Centers for Medicare & Medicaid Services (CMS)
Healthcare Common Procedure Coding System (HCPCS)
Public Meeting Summary Report
Drugs, Biologicals, and Radiopharmaceuticals
Wednesday, May 18, 2011

Introduction and Overview

Approximately 100 people attended. The agenda included 19 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.

Anne Hauswald, Acting Director of the Division of Ambulatory Services (DAS), provided an overview of the Medicare payment methodology for Part B drugs, biologicals, and radiopharmaceuticals. A copy of the overview was provided in a written document and is attached to this summary.

Prior to the Public Meetings, over the course of several months, the CMS HCPCS Workgroup convene, discuss, and establish preliminary coding recommendations on all HCPCS code applications and make preliminary coding recommendations. At the same time, CMS assigns preliminary recommendations regarding the applicable Medicare payment category and methodology that will be used to set a payment amount for the items on the agenda. The preliminary coding and payment recommendations are posted on the CMS HCPCS web site, specifically at www.cms.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 18, 2011 9:00 am – 5:00 pm
CMS Auditorium
7500 Security Boulevard
Baltimore (Woodlawn), Maryland 21244-1850

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

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

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

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

AGENDA ITEM #1
Attachment#11.014
Request to establish a code for hexaminolevulinate hydrochloride, trade name: Cysview.

Primary Speaker: Jane Majcher of GE Healthcare

AGENDA ITEM #2
Attachment#11.027
Request to establish a code for Ioflupane, trade name DaTscan™.

No Primary Speaker

AGENDA ITEM #3
Attachment#11.071
Request to establish a code for Gadobutrol injection, trade name: Gadavist.

Primary Speaker: Denise Merlino of Merlino HealthCare Consulting Corporation

AGENDA ITEM #4
Attachment#11.122
Request to establish a code for reconstructive tissue matrix, trade name: Strattice™.

No Primary Speaker

AGENDA ITEM #5
Attachment#11.042
Request to establish a code for extracellular matrix, trade name: Oasis® Ultra Tri-Layer Matrix.

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

AGENDA ITEM #6
Attachment#11.045
Request to establish a code for meshed collagen-glycosaminoglycan matrix, trade name: Integra™ Meshed Bilayer Wound Matrix.

No Primary Speaker

AGENDA ITEM #7
Attachment#11.068
Request to establish a code for wound matrix, trade name: Talymed™.

No Primary Speaker

AGENDA ITEM #8
Attachment#11.075
Request to establish a code for collagen based wound dressing, trade name: Unite™ Biomatrix.

No Primary Speaker

AGENDA ITEM #9
Attachment#11.076
Request to establish a code for a collagen scaffold used for soft tissue repair and reinforcement, trade name: OrthADAPT® Bioimplant.

Primary Speaker: John Brunelle of Synovis Life Technologies, Inc.

AGENDA ITEM #10
Attachment#11.069
Request to establish a "Q" code for Acellular Human Dermis, trade name: FlexHD®.

No Primary Speaker

AGENDA ITEM #11
Attachment#11.070
Request to establish a code for acellular human dermis, trade name: AlloPatchHD™ Acellular Human Dermis.

No Primary Speaker

AGENDA ITEM #12
Attachment#11.118
Request to establish a code for an allograft made from human dermis, trade name: AlloMax™.

Primary Speaker: Dr. Adam Vernadakis of Lahey Clinic Division of Plastic Surgery

AGENDA ITEM #13
Attachment#11.028
Request to establish a code for meshed cadaveric dermis, trade name: AlloSkin™ RT.

No Primary Speaker

AGENDA ITEM #14
Attachment#11.057
Request to establish a code for decellularized human skin allograft, trade name: Arthroflex™.

Primary Speaker: Dr. Brandon Roller of Arthrex, Inc.

AGENDA ITEM #15
Attachment#11.022
Request to establish a code for regenerative human dermal allograft, trade name: DermACELL™.

Primary Speaker: Dr. Adam Landsman of Harvard Medical School

AGENDA ITEM #16
Attachment#11.067
Request to establish a code for acellular dermal matrix, trade name: Repriza™.

No Primary Speaker

AGENDA ITEM #17
Attachment#11.065
Request to establish a code for human acellular dermis allograft tissue, trade name: MemoDerm™ Acellular Dermal Matrix.

No Primary Speaker

AGENDA ITEM #18
Attachment#11.009
Request to establish a code for human skin allograft, trade name: Matrix™ HD.

Primary Speaker: Carrie Hartill of RTI Biologics

AGENDA ITEM #19
Attachment#11.010
Request to establish a code for sterilized non-irradiated human tendon tissue, trade name: BioCleanse® Sterilized Allograft Tendons.

Primary Speaker: Carrie Hartill of RTI Biologics

HCPCS Public Meeting Agenda Item #1
05/18/2011

Attachment# **11.014**

Topic/Issue:

Request to establish a code for hexaminolevulinate hydrochloride, trade name: Cysview. Applicant's suggested language: A95xx "Hexaminolevulinate HCl, 100 mg/50 mL, per study dose".

Background/Discussion:

According to the requester, Cysview is indicated for use in the cystoscopic detection of non-muscle invasive papillary cancer of the bladder among patients suspected or known to have lesion(s) on the basis of a prior cystoscopy. 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 there is no existing code that accurately describes Cysview.

CMS HCPCS Workgroup Preliminary Decision:

A national program operating need to establish a new code for Cysview was not identified by Medicare, Medicaid or the Private Insurance Sector. 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.

Summary of Primary Speaker Comments at the Public Meeting:

The applicant provided comments that a new code is needed for non-Medicare users "because C codes can only be used in HOPPS." The applicant asked that the HCPCS Workgroup reconsider this request. The applicant further asked for "more appropriate payment if a product is identified with its own code."

HCPCS Public Meeting Agenda Item #2
05/18/2011

Attachment# **11.027**

Topic/Issue:

Request to establish a code for Ioflupane, trade name DaTscan™. Applicant's suggested language: "Ioflupane I-123 injection, diagnostic, per study dose".

Background/Discussion:

According to the requester, DaTscan™ is a radiopharmaceutical indicated for striatal dopamine transporter visualization using single photon emission computed tomography (SPECT) brain imaging to assist in the evaluation of adult patients with suspected Parkinsonian syndromes (PS). In these patients, DaTscan may be used to help differentiate essential tremor from tremor due to PS (idiopathic Parkinson's disease, multiple system atrophy, and progressive supranuclear palsy). The active drug substance in DaTscan™, is Ioflupane (I 123), binds reversibly to the human recombinant dopamine transporter (DaT). Following administration of DaTscan, radioactive decay of the iodine (I 123) emits gamma radiation, which can be detected externally using gamma detectors, allowing visualization of the brain striata (caudate nucleus and putamen) through SPECT imaging. Decreased activity within the caudate and the putamen are indicative of neurodegeneration of the DaT terminals as seen in patients with Parkinsonism.
The recommended dose of DaTscan™ is 111 to 185 MBq (or 3 mCi to 5 mCi) administered intravenously. DaTscan™ is supplied in a single-use 10 mL glass vial containing a total volume of 2.5 mL sterile solution with a total radioactivity of 185 MBq (5 mCi) at calibration time. According to the requester, DaTscan is the first radiopharmaceutical imaging agent approved by the FDA for use in helping to differentiate PS from Essential Tremor, which may enable more timely and accurate diagnosis and prognosis of these similar, but distinct patient populations. DaTscan is an adjunct to other diagnostic evaluations. The FDA has waived the pediatric study requirement under the Pediatric Research Equity Act (PREA) (21 U.S.C. 335c) because "necessary studies are impossible or highly impracticable and because the disease/condition does not exist in children."

CMS HCPCS Workgroup Preliminary Decision:

Establish Axxxx IODINE I-123 IOFLUPANE, DIAGNOSTIC, PER STUDY DOSE, UP TO 5 MILLICURIES

Summary of Primary Speaker Comments at the Public Meeting:

The applicant agreed with CMS' preliminary coding decision.

HCPCS Public Meeting Agenda Item #3
05/18/2011

Attachment# **11.071**

Topic/Issue:

Request to establish a code for Gadobutrol injection, trade name: Gadavist. Applicant's suggested language: "Injection, gadobutrol Gadavist, per 0.5 mL".

Background/Discussion:

According to the requester, Gadavist is a gadolinium-based contrast agent indicated for intravenous use in diagnostic magnetic resonance imaging (MRI) in adults and children (2 years of age and older) to detect and visualize areas with disrupted blood brain barrier (BBB) and/or abnormal vascularity of the central nervous system. Magnetic resonance imaging contrast agents are used to help provide a clear picture during MRI. The recommended dose of Gadavist is 0.1 mL/kg body weight (0.1 mmol/kg) administered undiluted as a single intravenous bolus injection, manually or by power injector, at a flow rate of approximately 2 mL per second. Gadavist is formulated at a higher concentration (1 mmol Gadobutrol per milliliter) compared to certain other gadolinium-based contrast agents, resulting in a lower volume of administration. It is supplied in the following sizes: 7.5 mL, 10 mL, and 15 mL single-dose vials in cartons of 10, boxes of 20. It is supplied in 7.5 mL, 10 mL, and 15 mL single-dose pre-filled syringes in cartons of 10, boxes of 5. According to the requester, Gadobutrol injection is a single source product, and as such, separate Medicare ASP pricing and separate coding is warranted.

CMS HCPCS Workgroup Preliminary Decision:

Establish Axxxx INJECTION, GADOBUTROL, 0.1 ML

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker was appreciative of CMS' assignment of a separate code for Gadavist™ (gadobutrol injection) but respectfully requested the workgroup to reconsider the proposed 0.1mL dose descriptor and instead approve a 0.5mL descriptor in order to enable billing whole units. A 1 mL dose descriptor is likely to result in over- or under-billing when the 7.5 mL vial size is used.

HCPCS Public Meeting Agenda Item #4
05/18/2011

Attachment# **11.122**

Topic/Issue:

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

Background/Discussion:

According to the requester, Strattice TM is a reconstructive tissue matrix derived from porcine dermis. Strattice TM is surgically implanted. Once applied, it promotes revascularization and provides for management and strong repair of partial and full thickness wounds; pressure ulcers; venous ulcers; diabetic ulcer; chronic vascular ulcers; tunneled/undermined wounds; surgical wounds; trauma wounds; draining wounds; or other bleeding surface wounds. Strattice TM is available to physicians 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. The physician will determine the most appropriate size and version to be used based on each individual patient case. The requester is asking for a brand-specific code for Strattice, consistent with coding for other, similar products.

CMS HCPCS Workgroup Preliminary Decision:

Establish Qxxxx STRATTICE TM, PER SQUARE CENTIMETER

Summary of Primary Speaker Comments at the Public Meeting:

The applicant submitted a written comment in support of the Workgroup's preliminary decision.

HCPCS Public Meeting Agenda Item #5

05/18/2011

Attachment# **11.042**

Topic/Issue:

Request to establish a code for extracellular matrix, trade name: Oasis® Ultra Tri-Layer Matrix. Applicant's suggested language: "OASIS® Ultra Tri-Layer Matrix, per square centimeter".

Background/Discussion:

According to the requester, OASIS® Ultra Tri-Layer Wound Matrix is an extracellular matrix derived from porcine small intestinal submucosa (SIS). It is indicated for the management of wounds, including partial and full-thickness wounds, pressure ulcers, venous ulcers, chronic vascular ulcers, diabetic ulcers, trauma wounds (abrasions, lacerations, second degree burns, skin tears), drainage wounds, and surgical wounds. After the wound bed is free of exudates and devitalized tissue, the wound matrix is applied over the wound. Once applied, tissues adjacent to the SIS matrix deliver cells and nutrients to the wounded tissues using the SIS material as a conduit. The cells rapidly invade the SIS material and capillary growth follows, allowing nutrients to enter the matrix. SIS is strong at the time of placement, and is gradually remodeled while the host system reinforces and rebuilds the damaged site with host tissue. As healing occurs, sections of OASIS® Ultra Tri-Layer Wound Matrix may gradually peel. All dressings should be changed every 7 days, or as necessary. OASIS® Ultra Tri-Layer Wound Matrix is supplied in sterile peel-open packages intended for one-time use. It is supplied in two sizes: 7 x 10 cm and 7 x 20 cm. According to the requester, OASIS® Ultra Tri-Layer Wound Matrix is not accurately described by existing codes because there is no HCPCS code to describe a wound matrix with 3 layers.

CMS HCPCS Workgroup Preliminary Decision:

Establish Qxxxx OASIS ULTRA TRI-LAYER WOUND MATRIX, PER SQUARE CENTIMETER

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker agreed with the workgroup's preliminary decision to establish a new code to identify this "distinct biological" product with the descriptor "OASIS® Ultra Tri-Layer Matrix, per square centimeter."

HCPCS Public Meeting Agenda Item #6
05/18/2011

Attachment# **11.045**

Topic/Issue:

Request to establish a code for meshed collagen-glycosaminoglycan matrix, trade name: Integra™ Meshed Bilayer Wound Matrix. Applicant's suggested language: "Skin substitute (Integra Meshed Bilayer Wound Matrix), per square centimeter."

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 glycosaminoglycan with a polysiloxane (silicone) layer. The meshed bilayer matrix allows draining of wound exudate and provides a flexible adherent covering for the wound surface. It provides a scaffold for cellular invasion and capillary growth. Integra™ Meshed Bilayer Wound Matrix is indicated for the management of wounds including: partial and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, surgical wounds, trauma wounds, and draining wounds. The bilayer is intended for use as a substitute for conventional skin autograft in skin replacement surgery. It creates immediate wound closure. Following dermal regeneration, the silicone membrane can be removed and the new dermal tissue will accept an autograft of epidermal tissue for permanent healing. Integra™ Meshed Bilayer Wound Matrix is intended for one-time use and may be used in conjunction with negative pressure wound therapy. After the wound bed is free of debris and necrotic tissue, the matrix is cut to size and applied immediately to the wound and secured using surgical staples, sutures, or other mechanical means. Any air bubbles should be carefully removed to maintain contact with the wound. After application, appropriate secondary dressings are used to maintain dressing adherence and protect the wound area. It is packaged in 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" x 10" sheets), 125 square centimeters (4" x 5" sheets), and 25 square centimeters (2" x 2" sheets). According to the requester, there is a HCPCS code (C9363 SKIN SUBSTITUTE (INTEGRA MESHED BILAYER WOUND MATRIX), PER SQ CM) available for assignment, however, the payment rate is set to expire in 2011 and C codes are not eligible to be used in the physician's offices.

CMS HCPCS Workgroup Preliminary Decision:

Existing code C9363 SKIN SUBSTITUTE, INTEGRA MESHED BILAYER WOUND MATRIX, PER SQUARE CENTIMETER adequately describes this product and is available for assignment by insurers. A national program operating need to establish a new code for this product was not identified by Medicare, Medicaid or the Private Insurance Sector, even when the C code expires.

Summary of Primary Speaker Comments at the Public Meeting:

The applicant submitted written comments that CMS did not articulate a reason for not establishing a new code in addition to existing "C" code (C9363); asking that the Workgroup provide a clearer basis for its preliminary decision; and urging CMS and the Workgroup to treat Integra Meshed Bilayer Wound Matrix as it has other "Similarly situated products," by establishing a "Q" code.

HCPCS Public Meeting Agenda Item #7
05/18/2011

Attachment# **11.068**

Topic/Issue:

Request to establish a code for wound matrix, trade name: Talymed™. Applicant's suggested language: "Skin substitute, Talymed wound matrix, per square centimeter".

Background/Discussion:

According to the requester, Talymed™ is a sterile wound matrix comprised of shortened fibers of poly-N-acetylglucosamine, isolated from microalgae. Talymed™ is indicated for the management of wounds including: diabetic ulcers, venous ulcers, pressure wounds, ulcers caused by mixed vascular etiologies, full thickness and partial thickness wounds, second degree burns, surgical wounds, traumatic wounds healing by secondary intention, chronic vascular ulcers and dehisced surgical wounds and bleeding surface wounds, abrasions and lacerations. Talymed™ is placed on the open wound and covered with a transparent dressing. New wound matrix can be reapplied as necessary. Talymed™ is provided as a 5 x 5 cm and 10 x 10 cm patch that should be cut to fit wound size. According to the requester, Talymed™ is similar to Oasis Wound Matrix, Integra Flowable Wound Matrix, and PriMatrix Dermal Repair Scaffold, but is created from a different source and has a different mechanism of action. Existing codes are inadequate to describe Talymed™ because they are brand-specific.

CMS HCPCS Workgroup Preliminary Decision:

Establish Qxxxx TALYMED, PER SQUARE CENTIMETER

Summary of Primary Speaker Comments at the Public Meeting:

The applicant submitted a written comment agreeing with CMS' preliminary coding recommendation.

HCPCS Public Meeting Agenda Item #8
05/18/2011

Attachment# **11.075**

Topic/Issue:

Request to establish a code for collagen based wound dressing, trade name: Unite™ Biomatrix.
Applicant's suggested language: "Unite Biomatrix (ECM) (equine pericardium), per square centimeter".

Background/Discussion:

According to the requester, Unite™ Biomatrix is a wound biomodulating extracellular matrix (ECM) that is sourced from equine pericardium. Unite™ Biomatrix is indicated for local management of moderately to heavily exudating wounds. It is applied to the debrided wound bed without promoting an inflammatory response, while maintaining integrity as the wound heals. To apply, cut the rinsed Unite™ Biomatrix to a size slightly larger than the outline of the wound area and secure in place by sutures or staples. As healing occurs, sections of the matrix may gradually peel and may be removed during dressing changes. Additional Unite™ Biomatrix may be applied to discrete areas of the wound that have not yet healed satisfactorily. Unite™ Biomatrix is packaged in a chemical solution and is available pre-fenestrated or non-fenestrated. According to the requester, there are no existing codes that describe decellularized equine pericardial implants.

CMS HCPCS Workgroup Preliminary Decision:

Establish Qxxxx UNITE BIOMATRIX, PER SQUARE CENTIMETER

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item #9
05/18/2011

Attachment# **11.076**

Topic/Issue:

Request to establish a code for a collagen scaffold used for soft tissue repair and reinforcement, trade name: OrthADAPT® Bioimplant. Applicant's suggested language: "OrthADAPT® Bioimplant (equine pericardium), per square centimeter".

Background/Discussion:

According to the requester, OrthADAPT® Bioimplant is a highly organized Type 1 collagen scaffold derived from Equine Pericardium used as a scaffold for soft tissue repair and reinforcement. OrthADAPT® Bioimplant is intended to be used for implantation to reinforce the repair or reconstruction of soft tissues, including the reinforcement of soft tissues repaired by sutures or suture anchors during surgical repair. The inherent properties of this xenograft provide support to challenging tendon repairs in both sports medicine and lower extremity surgical repairs, such as reinforcement of rotator cuff, patellar, Achilles, biceps, quadriceps, or other tendons. Although this product is classified by the FDA as a surgical mesh, the applicant claims that it is not a mesh and that it should be distinguished from other skin substitutes via a unique HCPCS code.

CMS HCPCS Workgroup Preliminary Decision:

A national program operating need to establish a HCPCS Level II code to report use of this product in a physician's office setting was not identified Medicare, Medicaid, or the Private Insurance Sector. The HCPCS code to report for HOPD and ASC settings is C1781 "MESH (IMPLANTABLE)." This product is not separately reported in an inpatient setting. The link to the latest device category C-codes is: http://www.cms.gov/HospitalOutpatientPPS/Downloads/DeviceCats_OPPSUpdate.pdf.

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker respectively disagreed with the Workgroup's preliminary decision and requested reconsideration and the establishment of a "Q" code for OrthADAPT® because it is used in the same manner as other products with Q codes, (e.g. GraftJacket™, AlloDerm™ and AlloPatch HD™).

HCPCS Public Meeting Agenda Item #10
05/18/2011

Attachment# **11.069**

Topic/Issue:

Request to establish a "Q" code for Acellular Human Dermis, trade name: FlexHD®. Applicant's suggested language: "FlexHD, per square centimeter.

Background/Discussion:

According to the requester, FlexHD is a human allograft skin minimally processed to remove epidermal and dermal cells. It is processed using proprietary procedures developed by Musculoskeletal Transplant Foundation (MTF) to preserve and maintain the natural biomechanical, biochemical and matrix properties of the dermal graft. FlexHD is used to support cellular repopulation and vascularizaton in applications at the surgical site. It is indicated for use to replace damaged or inadequate integumental tissue. According to the requester, a product-specific code is needed in order to process claims.

CMS HCPCS Workgroup Preliminary Decision:

Establish Qxxxx FLEXHD OR ALLOPATCHHD, PER SQUARE CENTIMETER

Summary of Primary Speaker Comments at the Public Meeting:

A representative of the requesting organization offered comments in agreement with CMS' preliminary recommendation.

HCPCS Public Meeting Agenda Item #11
05/18/2011

Attachment# **11.070**

Topic/Issue:

Request to establish a code for acellular human dermis, trade name: AlloPatchHD™ Acellular Human Dermis. Applicant's suggested language: "AlloPatchHD, per square centimeter".

Background/Discussion:

According to the requester, AlloPatchHD is a human allograft skin minimally processed to remove epidermal and dermal cells. It is processed using proprietary procedures developed by Musculoskeletal Transplant Foundation (MTF) to preserve and maintain the natural biomechanical, biochemical and matrix properties of the dermal graft. AlloPatchHD is used to support cellular repopulation and vascularization in applications at the surgical site. It is indicated for use to replace damaged or inadequate integumental tissue. According to the requester, a product-specific code is needed in order to process claims.

CMS HCPCS Workgroup Preliminary Decision:

Establish Qxxxx FLEXHD OR ALLOPATCH HD, PER SQUARE CENTIMETER

Summary of Primary Speaker Comments at the Public Meeting:

A representative of the requesting organization agreed with CMS' preliminary decision.

HCPCS Public Meeting Agenda Item #12
05/18/2011

Attachment# **11.118**

Topic/Issue:

Request to establish a code for an allograft made from human dermis, trade name: AlloMax™. Applicant's suggested language: "AlloMax™, per square centimeter".

Background/Discussion:

According to the requester, AlloMax™ is an allograft made from donated human skin consisting of epidermal and dermal layers. AlloMax™ is a dry sheet of sterile, human dermis for use in repairing abdominal wall wounds, multi-layer surgical wounds/openings and other damaged tissue. When hydrated and placed in contact with healthy well vascularized tissue, the graft supports cell in-growth and revascularization, allowing the body to remodel the graft and over time close the wound. In breast reconstruction, it closes the space between the pectoralis muscle and the chest wall. For hernia repair, AlloMax™ is used to repair complex abdominal wall wounds. Often multiple pieces of AlloMax™ are sutured together to repair an abdominal wall wound or defect. AlloMax™ is supplied in an individualized sterile pouch in a variety of sizes. According to the requester, there are significant differences in product attributes even among similar products and therefore existing HCPCS codes do not describe AlloMax.

CMS HCPCS Workgroup Preliminary Decision:

Establish Qxxxx ALLOMAX, PER SQUARE CENTIMETER

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker agreed with CMS' preliminary decision to create a "Q" code for AlloMax™, per square centimeter, and asked that this decision be finalized. The speaker commented and provided written materials claiming that AlloMax is used in the following surgical indications: 1) Abdominal wall repair (trauma); 2) Hernia repair (repairs defects in abdominal wall); 3) Breast reconstruction.

HCPCS Public Meeting Agenda Item #13
05/18/2011

Attachment# **11.028**

Topic/Issue:

Request to establish a code for meshed cadaveric dermis, trade name: AlloSkin™RT. Applicant's requested language: AlloSkin™ RT per cm^2. [human donor allograft, irradiated].

Background/Discussion:

According to the requester, AlloSkin™ RT human allograft is a meshed, biologic wound covering comprised of human cadaveric dermis. It is low-dose, e-beam irradiated, allowing its use in clinical settings where there is no access to a cryo-rated freezer. AlloSkin™ RT is for homologous use and is used clinically as a temporary skin replacement for closure of partial or full-thickness wounds due to burns, trauma or chronic wounds, such as venous and arterial ulcers, neurophathic diabetic ulcers and pressure ulcers. AlloSkin is surgically applied and secured to the skin by anchoring method chosen by the surgeon (sutures, staples, adhesive glue, etc.). The allograft sloughs in 7-14 days as granulation of the wound bed proceeds, and might be reapplied to provide a skin replacement that helps promote wound healing by protection of the injured tissues and supporting final closure of the wound. The applicant claims that there is no identical product to AlloSkin RT and no existing Q codes to describe it. AlloSkin™ RT is processed differently than similar products.

CMS HCPCS Workgroup Preliminary Decision:

Establish Qxxxx ALLOSKIN RT, PER SQUARE CENTIMETER

Summary of Primary Speaker Comments at the Public Meeting:

A representative of the applicant provided comments in support of CMS' preliminary decision.

HCPCS Public Meeting Agenda Item #14
05/18/2011

Attachment# **11.057**

Topic/Issue:

Request to establish a code for decellularized human skin allograft, trade name: Arthroflex™. Applicant's suggested language: "Skin substitute, Arthroflex™, per square centimeter".

Background/Discussion:

According to the requester, Arthroflex™ is a decellularized human skin allograft that can be used "for the treatment of chronic wounds that have not healed as a result of prior treatments." The applicant also provides a general statement that "human allografts are indicated in the treatment of chronic wounds, such as diabetic foot ulcers and large surgical wounds." Arthroflex™ contains both collagen and elastin which provide structural support for resilience, a compliment of growth factors to assist healing, as well as multiple cytokines that assist in epithelialization and modulate the proliferation and differentiation of epithelium, and finally fully developed extracellular matrix which allows for infiltration of recipient cells. The extracellular matrix stimulates epithelialization from the wound periphery and from remnant epidermal appendages when placed in contact with the wound. Arthroflex™ provides a physiological barrier that decreases water loss, electrolytes, proteins and heat from the wound bed and creates a mechanical barrier that reduces environmental microbiological contamination. Arthroflex™ is applied directly to the wound or ulcer and secured to the site in one of several ways, including the use of sutures, staples, or skin adhesive strips. It is currently provided with a thickness of 1.26 mm to 1.75 mm and two scaffold sizes: 35 mm x 35 mm and 40 mm x 70 mm. It is likely that the manufacturer will provide additional product sizes and thicknesses in the future. According to the requester, there is not a unique HCPCS code to describe this product.

CMS HCPCS Workgroup Preliminary Decision:

Establish Qxxxx ARTHROFLEX, PER SQUARE CENTIMETER

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker fully supported the Workgroup's preliminary decision to establish a new Product-Specific Q code for ARTHROFLEX™, and also offered a comment that the company makes no claim of wound healing.

HCPCS Public Meeting Agenda Item #15
05/18/2011

Attachment# **11.022**

Topic/Issue:

Request to establish a code for regenerative human dermal allograft, trade name: DermACELL™. Applicant's suggested language: "DermACELL™, per square centimeter decellularized human dermal allograft".

Background/Discussion:

According to the requester, DermACELL™ is a regenerative human dermal allograft procured and processed from donated human tissue. DermACELL™ is used to provide a physiological and mechanical barrier that reduces environmental contamination and assists in promotion of granulation tissue and epithelialization for any topical or surgical wound. It is sutured topically to wounds, such as chronic non-healing wounds or partial and full thickness burns, and is sutured surgically to muscle flaps or other connective tissue for indications such as closing of complicated ventral/incisional hernias, breast reconstruction, temporal defects, tendon and ligament damage, and in guided tissue regeneration in oral applications. As an allograft collagen scaffold, DermACELL supports a patient's own cellular in-growth, resulting in tissue regeneration. DermACELL™ is supplied as one packaged allograft in various sizes, from 4 to 96 square centimeters and from 0.2-0.4 mm thick. According to the requester, there are similar products on the market, however, they are identified using product and brand-specific codes therefore, and currently available codes do not adequately describe this product.

CMS HCPCS Workgroup Preliminary Decision:

Establish Qxxxx DERMACELL, PER SQUARE CENTIMETER

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker agreed with CMS' preliminary decision to establish a "Q" code for DermACELL and with the proposed code text. The speaker indicated that based on witnessed accounts, scientific data and positive clinical outcomes that DermACELL healed chronic non-healing wounds in a shorter timeframe than other alternative products.

HCPCS Public Meeting Agenda Item #16
05/18/2011

Attachment# **11.067**

Topic/Issue:

Request to establish a code for acellular dermal matrix, trade name: Repriza™. Applicant's suggested language: "Repriza, per square centimeter".

Background/Discussion:

According to the requester, Repriza™ is an acellular dermal matrix derived from human allograft tissue. It is intended for implantation during plastic and reconstructive surgeries wherever an acellular dermal matrix may be used. For example, it may be used to support implants in a defined pocket such as in breast reconstruction, and abdominal wall reconstruction procedures. Repriza™ can also be used in a range of applications to augment soft tissue irregularities and for implantation in irregularities such as a depression over the nasal bridge. Repriza™ is a "surgical implant" and "would have no other use outside the surgical setting". The scaffold is gradually integrated with, and ultimately replaced by the body's own tissue. The quantity of product used varies based upon surgical application, individual patient circumstances, and the dimensions of the surgical site. Repriza™ is supplied sterile and ready to use in two sizes: 4 x 12 cm and 6 x 16 cm. Custom sizes and thicknesses are available upon request. According to the requester, Repriza™ is used in the same indications and same manner as Alloderm and Graft Jacket; however, there is a significant difference in the cost of the materials. Pursuant to Section 1847A of the Social Security Act, as amended by the Medicare Modernization Act of 2003, Repriza™ meets the criteria to be assigned a unique price under Medicare's ASP payment program and as such, a unique HCPCS code is warranted.

CMS HCPCS Workgroup Preliminary Decision:

A national program operating need to establish a HCPCS Level II code for this product was not identified by Medicare, Medicaid or the Private Insurance Sector. CMS suggests that you contact the American Medical Association (AMA) for CPT coding guidance. If the product is implanted or 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 biologic under the hospital OPPS.

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item; however, written comments were submitted on behalf of the applicant that are not consistent with statements formally attested to in the application regarding indications for use of Repriza.

HCPCS Public Meeting Agenda Item #17

05/18/2011

Attachment# **11.065**

Topic/Issue:

Request to establish a code for human acellular dermis allograft tissue, trade name: MemoDerm™ Acellular Dermal Matrix. Applicant's suggested language: "MemoDerm™ Acellular Dermal Matrix, per square centimeter".

Background/Discussion:

According to the requester, MemoDerm™ is an acellular dermal allograft derived from aseptically processed cadaveric human skin tissue that is terminally sterilized. It is intended 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 of collagen and elastin fibers that are preserved during the process that renders the allograft acellular. During the granulation phase of the wound repair/regeneration cycle, the matrix of intact collagen network and preserved vascular channels in MemoDerm™ acts as a scaffold to facilitate angiogenesis and migration of growth factors that stimulate cell migration. When applied to wounds, MemoDerm™ has been shown to become vascularized and incorporated into the wound bed and provides an effective means for wound closure. MemoDerm™ is supplied freeze-dried and must be rehydrated prior to use. Once rehydrated, the allograft can be applied topically to the wound and secured by suturing and stapling to the skin surrounding the wound. According to the requester, HCPCS codes for synthetic and biologic wound healing technologies are product and brand specific, and a new code for MemoDerm is warranted because there is not an existing code that specifically describes it.

CMS HCPCS Workgroup Preliminary Decision:

Establish Qxxxx MEMODERM, PER SQUARE CENTIMETER

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item #18
05/18/2011

Attachment# **11.009**

Topic/Issue:

Request to establish a code for human skin allograft, trade name: Matrix™ HD. Applicant's suggested language: "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 typically used in conjunction with a chronic wound care management regime for the treatment of 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.

CMS HCPCS Workgroup Preliminary Decision:

A national program operating need to establish a HCPCS Level II code for this product was not identified by Medicare, Medicaid or the Private Insurance Sector. CMS suggests that you contact the American Medical Association (AMA) for CPT coding guidance. If the product is implanted or 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 biologic under the hospital OPPS.

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with CMS' preliminary decision that a program operating need was not identified to establish a HCPCS code for Matrix ™ HD. The speaker indicated that their product is similar to other skin substitute graft materials that were recommended for "Q" codes. The speaker commented that "market-wise" their product is at a disadvantage because they don't have a HCPCS code; and hospitals, ASCs and

wound care centers won't purchase homologous allograft products without a code. The speaker stated that physicians should be able to determine the best human allograft product even without a HCPCS code. In addition, the speaker claims it is impossible to compare the effectiveness of their product to alternative allografts without a means, [e.g., a code] to track it.

HCPCS Public Meeting Agenda Item #19
05/18/2011

Attachment# **11.010**

Topic/Issue:

Request to establish a code for sterilized non-irradiated human tendon tissue, trade name: BioCleanse® Sterilized Allograft Tendons.

Background/Discussion:

According to the requester, BioCleanse® processed human allograft tendons are used in various areas of the body to repair, replace or reconstruct the native tendon or ligament. The tendon is surgically implanted into the body to recreate the normal anatomy and restore basic function. It can be used to repair anterior cruciate ligaments, posterior cruciate ligaments, medial collateral ligaments, lateral collateral ligaments, posterior lateral corner, medial patella femoral ligament, Achilles tendons, biceps, acromioclavicular joints, lateral ankle stabilizations, ulnar collateral ligaments and any soft tissue repair augmentation. By using BioCleanse® tendons instead of an autograft, the surgeon may minimize operating time and eliminate second-site donor morbidity. BioCleanse® tendons are restricted to homologous use for the repair, replacement or reconstruction of musculoskeletal defects by a qualified healthcare professional. According to the requester, there are no HCPCS codes to describe human allograft tendons. Without a code, these graft products are not captured with the related procedures, thus creating an unclear coding and billing environment for utilization, cost tracking and reimbursement.

CMS HCPCS Workgroup Preliminary Decision:

A national program operating need to establish a HCPCS Level II code to report use of this product in a physician's office setting was not identified by Medicare, Medicaid or the Private Insurance Sector.

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with CMS's preliminary decision. The speaker claimed that the preliminary decision was based on a misunderstanding of the physician's office setting, and that a national program operating need to establish a HCPCS Level II code was not reported. The speaker also stated that the "physician office setting is not an appropriate setting for allograft tendon surgical procedures. Instead, the procedure is always performed in the hospital and ambulatory surgery setting where HCPCS Level II codes are used. Without a specific HCPCS code, facilities have no way to track utilization and costs or means for product reimbursement. Furthermore, BioCleanse® is

a unique sterilization technique, which does not rely on irradiation, which has been shown to have higher failure rates. We are supplying sales and pricing data to supplement the original application."

PAYMENT FOR PART B DRUGS, BIOLOGICALS AND RADIOPHARMACEUTICALS

Background

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

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

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

Drugs Paid on a Cost or Prospective Payment Basis

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

Part B Drug Payment Methodology

Historical Payment Methodology

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

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

Current Methodology

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

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

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

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

Exceptions to ASP pricing methodology

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

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

Payment for Radiopharmaceuticals

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

Dispensing/Supplying/Furnishing Fees

Dispensing Fees

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

applicable only to beneficiaries who are using inhalation drugs for the first time as Medicare beneficiaries.

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

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

Supplying Fees

For 2005, Medicare provided a supplying fee of $24 to a pharmacy for each supplied prescription of immunosuppressive drugs, oral anti-cancer drugs and oral anti-emetic drugs used as part of an anti-cancer chemotherapeutic regimen. The pharmacy also received a supplying fee of

$50 for the initial supplied prescription of the above-mentioned drugs during the 1st month following the beneficiary's transplant.

During CY 2010, Medicare paid a supplying fee of $24.00 for the first prescription of immunosuppressive, oral anti-cancer, or oral anti-emetic drugs supplied to a beneficiary during a 30-day period. Each pharmacy that supplies the above-mentioned drugs to a beneficiary during a 30-day period will be eligible for one $24 fee in that 30-day period. The pharmacy will be limited to one $24 fee per 30-day period even if the pharmacy supplies more than one category of the above-mentioned drugs (for example, an oral anti-cancer drug and an oral anti-emetic drug) to a beneficiary.

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

Furnishing Fees

In 2005, Medicare began a furnishing fee per unit of clotting factor to entities that furnish blood clotting factor unless the costs of furnishing the

blood clotting factor are paid through another payment system. In each year, the prior year's fee is increased by the percentage increase in the consumer price index for medical care for the 12-month period ending June of the previous year. For CY 2010, this fee was $0.17 per unit.

Part B versus Part D

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

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

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

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

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