft skin tissue. It is indicated for the repair or replacement of damaged or inadequate integumental tissue or for other homologous uses of human integument. Integuply™ is typically used in conjunction with a chronic wound care management regimen for the treatment of diabetic ulcers, charcot foot ulcers, venous ulcers, trauma wounds, pressure ulcers, pressure ulcers, partial and full thickness wounds, and surgical wounds. When applied to wounds, Integuply™ becomes vascularized and incorporated into the wound bed to provide an effective means of wound closure. The matrix and preserved vascular channels in Integuply™ acts as a scaffold to facilitate angiogenesis and migration of growth factors that stimulate cell migration. Integuply™ is applied topically to the wound site and secured by suturing or stapling to the skin surrounding the wound. Typically only one application is needed. It can be meshed or non-meshed. Integuply™ is supplied in 38 different sizing and thickness configurations and is packaged freeze dried. According to the requester, there are several similar products but there are no existing codes to describe Integuply™ because HCPCS codes for skin substitutes are product and brand specific.

Preliminary Decision:

Revise existing code Q4126 which currently reads" MEMODERM, PER SQUARE CENTIMETER" to instead read: "MEMODERM, DERMASPAN, TRANZGRAFT OR INTEGUPLY, PER SQUARE CENTIMETER".

HCPCS Public Meeting Agenda Item #4
May 8, 2012

Attachment# 12.029

Topic/Issue:

Request to establish a code for allograft tissue cellular repair matrix, trade name: Grafix® core. Applicant's suggested language: Qxxxx "Grafix® Core, per square centimeter".

Background/Discussion:

According to the requester, Grafix®$_{CORE}$ is an allograft derived from human chorionic placental tissue "intended" for patients with acute and chronic wounds including, but not limited to, diabetic foot ulcers, venous stasis ulcers and pressure ulcers that have not responded to standard of care therapy. Grafix®$_{CORE}$ has one layer (a thick stromal layer), a collagen rich membrane, mesenchymal stem cells (MSCs), and anti-inflammatory cytokines and regenerative growth factors. The thick stromal layer of Grafix®$_{CORE}$ has been used in wounds with exposed bone and tendon to help promote granulation of deep tissue. The collagen matrix provides a physiological microenvironment for cells and proteins to promote cellular adhesion and migration in addition to supporting growth factor function. Cytokines and growth factors, epidermal growth factor and transforming growth factor-beta3 in Grafix®$_{CORE}$ mediate integral events such as angiogenesis, cell recruitment and proliferation. Once thawed and rinsed, Grafix®$_{CORE}$ is applied to the wound and covered with a standard, non-adherent dressing. Additional applications are used as needed with frequency ranging from every 7-14 days until the wound is closed. Grafix®$_{CORE}$ is supplied as a cryopreserved membrane mounted on nitrocellulose paper and is available in 2 sizes; 2cm x 2cm and 5cm x 5cm. According to the requester, the presence of MSCs in Grafix® distinguishes it from all other skin substitutes. Existing codes are inadequate to describe this product because codes skin substitute are brand and product specific.

Preliminary Decision:

Establish Qxxxx GRAFIX CORE, PER SQUARE CENTIMETER

HCPCS Public Meeting Agenda Item #4
May 8, 2012

Attachment# 12.030

Topic/Issue:

Request to establish a code for allograft tissue cellular repair matrix, trade name: Grafix® prime. Applicant's suggested language: Qxxxx "Grafix® prime, per square centimeter".

Background/Discussion:

According to the requester, Grafix®$_{PRIME}$ is an allograft derived from the amniotic membrane of human placental tissue used for the management of acute and chronic wounds including, but not limited to, diabetic foot ulcers, venous stasis ulcers and pressure ulcers that have not responded to standard of care therapy. Additional uses include burns, adhesion barriers, and Mohs procedures. Grafix®$_{PRIME}$ has two layers (epithelial layer and stromal layer) and is comprised of a collagen rich membrane, mesenchymal stem cells (MSCs), and anti-inflammatory cytokines and regenerative growth factors. The collagen matrix provides a physiological microenvironment for cells and proteins to promote cellular adhesion and migration in addition to supporting growth factor function. Cytokines and growth factors, epidermal growth factor and transforming growth factor-beta3 in Grafix®$_{PRIME}$ mediate integral events such as angiogenesis, cell recruitment and proliferation. Once thawed and rinsed, Grafix®$_{PRIME}$ is applied to the wound and covered with a standard, non-adherent dressing. Additional applications are used as needed with frequency ranging from every 7-14 days for up to 12 weeks or until the wound is closed. Grafix®$_{PRIME}$ is supplied as a cryopreserved membrane mounted on nitrocellulose paper and is available in 3 sizes; 2cm x 2cm and 5cm x 5cm, and 7.5cm x 15cm. According to the requester, the presence of MSCs in Grafix® distinguishes it from all other skin substitutes. MSCs coordinate the tissue repair process through down regulation of inflammation, by stimulating blood vessel formation (angiogenesis), and by supporting fibroblast and epithelial cells resulting in rapid wound closure. Existing codes are inadequate to describe this product because they are brand and product specific.

Preliminary Decision:

Establish Qxxxx GRAFIX PRIME, PER SQUARE CENTIMETER

HCPCS Public Meeting Agenda Item #5
May 8, 2012

Attachment# 12.041

Topic/Issue:

Request to establish a code for a skin/dermal substitute, trade name: hMatrix.

Background/Discussion:

According to the requester, hMatrix is a dermal substitute derived from the dermal layer of human skin by removing the epidermal layer and cellular components from the dermis. It is indicated for use to replace damaged or inadequate integumental tissue, indicated for homologous use only. Specific uses of hMatrix include use as a wound covering, abdominal wall repair, breast reconstruction, soft tissue grafting in craniomaxillofacial applications, and for use in supplement support, reinforcement, or covering of tendons or periosteum. hMatrix contains elastin, collagen, proteoglycans, and vascular channels which provide an ideal environment for revascularization and cellular repopulation when surgically implanted or grafted. When used as a wound covering, hMatrix is placed over the derided wound site and the graft is fixed via the use of sutures or staples. hMatrix is packaged frozen and is designed for single-use. It is provided in three thicknesses in specific sizes ranging from 1cm x 2cm to 5cm x 10cm to allow for patient specific needs, as determined by surgeons. Existing codes are inadequate to describe this product because they are brand and product specific, and none identify hMatrix.

Preliminary Decision:

Establish Qxxxx HMATRIX, PER SQUARE CENTIMETER

HCPCS Public Meeting Agenda Item #6
May 8, 2012

Attachment# 12.042

Topic/Issue:

Request to establish a permanent HCPCS Level II Q code for Integra Meshed Bilayer Matrix and discontinue existing code C9363, which presently identifies this product.

Background/Discussion:

According to the requester, ***Integra Meshed Bilayer Wound Matrix*** is an advanced wound care device comprised of a porous matrix of cross-linked bovine tendon collagen and glyscosaminoglycan with a polysiloxane (silicone) layer. It allows draining of wound exudates and provides a flexible adherent covering for the wound surface. The collagen-glycosaminoglycan biodegradable matrix provides a scaffold for cellular invasion and capillary growth. It is indicated for the management of wounds including: partial and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, second-degree burns, and skin tears) and draining wounds. It also may be used with negative pressure wound therapy. The dosage is based on size of the wound for this single use product. Integra Meshed Bilayer Wound Matrix is packaged in sterile, single-use, double peel packages containing phosphate buffer. It is available in four sizes: 500 square centimeters (8" x 10" sheets), 250 square centimeters (4"x10" sheets), and 125 centimeters (4"x5" sheets), and 25 square centimeters (2"x2" sheets). According to the requester, C codes are not eligible to be used in the physician's office, and since Integra Meshed Bilayer Wound Matrix is used in physician's offices, a Q code is needed to facilitate billing and payment.

Preliminary Decision:

Existing code Q4104 "INTEGRA BILAYER MATRIX WOUND DRESSING (BMWD), PER SQUARE CENTIMETER" adequately describes the product that is the subject of this request.

HCPCS Public Meeting Agenda Item #7
May 8, 2012

Attachment# 12.043

Topic/Issue:

Request to establish a code for human skin allograft, trade name: Matrix™ HD. Applicant's suggested language: Qxxxx "Matrix HD, per square centimeter".

Background/Discussion:

According to the requester, Matrix HD is a human dermal allograft restricted to homologous use for wound care; protection, reinforcement or covering of soft tissue in horizontal and vertical augmentation procedures. Matrix HD is dehydrated dermis from donated human tissue. The allograft provides a natural collagen scaffold skin substitute to support the body's regenerative processes. Matrix HD is used in wound care applications such as diabetic ulcers, charcot foot ulcers, venous ulcers, trauma wounds, pressure sore/ulcers, partial and full thickness wounds, and surgical wounds. Once the wound bed is prepared, the graft is placed and secured with sutures. Two allografts may be applied, one on top of the other, for optimal healing results. Matrix HD is supplied in patient-specific sizes, ranging from 2 x 3 cm to 10 x 10 cm, so that the surgeon can utilize the amount of tissue needed. The size is selected by the surgeon depending on the size of the wound. According to the requester, current HCPCS code options for skin substitute products and allografts are brand-name specific, rendering them inappropriate for use to describe Matrix HD.

Preliminary Decision:

Revise existing code Q4128 which currently reads: "FLEXHD OR ALLOPATCH HD, PER SQUARE CENTIMETER" to instead read: "FLEX HD, ALLOPATCH HD, OR MATRIX HD, PER SQUARE CENTIMETER".

HCPCS Public Meeting Agenda Item #8
May 8, 2012

Attachment# 12.044

Topic/Issue:

Request a new code or Mediskin.

Background/Discussion:

According to requester, Mediskin a frozen irradiated porcine xenograft that has a shelf life of 24 months. It may reduce pain, protein, and fluid loss, provide a barrier to external contamination and a moist wound healing site, and protect underlying tissue in the treatment of burns, abrasions, donor sites, decubitus and chronic vascular ulcers. It also provides an optimal environment for wound healing. Mediskin may also be used as temporary wound cover. It can be used on any person except those who have a known sensitivity to porcine products, on patients with histories of multiple serum allergies, or on wounds with large amounts of eschar. As the wound heals, Mediskin will naturally slough off. It is supplied in rolls (3" wide by 12, 24 or 48" long) and is also supplied in 7" x 18" sheets and patches of 3"x4" and 2"x2". According to the requester, there is no level II HCPCS code that describes a porcine xenograft, temporary skin substitute.

Preliminary Decision:

Establish Qxxxx MEDISKIN, PER SQUARE CENTIMETER

HCPCS Public Meeting Agenda Item #8
May 8, 2012

Attachment# 12.045

Topic/Issue:

Request a new code for EZ Derm.

Background/Discussion:

According to requestor, EZ-Derm is a porcine dermis xenograft that is used as temporary coverage for skin loss injuries. It reduces pain, fluid loss, and protein. It provides a barrier to external contamination and it provides a moist wound healing and thus protects underlying tissue in the treatment of burns, abrasions, donor sites, decubitus and chronic vascular ulcers. It can be used on any person except those who have a known sensitivity to porcine products, on patients with histories of multiple serum allergies, or on wounds with large amounts of eschar. As the wound heals, EZ-Derm will naturally slough off; as this occurs the dry edges may be trimmed off to avoid mechanical dislodgment (shearing). EZ Derm, all dermis porcine xenograft is supplied in rolls (3" wide by 12", 24" or 48" long). EZ Derm is also supplied in sheets, 7"x18" and patches, 3"x4" and 2"x2". Shelf life of EZ Derm is 18 months from date of manufacture, at room temperature storage. According to the requester, there is no level II HCPCS code that describes a porcine xenograft, temporary skin substitute.

Preliminary Decision:

Establish Qxxxx EZ-DERM, PER SQUARE CENTIMETER

HCPCS Public Meeting Agenda Item #9
May 8, 2012

Attachment# 12.046

Topic/Issue:

Request to establish a code for a six-layer Porcine Urinary Bladder Matrix (UBM), trade name: MatriStem Wound Matrix PSMX. Applicant's suggested language: "Skin substitute, MatriStem Multi-layer Wound Matrix PSMX, per square centimeter."

Background/Discussion:

According to the requester, MatriStem PSMX is a porcine-derived, lyophilized acellular extracellular matrix that maintains and supports a healing environment for wound management. It is indicated for the management of partial and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds, trauma wounds, and draining wounds. When applied to a wound, MatriStem PSMX changes the healing response, resulting in remodeled, functional, site specific tissue. MatriStem PSMX 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 PSMX 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 wound normally be expected. MatriStem PSMX is supplied as follows: 5cm x 5cm, 4cm x 12 cm, 7cm x 10cm, 6cm x 15cm, 8cm x 16cm, and 10cm x 15cm. According to the requester, MatriStem PSMX is distinct from the other similar skin substitute products because it is naturally occurring, non-crosslinked, completely resorbable, acellular, and has bimodal surface characteristics and antibacterial properties. Existing code Q4100 has been used as a "generic" code, however; Q4100 is not adequate to describe this product because 3rd party payers only reimburse for specific "Q" codes, similar to the "Q" codes that are assigned to the other devices listed under the skin substitute HCPCS code set. Existing code Q4119 "MATRISTEM WOUND MATRIX, PER SQUARE CENTIMETER" describes only single-layer MatriStem products.

Preliminary Decision:

Revise existing code Q4119 which currently reads: "MATRISTEM WOUND MATRIX, PER SQUARE CENTIMETER" to instead read: "MATRISTEM WOUND MATRIX, PSMX, RS OR PSM PER SQUARE CENTIMETER". Revised code Q4119 adequately describes MatriStem Wound Matrix PSMX.

HCPCS Public Meeting Agenda Item #9
May 8, 2012

Attachment# 12.047

Topic/Issue:

Request to establish a code for two-layer Porcine Urinary Bladder Matrix (UBM), trade name: MatriStem Wound Matrix RS. Applicant's suggested language: "Skin substitute, MatriStem Multi-layer Wound Matrix RS, per square centimeter."

Background/Discussion:

According to the requester, MatriStem Wound Matrix RS is a porcine-derived, lyophilized acellular extracellular matrix that maintains and supports a healing environment for wound management. It is indicated for the management of partial and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds, trauma wounds, and draining wounds. When applied to a wound, MatriStem Wound Matrix RS changes the healing response, resulting in remodeled, functional, site specific tissue. MatriStem Wound Matrix RS 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 Wound Matrix RS 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 wound normally be expected. MatriStem Wound Matrix RS is supplied as follows: 1.5 cm disc (box of 5 each), 2cm x 4cm, 5cm x 5cm, 7cm x 10cm, 6cm x 15cm, 8cm x 16cm, and 10cm x 15cm. According to the requester, MatriStem Wound Matrix RS is distinct from the other similar skin substitute products because it is naturally occurring, non-crosslinked, completely resorbable, acellular, and has bimodal surface characteristics and antibacterial properties. Existing code Q4100 has been used as a "generic" code, however; Q4100 is not adequate to describe this product because 3rd party payers only reimburse for specific "Q" codes, similar to the "Q" codes that are assigned to the other devices listed under the skin substitute HCPCS code set. Existing code Q4119 "MATRISTEM WOUND MATRIX, PER SQUARE CENTIMETER" describes only single-layer MatriStem products.

Preliminary Decision:

Revise existing code Q4119 which currently reads: "MATRISTEM WOUND MATRIX, PER SQUARE CENTIMETER" to instead read: "MATRISTEM WOUND MATRIX, PSMX, RS OR PSM PER SQUARE CENTIMETER". Revised code Q4119 adequately describes MatriStem Wound Matrix PSMX.

HCPCS Public Meeting Agenda Item #9
May 8, 2012

Attachment# 12.048

Topic/Issue:

Request to establish a code for three-layer Porcine Urinary Bladder Matrix (UBM), trade name: MatriStem Wound Matrix PSM. Applicant's suggested language: "Skin substitute, MatriStem Multi-layer Wound Matrix PSM, per square centimeter."

Background/Discussion:

According to the requester, MatriStem PSM is a porcine-derived, extracellular matrix that maintains and supports a healing environment for wound management. It is indicated for the management of partial and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds, trauma wounds, and draining wounds. When applied to a wound, MatriStem PSM changes the healing response, resulting in remodeled, functional, site specific tissue. MatriStem PSM 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 PSM 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 wound normally be expected. MatriStem PSM is supplied as follows: 1.5cm disc (box of 5 each), 5cm x 5cm, 4cm x 12 cm, 7cm x 10cm, 6cm x 15cm, 7cm x 15cm, and 10cm x 15cm. According to the requester, MatriStem PSM is distinct from the other similar skin substitute products because it is naturally occurring, non-crosslinked, completely resorbable, acellular, and has bimodal surface characteristics and antibacterial properties. Existing code Q4100 has been used as a "generic" code, however; code Q4100 is not adequate to describe this product because 3rd party payers only reimburse for specific "Q" codes, similar to the "Q" codes that are assigned to the other devices listed under the skin substitute HCPCS code set. Existing code Q4119 "MATRISTEM WOUND MATRIX, PER SQUARE CENTIMETER" describes only single-layer MatriStem products.

Preliminary Decision:

Revise existing code Q4119 which currently reads: "MATRISTEM WOUND MATRIX, PER SQUARE CENTIMETER" to instead read: "MATRISTEM WOUND MATRIX, PSMX, RS OR PSM PER SQUARE CENTIMETER". Revised code Q4119 adequately describes MatriStem Wound Matrix PSMX.

HCPCS Public Meeting Agenda Item #10
May 8, 2012

Attachment# 12.032

Topic/Issue:

Request to establish a code for immune globulin for subcutaneous use, trade name: Gammagard Liquid. Applicant's suggested language: Jxxxx "Injection, immune globulin (Gammagard Liquid), subcutaneous, nonlyophilized, (e.g., liquid), 500 mg".

Background/Discussion:

According to the requester, GAMMAGARD LIQUID for subcutaneous use is indicated for the treatment of patients with Primary Immunodeficiency (PI) associated with defects in humoral immunity for patients 2 years of age or older. GAMMAGARD LIQUID supplies a broad spectrum of opsonizing and neutralizing IgG antibodies against a wide variety of bacterial and viral agents. It also contains a spectrum of antibodies capable of interacting with and altering the activity of cells of the immune system as well as antibodies capable of reacting with cells such as erythrocytes. The recommended initial dose is 1.37 x previous IGIV dose divided by number of weeks between IGIV doses. Maintenance dose is based on clinical response and target IgG trough level. Doses are adjusted as necessary. GAMMAGARD LIQUID is supplied in single use bottles containing the labeled amount of functionally active IgG, (aqueous solution containing 10% IgG (100 mg/mL)). According to the requester, existing code J1569 "INJECTION, IMMUNE GLOBULIN, (GAMMAGARD LIQUID), INTRAVENOUS, NONLYOPHILIZED, (E.G. LIQUID), 500 MG" does not adequately describe this product because it is specific to GAMMAGARD LIQUID for intravenous use.

Preliminary Decision:

Revise existing code J1569 which currently reads: "INJECTION, IMMUNE GLOBULIN, (GAMMAGARD LIQUID), INTRAVENOUS, NON-LYOPHILIZED, (E.G. LIQUID), 500 MG" to instead read: "INJECTION, IMMUNE GLOBULIN, (GAMMAGARD LIQUID), NON-LYOPHILIZED, (E.G. LIQUID), 500 MG".

HCPCS Public Meeting Agenda Item #11
May 8, 2012

Attachment# 12.035

Topic/Issue:

Request to establish a code for Mometasone furoate implant, trade name: Propel™. Applicant's suggested language: Jxxxx "Mometasone furoate sinus implant, each".

Background/Discussion:

According to the requester, Propel™ is a steroid-releasing sinus implant that is inserted into the ethmoid sinus. It is indicated for maintaining sinus patency following functional endoscopic sinus surgery (FESS) by reducing inflammation, significant polyp formation, adhesions, and edema in patients 18 years of age and older. This steroid releasing implant is comprised of a synthetic bioabsorbable co-polymer and is self-expanding, which allows it to conform to the highly variable contours and size of the sinus anatomy. Propel™ is inserted into the ethmoid sinus cavity by a physician under endoscopic visualization. Upon insertion, the implant expands radially to conform to the sinus cavity. The delivery system is then removed and discarded. Once Propel™ is in place, mometasome furoate is released over a period of 30 days. Dosages for Propel™ are measured in terms of the number of implants inserted in a patient's sinus cavities. Each steroid-releasing implant contains 370 micrograms of mometasome furoate. Propel™ is packaged together with a single-use delivery system. According to the requester, there are no similar implantable products and no existing codes to describe Propel™, and a "J" code is needed to facilitate provider billing and reimbursement.

Preliminary Decision:

Use newly established code S1090 "MOMETASONE FUROATE SINUS IMPLANT, 370 MICROGRAMS," effective July 1, 2012.

HCPCS Public Meeting Agenda Item #12
May 8, 2012

Attachment# 12.037

Topic/Issue:

Request to establish a code for influenza virus vaccine, trade name: AGRIFLU.

Background/Discussion:

According to the requester, AGRIFLU is an influenza virus vaccine. AGRIFLU is a trivalent, inactivated, surface antigen vaccine containing 15 micrograms of hemagglutin from each of the selected influenza virus vaccine strains. It is indicated for active immunization for patients 18 years of age and over. AGRIFLU works by stimulating protective immune response. Dosage is 0.5 mL administered as an intramuscular injection. AGRIFLU is supplied as a package of ten prefilled syringes containing 0.5 mL of vaccine and a luer-lok. According to the requester, similar products are described by brand or product specific codes, and a brand-specific code is needed for Agriflu to facilitate accurate reimbursement and tracking.

Preliminary Decision:

Use newly established code Q2034 "INFLUENZA VIRUS VACCINE, SPLIT VIRUS, FOR INTRAMUSCULAR USE (AGRIFLU)," effective July 1, 2012.

HCPCS Public Meeting Agenda Item #13
May 8, 2012

Attachment# 12.022

Topic/Issue:

Request to establish a new unique, simplified, permanent code for Sipuleucel-T, trade name: PROVENGE®. Applicant's suggested language: Jxxxx "Sipuleucel-T, 250 mL".

Background/Discussion:

According to the Requester, PROVENGE® (sipuleucel-T) is an autologous cellular immunotherapy indicated for the treatment of a symptomatic or minimally symptomatic metastatic castrate resistant (hormone refractory) prostate cancer. The patient's peripheral blood mononuclear cells are obtained via a standard leukapheresis procedure approximately 3 days prior to the infusion date. The active components of PROVENGE® are autologous APCs and PAP-GM-CSF. During culture, the recombinant antigen can bind to and be processed by APCs into smaller protein fragments. While the precise mechanism of action is unknown, the recombinant antigen is designed to target APCs and may help direct the immune response to PAP. Minimal residual levels of the intact PAP-GM-CSF are detectable in the final PROVENGE® product. The cellular composition of PROVENGE® is dependent on the composition of cells obtained from the patient's leukapheresis. In addition to APCs, the final product contains T cells, B cells, natural killer (NK) cells, and other cells. The number of cells present and the cellular composition of each PROVENGE® dose will vary. The course of therapy for PROVENGE® (sipuleucel-T) is 3 doses, 250 mL each, given at approximately 2-week intervals by intravenous infusion over approximately 60 minutes. PROVENGE® (sipuleucel-T) is supplied in a sealed, patient-specific infusion bag containing a minimum of 50 million autologous CD54+ cells activated with PAP-GM-CSF suspended in 250 mL of Lactated Ringer's Injection, USP. According to the requester, existing code Q2043 is confusing because it includes the raw ingredients for making PROVENGE®; is too long to fit into many billing systems; does not describe the amount administered in simple terms; and is a “temporary” code (where a permanent “J” code describing a drug a preferred).

Preliminary Decision:

Existing code Q2043 "SIPULEUCEL-T, MINIMUM OF 50 MILLION AUTOLOGOUS CD54+ CELLS ACTIVATED WITH PAP-GM-CSF, INCLUDING LEUKAPHERESIS AND ALL OTHER PREPARATORY PROCEDURES, PER INFUSION" adequately describes the product that is the subject of this request.

HCPCS Public Meeting Agenda Item #14
May 8, 2012

Attachment# 12.065

Topic/Issue:

Request to discontinue code J8561 "EVEROLIMUS, ORAL, 0.25 MG" and replace it with a new code for the same product in the J7xxx series. Applicant's suggested language: J7xxx "Everolimus, Oral (Zortress), 0.25 mg".

Background/Discussion:
According to the requester, Zortress® is a macrolide immunosuppressant indicated for the prophylaxis of organ rejection in adult kidney transplant patients at low to moderate immunologic risk, who are receiving a kidney transplant. It allows for use of reduced doses of nephrotoxic calcineurin inhibitors without loss of immunosuppressive activity while maintaining renal function. The requester is asking CMS to discontinue code J8561 "EVEROLIMUS, ORAL, 0.25 MG) and reassign the code to the J7xxx series for the following reasons: 1) traditionally HCPCS codes beginning with "J8" are considered "oral chemotherapy drugs; 2) Some HCPCS publications categorized codes beginning with "J8" as oral chemotherapy drugs; and 3) traditionally HCPCS codes for immunosuppressant drugs begin with "J7". In the absence of a "J7" code for everolimus, one may erroneously conclude that no such code exists as it is not within the expected section of HCPCS.

Preliminary Decision:

1) Discontinue J8561 EVEROLIMUS, ORAL, 0.25 MG (effective 12/31/2012)

2) Establish J7xxx EVEROLIMUS, ORAL, 0.25 MG (effective 1/1/12013)

HCPCS Public Meeting Agenda Item #15
May 8, 2012

Attachment# 12.024

Topic/Issue:

Request to establish a new HCPCS "J" code for lidocaine/tetracaine topical patch, trade name: Synera®. Applicant's suggested language: Jxxxx "Lidocaine 70 mg/tetracaine 70 mg, per patch".

Background/Discussion:

According to the requester, SYNERA® is a single-use topical anesthetic patch with a novel, Controlled Heat-assisted Drug Delivery (CHADD) device that enhances the delivery of two local anesthetics, a eutectic mixture of lidocaine and 70 mg tetracaine. The CHADD technology warms the patch once it is removed from the packaging, which facilitates delivery of anesthetics into the skin, and provides faster onset and greater depth and duration of analgesia when compared to other topically-administered products. The SYNERA® patch is applied to intact skin to provide local dermal analgesia prior to painful procedures such as needle punctures and superficial dermatological procedures. SYNERA® is indicated for use in adults and children 3 years of age and older. It is applied 20 - 30 minutes prior to venipuncture or intravenous cannulation. For superficial dermatological procedures, SYNERA® is applied for 30 minutes prior to the procedure. SYNERA® is supplied as a package containing one SYNERA® patch and as a box of ten individually packaged patches. According to the requester, while HCPCS code C9285 is available for hospital outpatient use, there is no corresponding "J" code for physician office/clinic use.

Preliminary Decision:

Existing code C9285 "LIDOCAINE 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 new code for this product was not identified by Medicare, Medicaid or the Private Insurance Sector.

HCPCS Public Meeting Agenda Item #16
May 8, 2012

Attachment# 12.009

Topic/Issue:

Request to establish a new HCPCS code for Mitosol® (ophtalmic mitomycin USP).

Background/Discussion:
According to the requester, Mitosol™ is expected to be the only FDA-approved product for the treatment of refractory glaucoma as an adjunct to ab externo glaucoma surgery by topical application to the exposed site of a filtering bleb during trabeculectomy surgery to interrupt DNA synthesis and thereby prolong the closing of the surgically created fistula. This allows maintenance of sub-hypertensive intraocular pressure in patient's refractory to maximal medical therapy in whom trabeculectomy surgery is indicated. Mitosol™ is packaged in a carton containing 3 kits. Each kit contains 1 vial of 0.2 mg lyophilized mitomycin, 1 syringe with connector, 1 plunger rod, 1 vial adapter with spike, 1 zip-lock bag, 1 sterile rubber band, 1 TB syringe, luer lock, 1 pledget container, 12 absorbent pledgets, 6 half-moon sponges, 1 instrument wedge sponge, 1 alcohol prep pad and 1 chemotherapy waste bag. 0.2 mg of mitomycin and mannitol in a 1:2 concentration ratio is administered topically to the surgical site during glaucoma filtering procedures. Pledgets provided within the Mitosol™ kit should be fully saturated with the entire reconstituted contents. According to the requester, existing HCPCS codes do not adequately describe Mitosol™ and there are currently no therapeutically equivalent manufactured products. A specific HCPCS code would alleviate reimbursement issues and allow for accurate tracking of utilization for this product. The use of "not otherwise classified" codes results in manual claims processing causing delays in claim payment, errors in determining an accurate payment rate and the inability to track utilization for the product.

Preliminary Decision:

1) Establish Jxxxx MITOMYCIN, OPHTHALMIC, 0.2 MG

2) Revise code J9280 which currently reads: "MITOMYCIN, 5 MG" to instead read: "INJECTION, MITOMYCIN, 5 MG"

HCPCS Public Meeting Agenda Item #17
May 8, 2012

Attachment# 12.013

Topic/Issue:

Request to: 1) establish a code for Erwinia-derived asparaginase, trade name: ERWINAZE® and 2) revise the description of code J9020 which currently reads: "INJECTION, ASPARAGINASE, 10,000 UNITS" to instead read: "Injection, E.coli asparaginase, 10,000 units". Applicant's suggested language for new code: "Injection, asparaginase, per 10,000 units".

Background/Discussion:

According to the requester, ERWINAZE is an asparagine-specific enzyme derived from Erwinia chryansthemi that is indicated as part of a multi-agent chemotherapeutic regimen for the treatment of patients with acute lymphoblastic leukemia (ALL) who have developed hypersensitivity to Escherichia coli (E.coli)-derived L-asparaginase. Asparaginases work by depleting levels of asparagine in the blood which leukemic cells need to survive. Asparaginase hydrolyzes circulating asparagine resulting in the starvation and death of the malignant cells. ERWINAZE is administered by intramuscular (IM) injection. The recommended dose is 25,000 IU/m^2 IM three times a week for two weeks to replace each dose of pegasparaginase, or 25,000 IU/m^2 for each course of native E-coli asparaginase treatment. Each 10,000 IU/vial lyophilisate must be reconstituted in 1 or 2 mL sodium chloride before use. No more than 2 mL of reconstituted ERWINAZE should be given at any one injection site. If the volume of reconstituted ERWINAZE to be injected is greater than 2 mL, multiple injection sites should be used. ERWINAZE is supplied as a lyophilized powder in 3 mL vials. Each vial contains 10,000 U Erwinia-derived asparaginase. It contains no preservatives. According to the requester, there is no existing HCPCS code to describe this product.

Preliminary Decision:

1) Establish Jxxxx INJECTION, ASPARAGINASE (ERWINAZE), 1,000 IU

2) Revise existing code J9020 which currently reads: “INJECTION, ASPARAGINASE, 10,000 UNITS,” to instead read: “INJECTION, ASPARAGINASE, 10,000 UNITS, NOT OTHERWISE SPECIFIED”.

HCPCS Public Meeting Agenda Item #18
May 8, 2012

Attachment# 12.033

Topic/Issue:

Request to discontinue existing code J1680 "INJECTION, HUMAN FIBRINOGEN CONCENTRATE, 100MG) and replace with a temporary "Q" code for the remainder of year 2012; and establish a "J7xxx" code effective 1/1/13 to replace codes J1680 and Qxxxx so that Human Fibrinogen will be in the series with other clotting factors and the "unit" definition among the various clotting factors will be 1 mg. Applicant's suggested language: Qxxxx and Jxxxx "Injection, human fibrinogen concentrate, 1 mg".

Background/Discussion:

According to the requester, Riastap is the only FDA approved fibrinogen concentrate. Riastap is a highly purified, lyophilized fibrinogen (coagulation Factor I) manufactured from large pools of human plasma. It is indicated for patients with Congenital Fibrinogen Deficiency. It replaces missing, low, or malfunctioning coagulation factor, necessary to form a blood clot. The recommended initial dose for Riastap is 70 mg per kg of body weight, administered intravenously through a dedicated administration line. The injection rate should not exceed 5ml per minute. Any additional doses will be determined by the severity of the injury or bleeding event; and the baseline fibrinogen levels of the individual patient. Riastap is supplied in a single-use vial containing 900 to 1300 mg lyophilized fibrinogen concentrate powder for reconstitution. The fibrinogen potency for each lot is printed on the vial label. Riastap contains no preservatives and any unused portion is to be discarded. In January 2010 HCPCS code J1680 "INJECTION, HUMAN FIBRINOGEN CONCENTRATE, 100 MG" was established. Subsequent to the implementation date, a transmittal was issued which changed the language associated with payment of the clotting factor furnishing fee from "per IU" to "per unit". However, the term "unit" was not defined. As a result, the Part B MACs have applied varying interpretations to the application of the furnishing fee to RiaSTAP. Some define unit as "per 100mg" and others as "per mg". According to the requester, discontinuing code J1680 and establishing the proposed new code in the "J7xxx" series will place Human Fibrinogen with other clotting factors and standardize the "unit" definition among the various clotting factors at 1 mg.

Preliminary Decision:

1) Newly established code Q2045 INJECTION, HUMAN FIBRINOGEN CONCENTRATE, 1 MG" (effective July 1, 2012) adequately describes the product that is the subject of this request.

2) Discontinue Q2045 effective December 31, 2012

3) Establish Jxxxx INJECTION, HUMAN FIBRINOGEN CONCENTRATE, 1 MG" (effective January 1, 2013)

4) Discontinue J1680 effective December 21, 2012

HCPCS Public Meeting Agenda Item #19
May 8, 2012

Attachment# 12.040

Topic/Issue:

Request to establish a code for Aflibercept for intravitreal injection, trade name: EYLEA. Applicant's suggested language: Jxxxx "Aflibercept for intravitreal injection, 2 mg".

Background/Discussion:

According to the requester, EYLEA is a recombinant fusion protein consisting of portions of human vascular endothelial growth factor (VEGF) receptors 1 and 2 extracellular domains fused to the Fc portion of human IgG1 and specially purified and formulated as an iso-osmotic solution for intravitreal administration. It is indicated for the treatment of patients with neovascular (wet) Age-related Macular Degeneration (AMD). EYLEA acts as a soluble decoy receptor that binds VEGF-A and placental growth factor (PlGF) with high affinity, and thereby inhibits the binding and activation of their cognate VEGF receptors. Recommended dose for EYLEA is 2 mg (0.05 mL) every 4 weeks for the first 3 months, followed by 2 mg (0.05 mL) once every 8 weeks. EYLEA may be dosed as frequently as 2 mg every 4 weeks. It is supplied as a carton containing one single-use vial containing a 0.278 mL fill of 40 mg/mL EYLEA, one 5-micron, 1 filter needle for withdrawal of vial contents, 1 needle for intravitreal injection, and one 1-mL syringe for administration. According to the requester, there is no existing code to describe EYLEA.

Preliminary Decision:

1) Newly established code Q2046 "INJECTION, AFLIBERCEPT, 1 MG" adequately describes the product that is the subject of this request. (effective July 1, 2012)

2) Discontinue Q2046 effective 12/31/2012

3) Establish Jxxxx INJECTION, AFLIBERCEPT, 1 MG (effective January 1, 2013)

4) Existing code C9291 “INJECTION, AFLIBERCEPT, 2 MG VIAL” is available for assignment by insurers if they deem appropriate, until such time as code Q2046 is implemented.

HCPCS Public Meeting Agenda Item #20
May 8, 2012

Attachment# 12.007

Topic/Issue:

Request to establish a code for belatacept, trade name: Nulojix®. The applicant submitted two different suggested code descriptors: "Injection, Belatacept, 1 mg", and "Injection, Belatacept, 250 mg per vial".

Background/Discussion:

According to the requester, NULOJIX™ is a novel, selective T-cell costimulation blocker indicated for prophylaxis of organ rejection in adult patients receiving a kidney transplant. It binds to CD80 and CD86 on antigen-presenting cells thereby blocking CD28 mediated costimulation of T lymphocytes. In vitro, NULOJIX inhibits T lymphocyte proliferation and the production of the cytokines interleukin-2, interferon-*y*, interleukin-4, and TNF-*a*. Activated T lymphocytes are the predominant mediators of immunologic rejection. NULOJIX is supplied in 250 mg single-use vials. The entire infusion is administered over a period of approximately 30 minutes. Treatment with NULOJIX will be initiated at the time of kidney transplant with subsequent infusions at Day 5, Day 14, and Day 28 post-transplant before moving to monthly (every 4 weeks ±3 days) maintenance infusions for the life of the transplanted kidney. The recommended dose for the initial treatment phase (through 12 weeks post transplant) is 10 mg/kg. The recommended dose for the maintenance phase of treatment (beginning at week 16 post-transplant) is 5 mg/kg. According to the requester, NULOJIX (belatacept) is a unique biologic treatment for prophylaxis of organ rejection in adult patients receiving a kidney transplant. No current code exists to appropriately describe NULOJIX. Applicant's code language suggestions: "Injection, belatacept, 1 mg "and" Injection, balatacept, 250 mg pervial".

Preliminary Decision:

Establish Jxxxx INJECTION, BELATACEPT, 1 MG

HCPCS Public Meeting Agenda Item #21
May 8, 2012

Attachment# 12.039

Topic/Issue:

Request to establish a code for brentuximab vedotin, trade name: ADCETRIS™. Applicant's suggested language: Jxxxx "Injection, brentuximab vedotin, 1 mg".

Background/Discussion:

According to the requester, ADCETRIS is a targeted antibody-drug conjugate (ADC) developed to treat malignancies that express the cell surface molecule CD30. It is approved for the treatment of Hodgkin lymphoma (HL) after failure of autologous stem cell transplant or after failure of at least two prior multi-agent chemotherapy regimens in patients not eligible for transplant. ADCETRIS is also indicated for the treatment of systemic anaplastic large cell lymphoma (sALCL) after failure of at least one prior multi-agent chemotherapy regimen. Nonclinical data suggest that the anticancer activity of ADCETRIS is due to the binding of the ADC to CD30-expressing cells, followed by internalization of the ADC-CD30 complex, and the release of monomethyl auristatin E(MMAE) via proteolytic cleavage. Binding of MMAE to tubulin disrupts the microtubules network within the cell, subsequently inducing cell cycle arrest and apoptotic death of the cells. Dosage is 1.8 mg/kg every three weeks for a maximum of 16 cycles, disease progression or unacceptable toxicity. ADCETRIS is delivered via a 30-minute IV infusion. It should not be delivered via an IV push or bolus IV infusion. ADCETRIS is supplied as a lyophilized cake or powder in 50 mg, single-use vials. According to the requester, there is no existing code to describe ADCETRIS.

Preliminary Decision:

Establish Jxxxx INJECTION, BRENTUXIMAB VEDOTIN, 1 MG

HCPCS Public Meeting Agenda Item #22
May 8, 2012

Attachment# 12.026

Topic/Issue:

Request to establish another HCPCS code for a new formulation of Epoprostenol for Injection, trade name: VELETRI®. Applicant's suggested language: "Injection, Epoprostenol, Saline Diluent, 1.5 mg".

Background/Discussion:

According to the requester, VELETRI® is prostanoid vasodilator that is delivered via intravenous injection, indicated for the treatment of pulmonary arterial hypertension (PAH). VELETRI® is a new formulation that contains the same active ingredient, but with different excipients. VELETRI® omits sodium chloride and substitute's arginine for glycine. According to the requester, VELETRI® is not therapeutically equivalent to the other formulations of epoprostenol and therefore existing code, J1325 "Injection, epoprostenol, 0.5mg" does not adequately describe it. VELETRI® is administered by continuous intravenous infusion via a central venous catheter using an ambulatory infusion pump. It is supplied in 1.5mg/10mLvials. Although VELETRI® is rated as therapeutic equivalent in the FDA's Orange Book, the requester claims that VELETRI® is a unique single-source drug without therapeutic equivalents.

Preliminary Decision:

Existing code J1325 "INJECTION, EPOPROSTENOL, 0.5 MG" adequately describes the product that is the subject of this request.

HCPCS Public Meeting Agenda Item #23
May 8, 2012

Attachment# 12.006

Topic/Issue:

Request to establish a code for Ibuprofen for intravenous injection, trade name: Caldolor.

Background/Discussion:

According to the requester, Caldolor is an intravenous formulation of Ibuprofen that fulfills the need for an alternative route of administration when a non-oral route is necessary or preferable. It is indicated for use in adults only, for the management of mild to moderate pain, the management of moderate to severe pain, and the reduction of fever. Caldolor is intended for intravenous infusion only and must be diluted before administration. Caldolor is not comparable to other products in the "ibuprofen & other NSAID category" with respect to indication, vial size/product strength, typical dosage per administration, route of administration, initiation-of and length-of treatment limitations, black box warnings. There are two different strengths, with different costs, with one used to treat pain and the other to treat fever. It is administered as follows: 400 mg to 800 mg intravenously administered over 30 minutes every 6 hours as necessary for pain; and 400 mg intravenously administered over 30 minutes, followed by 400 mg every 4 to 6 hours or 100-200 mg every 4 hours as necessary for fever. Caldolor is available as a 400 mg/4 ml single-dose vial (100 mg/ml) and also as an 800 mg/8 ml single-dose vial (100 mg/ml). According to the requester, existing code C9279 "INJECTION, IBUPROFEN, 100 MG" adequately describes this product, however, a "J" code is needed to report for reimbursement when used in hospital settings.

Preliminary Decision:

Establish Jxxxx INJECTION, IBUPROFEN, 100 MG effective January 1, 2013

Existing code C9279 “INJECTION, IBUPROFEN, 100 MG” is currently available for assignment by insurers if they deem appropriate.

HCPCS Public Meeting Agenda Item #24
May 8, 2012

Attachment# 12.008

Topic/Issue:

Request to establish a code for bupivacaine liposome injectable suspension, trade name: Exparel.

Background/Discussion:

According to the requester, EXPAREL is a liposomal injection of bupivacaine indicated for administration into the surgical site to produce postsurgical analgesia. This non-opiod local analgesic provides postsurgical pain control for up to 72 hours with a single intraoperative injection given at the close of surgery. EXPAREL is not cleared for pediatric use. EXPAREL utilizes the bupivacaine in a DepoFoam delivery system and works by a sodium channel blocker mechanism of action. DepoFoam is a multivesicular liposomal product delivery technology that encapsulates drugs without altering the molecular structure and releases them over a desired period of time from 1 to 30 days. EXPAREL is intended for single-dose administration via infiltration, and the recommended dosage is based on the surgical site and the volume required to cover the area. A local infiltration of EXPAREL releases bupivacaine over 96 hours. It is supplied in 10 ml and 20 ml single use vials, 1.3% (13.3mg/ml). According to the requester, EXPAREL differs from similar products because other products are used in multiple routes of administration and are indicated for the production of anesthesia or analgesia for surgery, diagnostic and therapeutic procedures. EXPAREL has a significant therapeutic distinction over similar products used for managing postsurgical pain because it addresses two unmet market needs through a single-dose intraoperative administration: postsurgical analgesia for up to 72 hours and a reduction in opioid requirements. Existing codes do not describe EXPAREL because there are no therapeutically equivalent products.

Preliminary Decision:

Existing code C9290 "INJECTION, BUPIVACAINE LIPOSOME, 1 MG" adequately describes the product that is the subject of this request. A national program operating need to establish a new code for this product was not identified by Medicare, Medicaid or the Private Insurance Sector, to establish a new code to describe this product which is used intraoperatively, as part of a procedure.

HCPCS Public Meeting Agenda Item #25
May 8, 2012

Attachment# 12.018

Topic/Issue:

Request to establish a code for Centruroides (Scorpion) Immune $F(ab')_2$ (Equine) injection, trade name: Anascorp®. Applicant's suggested language: "Injection, Centruroides (Scorpion) Immune $F(ab')_2$ (Equine) Injection, 1 vial".

Background/Discussion:

According to the requester, Anascorp® is an equine-derived antivenom indicated for intravenous treatment of patients with clinical signs of scorpion envenomation. It works by binding and neutralizing venom toxins, facilitating their redistribution away from target tissues and their elimination from the body. Anascorp® is supplied in vials containing a sterile, lyophilized preparation of not more than 120 milligrams total protein and not less than 150 LD_{50} (mouse) neutralizing units. Each box contains one vial of Anascorp®. The initial dose is 3 vials infused intravenously over 10 minutes. Additional doses are administered as needed and administered one vial at a time at 30 - 60 minute intervals. Vials are diluted to a total of 50 milliliters with sterile saline. Partially used vials should be discarded. According to the requester, Anascorp® is the first and only FDA approved product for scorpion envenomation.

Preliminary Decision:

Establish Jxxxx INJECTION, CENTRUROIDES IMMUNE FAB, UP TO 120 MILLIGRAMS

HCPCS Public Meeting Agenda Item #26
May 8, 2012

Attachment# 12.020

Topic/Issue:

Request to establish a code for methylnaltrexone bromide, trade name: Relistor. Applicant's suggested language: "Injection, methylnaltrexone bromide, up to 12 mg".

Background/Discussion:

According to the requester, Relistor is currently the only product available within the U.S. healthcare market indicated for the treatment of opioid-induced constipation (OIC). Relistor is not cleared for use in children 5-17 years. One dose of Relistor is administered subcutaneously. The appropriate dosage is determined by the patient's weight. Relistor inhibits opioid-induced delay of gastrointestinal transit time in a dose-dependent manner by preventing the opioid from binding to peripheral receptors in the gut, decreasing the opioid's constipating effects and inducing laxation. The recommended dose of Relistor is 8mg for patients weighing 38 kg to less than 62 kg (82 lb to less than 136 lb) or 12 mg for patients weighing 62 kg to 114 kg (136 lb to 251 lb). Relistor is administered via subcutaneous injection. The usual schedule is one dose every other day, as needed, but no more frequently than one dose in a 24-hour period.

Preliminary Decision:

Establish Jxxxx INJECTION, METHYLNALTREXONE, 0.1 MG

HCPCS Public Meeting Agenda Item #27
May 8, 2012

Attachment# 12.027

Topic/Issue:

Request to establish a code for icatibant injection, trade name: FIRAZYR®. Applicant's suggested language: Jxxxx "Injection, icatibant, 1 mg".

Background/Discussion:

According to the requester, FIRAZYR® is a bradykinin B2 receptor antagonist indicated for treatment of acute attacks of hereditary angioedema (HAE) in adults 18 years of age and older. HAE is a chronic rare genetic disease caused by low levels or a dysfunction of C1 esterase inhibitor (C1-INH). Reduced C1-INH activity can lead to elevated plasma levels of bradykinin, the key mediator of HAE symptoms. HAE is characterized by recurrent sudden attacks of edema of the skin or the mucous membranes which can be painful or disfiguring. In some patients, HAE symptoms include swelling in the larynx, which is potentially life threatening due to the risk of suffocation. The active ingredient (Icatibant) in FIRAZYR® inhibits bradykinin from binding to the B2 receptor and thereby treats the clinical symptoms of acute, episodic attacks of HAE. Recommended dose of FIRAZYR® is 30 mg administered via subcutaneous injection in the abdominal area. Additional doses of 30 mg may be administered at intervals of at least 6 hours if response is inadequate or symptoms recur. No more than 3 doses may be administered in any 24 hour period. FIRAZYR® can be self-administered. FIRAZYR® is supplied as a single-use prefilled syringe. Each syringe keeps 3 mL (30 mg) of Icatibant acetate. FIRAZYR® is available in cartons containing one single-use, prefilled syringe and one 25 G Luer lock needle; and as a pack containing 3 cartons. According to the requester, there is no existing code to describe this orphan drug.

Preliminary Decision:

Establish Jxxxx INJECTION, ICATIBANT, 1 MG

HCPCS Public Meeting Agenda Item #28
May 8, 2012

Attachment# 12.034

Topic/Issue:

Request to establish a code for clevidipine butyrate injectable emulsion for intravenous use, trade name: Cleviprex®. Applicant's suggested language: "Cleviprex Injectable Emulsion, 1 mg".

Background/Discussion:

According to the requester, Cleviprex is an intravenous dihydropyridine calcium channel blocker indicated for the reduction of blood pressure when oral therapy is not feasible or not desirable. Clevidipine reduces mean arterial blood pressure by decreasing systemic vascular resistance (SVR). Cleviprex can be titrated to achieve the desired blood pressure reduction. The dose should be initiated at 1-2 mg/hour. The dose be doubled at 90 second intervals initially. An approximately 1-2 mg/hour increase will generally produce an additional 2-4 mmHg decrease in systolic pressure. Cleviprex injectable emulsion is supplied as a sterile, milky white liquid emulsion product in single-use 50 mL or 100 mL glass vials at a concentration of 0.5 mg/mL of clevidipine. According to the requester, no existing "J" code describes the active ingredient, dosing regimen or manner in which Cleviprex is supplied. In addition, "a temporary ["C"] code may not permit appropriate identification of clevidipine to all payers [and] may inhibit patient access in the Medicaid population.

Preliminary Decision:

Existing code C9248 "INJECTION, CLEVIDIPINE BUTYRATE, 1 MG" adequately describes the product that is the subject of this request and is available for assignment by insurers if they deem appropriate. The code descriptor does not preclude use of the code to identify Cleviprex. A national program operating need to establish a new code was not identified by Medicare, Medicaid, or the Private Insurance Sector.

HCPCS Public Meeting Agenda Item #29
May 8, 2012

Attachment# 12.028

Topic/Issue:

Request to establish a permanent HCPCS code for hexaminolevulinate hydrochloride, trade name: Cysview, to replace existing code C9275. Applicant's suggested language: "Hexaminolevulinate HCl, 100mg/50mL per dose".

Background/Discussion:

According to the requester, Cysview is a fluorescent optical imaging agent indicated for use in the cystoscopic detection of non-muscle invasive papillary cancer of the bladder. It is used with the Karl Storz D-light C Photodynamic Diagnostic (PDD) system to perform cystoscopy with the blue light setting (Mode 2) as an adjunct to the white light setting (Mode 1). Hexaminolevulinate is the ester of an endogenous early precursor in the biosynthesis of heme. In the heme synthetic pathway, formation of heme from porphrin-intermediates is regulated by negative feedback. Intravesical instillation of hexaminolevulinate HCl bypasses the feedback and results in intracellular accumulation of porphyrins in lesions. These porphyrins are fluorescing compounds that emit red light upon excitation by blue light. As a result, premalignant and malignant lesions will glow red on a blue background. Recommended dosage for adults is 50 mL of reconstituted solution of Cysview, instilled into the bladder via a urinary catheter. It is supplied as a kit containing: one vial of 100 mg of Cysview, one vial containing 50 mL of diluent, and one luer lock catheter adapter. According to the requester a permanent code is needed to enable all payers, including hospital inpatient and outpatient facilities and ambulatory surgical centers to reimburse for the use of Cysview.

Preliminary Decision:

Existing code C9275 "INJECTION, HEXAMINOLEVULINATE HYDROCHLORIDE, 100 MG, PER STUDY DOSE" 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 new code for this product was not identified by Medicare, Medicaid or the Private Insurance Sector.

HCPCS Public Meeting Agenda Item #30
May 8, 2012

Attachment# 12.031

Topic/Issue:

Request to establish a code for pre-storage pooled, leukocyte reduced platelets. Applicant's suggested language: "Platelets, pre-storage pooled, leukocyte reduced, each unit."

Background/Discussion:

According to the requester, platelet products are derived from two different sources: apheresis and whole blood collections. There are advantages and disadvantages associated with each. Pre-storage pooled platelets are a relatively new product and combine the best of each of these existing platelet products. Like apheresis platelets, pre-storage pooled platelets are produced at a blood center, and provided to hospitals as a *therapeutic dose of platelets*, however, they are produced from whole blood platelet concentrates (PCs) that are pooled using Acrodose™ Systems. As a result of this processing, pre-storage pooled platelets retain the advantages of whole blood platelets while also acquiring the clinical advantages of apheresis platelets. The safety profile of the pre-storage pooled platelets has been shown to be as good as, if not better than those other platelet products. Also, according to the requester, there are a number of codes of for platelets, but none capture the important collective attributes (pooled ABO-matched and bacteria tested) of the platelets that are the subject of this application, such as longer shelf life, more sensitive bacteria testing and standardized dosing. These attributes confer a significant therapeutic distinction and are a unique outcome of using the Acrodose™ Systems. The requester claims that previously assigned code P9031 is used for individual PCs; not pre-storage pooled platelets, and the clinical benefits of pre-storage pooled platelets are not reflected in code P9031.

Preliminary Decision:

Existing code P9031 "PLATELETS, LEUKOCYTES REDUCED, EACH UNIT" adequately describes the product that is the subject of this request.

HCPCS Public Meeting Agenda Item #31
May 8, 2012

Attachment# 12.023

Topic/Issue:

Request to establish a code for Peginesatide Acetate, trade name: Omontys. Applicant's suggested language: "Injection, peginesatide acetate, 1 mg".

Background/Discussion:

According to the requester, Peginesatide is a [novel], synthetic, PEGylated peptide-based compound that binds to and stimulates the erythropoietin receptor and thus acts as an erythropoiesis-stimulating agent (ESA). It is indicated for the treatment of anemia associated with chronic kidney disease (CKD) for adult patients on dialysis. Peginesatide is distinct from current biologic-based ESA's. Compared to currently available ESAs, peginesatide is the only synthetic, non-erythropoietin analog (non-biologic). Peginesatide is not a fragment of erythropoietin. Peginesatide stimulates red blood cell production to treat anemia in dialysis patients. The recommended starting dose for the treatment of anemia in patients who are currently treated with an ESA is 0.04-0.08 mg/kg body weight. It is administered as a single IV or SC injection once monthly. It is available in multiple dose vials, single dose vials and single pre-filled syringes; each with a range of doses.

Single Dose Vials: 2, 3, 4, and 6 mg peginesatide /0.5 mL.

Single Dose Pre-filled Syringes: 1, 2, 3, 4, 5, and 6 mg peginesatide /0.5 mL.

Multiple Dose Vials: 10 mg peginesatide / mL (1 mL fill volume) and 20 mg peginesatide / 2 mL.

Preliminary Decision:

1) Use newly established code Q2047 “INJECTION, PEGINESATIDE, 0.1 MG (FOR ESRD ON DIALYSIS) effective July 1, 2012.

2) Discontinue Q2047 effective December 31, 2012

3) Establish Jxxxx “INJECTION, PEGINESATIDE, 0.1 MG (FOR ESRD ON DIALYSIS) effective January 1, 2013

HCPCS Public Meeting Agenda Item #32
May 8, 2012

Attachment# 12.038

Topic/Issue:

Request to establish a code for Florbetapir F 18, trade name: AMYViD™. Applicant's suggested language: "Injection, florbetapir F 18, diagnostic, per study dose".

Background/Discussion:

According to the requester, AMYVID™ is a radiopharmaceutical for use in positron emission tomography (PET) imaging of aggregated ß-amyloid (plaques) in the brains of adult patients with cognitive impairment who are being evaluated for suspected Alzheimer's Disease (AD) it is an adjunct to other diagnostic evaluations. AMYVID™ contains florbetapir F 18, a molecular imaging agent which binds to ß-amyloid aggregates. A positive scan indicates moderate to frequent plaques, which demonstrates the presence of AD pathology. A negative scan indicates sparse or no plaques, which is not consistent with a diagnosis of AD. At the time of calibration, each single-use vial or syringe contains a apyrogenic aqueous solution of up to a maximum 10 mL total volume containing 370 MBq Florbetapir F 18. Patients receive a single IV bolus of 370 MBq (10 mCi) of florbetapir followed by brain PET imaging for 10 minutes duration, beginning between 30 to 50 minutes post-injection. According to the requester, there are no current HCPCS codes to describe AMYVID™.

Preliminary Decision:

Establish Axxxx FLORBETAPIR F 18, DIAGNOSTIC, PER STUDY DOSE, UP TO 10 MILLICURIES