Centers for Medicare & Medicaid Services (CMS)
HCPCS Public Meeting Summary Report for:
Supplies and Other Public Meeting
Wednesday, June 22, 2005

Public Meeting Introduction and Overview

Robin Williams, CMS Office of Operations Management, moderated the meeting. Approximately 55 people attended. The agenda included 23 items.

Cindy Hake provided an overview of the public meeting process and the overall HCPCS process. She also discussed the survey of stakeholders regarding needed changes to the HCPCS process, the nature of responses to the survey, and the nature of changes already made, as well as pending changes, included in the reformation of the HCPCS process. Monitor the HCPCS world-wide website for announcement of changes to the HCPCS coding process at www.cms.hhs.gov/medicare/hcpcs.

Joel Kaiser presented an educational overview of the variety of methods used for setting the payment amount for items, and when the different methods are used. This overview was also provided as a written attachment to the agenda. For additional information, the DME payment rules are located at Section 1834(a) of the Social Security Act. The Medicare fee schedule for DME, Prosthetics, Orthotics and Supplies, and background information, can be accessed and downloaded free of charge at: http://cms.hhs.gov/providers/pufdownload/default.asp#dme.

CMS HCPCS Public Meetings provide an opportunity for CMS to share its preliminary coding decisions and payment recommendations, and an opportunity for interested parties to make oral presentations and submit written comments in reaction to CMS' these coding and pricing recommendations.

Prior to the Public Meetings the CMS HCPCS workgroup meets to review the coding requests on the public meeting agenda, and to make a preliminary coding decision. CMS also makes preliminary decisions regarding the applicable 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 included in the public meeting agendas.

Following the public meeting, the CMS HCPCS workgroup will reconsider its preliminary coding decisions based on the input heard at the Public Meetings. Afterwards, the workgroup will decide on its final recommendations. 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.

HCPCS Public Meetings are not workgroup meetings. No final decisions are made at the public meetings. All requestors will be notified in writing, in early November, of the workgroup's final decision regarding the HCPCS code request(s) they submitted.

The process for developing agendas and speaker lists for the public meetings, and Guidelines for Proceedings at CMS' Public Meetings for new supplies are posted on the official HCPCS world wide web site at: http://cms.hhs.gov/medicare/hcpcs/default.asp. The standard application form for requesting a modification to the HCPCS Level II Coding System, along with instructions for completion and background information regarding the HCPCS Level II coding process is available on the same web site.

Public Meeting Summary

The following information includes a detailed summary of each request on the Public Meeting Agenda, along with CMS' preliminary decisions and rationale, and summaries of presentations made by primary speakers.

Meeting Agenda Item #1
June 22, 2005
HCPCS Request #05.04

Background/Discussion:

Lisa Burg of MED-TEC Inc. submitted a request to establish a code for implanted gold markers, trade name: Acculoc implanted gold localization markers. According to the requester, Acculoc implanted markers establish a permanent, accurate, internal reference system ensuring sub-millimeter localization accuracy at each delivery of radiation therapy dose. The markers show up distinctly on film, EPID, or CR images. These images are then brought into the Acculoc software, and 3D algorithms output the exact, sub-millimeter moves necessary to accurately position the patient, and the target, for high-precision radiotherapy dose delivery. This allows the radiation dose to be delivered to the tumor/target, sparing surrounding healthy tissue and critical structures.

CMS HCPCS Workgroup Preliminary Decision: Use existing CPT code as directed by insurer. Refer to the American Medical Association CPT editorial panel for inquiries related to the establishment of a new CPT code including markers used for precise targeting.

No insurer identified a national program operating need to alter the existing code set to identify a specific type of markers used for precise targeting of x-ray, used as part of a procedure. For guidance regarding appropriate coding of radiation therapy, including markers, contact the insurer in whose jurisdiction a claim would be filed. For Medicare OPPS, localization is packaged in various APCs, and not separately payable. For APCs, separate payment is not allowed for supplies. In a physician's office, unlisted surgical procedure CPT codes are available for various anatomic areas of the body. Payment is based on carrier pricing. For coding guidance for private insurance systems, please contact the individual insurance contractor. For Medicaid systems, please contact the Medicaid Agency in the state in which a claim would be filed. The applicant is referred to the American Medical Association (AMA) CPT Editorial Panel for requests to establish a CPT code for insertion of radiologic markers for precise targeting in areas of the body for which CPT codes may not currently exist and for discussion of the valuation of the code and consideration of the markers in the practice expense.

There was no Primary Speaker for this item.

Meeting Agenda Item #2
June 22, 2005
HCPCS Request #05.157

Background/Discussion:

Wayne Urban of LS Products LLC submitted a request to establish a code for a leg sling, trade name: Webb's Leg Sling. According to the requester, Webb's Leg Sling is a lightweight shoulder harness that suspends a patient's injured leg in a flexible position for patients using crutches or walkers. The harness is designed to keep weight off of one leg for the purpose of supporting a weak or injured foot or ankle in a physician ordered non-weight bearing circumstance. It functions by transferring the weight of the lower leg to the opposite shoulder using a harness made of durable, high strength, polypropylene webbing. Another similar harness is worn around the injured foot and ankle of the injured limb. An elastic mid-section connects the two harnesses near the hip area. The shoulder harness is adjustable in order to support the injured foot a few inches off the ground. The shoulder harness and shin/ankle cuff are padded for comfort and protection. According to the applicant, existing code A4565 "Slings" does not adequately describe this product, and A4565 " is an old code which describes cloth and canvas arm slings" and payment rates are inadequate to cover manufacturing costs of this product.

CMS HCPCS Workgroup Preliminary Decision:

1) Use existing code A4565 Slings.

2) Discontinue code L1750 and crosswalk to A4565 effective 12/31/2005.

An existing code, A4565, adequately describes a category of items that perform a function similar to the item in this coding request. This item does not meet Medicare's definition of an orthotic. There are no significant therapeutic distinctions between the category of items described in this A4565 and the item in the coding request. No insurer identified a national program operating need to alter the existing code set to distinguish slings based on the limb it's used for or material used in fabrication. It is not within the jurisdiction of HCPCS code set maintainers to assign fees to codes. Any concerns or inquires regarding reimbursement, such as those raised in your application, should be submitted directly to the insurer. For Medicare, please contact CMS' Inherent Reasonableness Authority. For private sector health insurance systems, please contact the individual insurance contractor. For Medicaid systems, please contact the Medicaid Agency in the state in which the claim would be filed.

Primary Speaker – Wayne Urban, of LS Products, disagreed with the preliminary decision. The presentation documented Mr. Urban's response to the workgroup's preliminary decision, including claims therapeutic distinctions between a leg sling and other slings; that A4565 is for use for arm slings only; and that L1750 is disease specific. Mr. Urban requests that either the code descriptor for L1750 be modified to include leg slings or a new E code be established for leg slings with elastic.

Meeting Agenda Item #3
June 22, 2005
HCPCS Request #05.161

Background/Discussion:
John Neet and Geoffrey Hartzler, M.D. of IntraLuminal Therapeutics, Inc. have submitted a request to establish a code for a radio frequency total occlusion crossing system, Trade Name: The Safe-Cross® Radio Frequency Total Occlusion Crossing Wire. According to the requestor, the Safe-Cross Radio Frequency Total Occlusion Crossing Wire is a sterile, single use guide wire with an intelligent optical guidance capacity and controlled radio frequency micro-ablation technology built into the tip. It is used to cross total occlusions in the coronary and peripheral arteries. With an optical fiber embedded into the guide wire, the system is able to provide guidance feedback to the operator through optical coherence reflectometry.

CMS HCPCS Workgroup Preliminary Decision: Do not establish a code.

The item that is the subject of this request is a component of a surgical procedure. The guidewire is included in the procedure code and it is not separately payable. For Medicare OPPS, code C1769 is used for reporting only; although the guidewire is not separately payable. No insurer identified a national program operating need to alter the existing code set to identify this item. For information regarding the surgical procedure coding, contact the American Medical Association CPT division.

There was no Primary Speaker for this item.

Meeting Agenda Item #4
June 22, 2005
HCPCS Request #05.163

Background/Discussion:
Darralyn Alexander of MD Anderson Cancer Center submitted a request to establish a code for an anatomical model, trade name: ClearView® Anatomical View. According to the requester, these anatomic models are life-sized diagnostic models that duplicate the bone and/or soft tissues of an individual patient's anatomy in polymer-type materials. The models are produced using digital information gained from the patient's routine diagnostic computer assisted tomography scan (CT scan) obtained from the treating hospital. These models are used to plan for surgery for obliterated skull and facial bones, spinal deformities, and large bone defects and injuries of the hips, legs and arms and etc. Use of anatomical models enable the surgeons to better plan a procedure and evaluate possible surgical options and problems by evaluating a physical duplication of the anatomy before surgery is initiated and an incision is made. It allows physicians to test a number of surgical options, and choose the best technique to achieve the sought after outcome, with more accuracy and to carry it out more effectively and in less time that might be needed without the use of such a diagnostic and evaluative technology. The applicant states that "no CPT code allows reimbursement" for the cost of the model. The requester is seeking a remedy via HCPCS coding.

CMS HCPCS Workgroup Preliminary Decision: Do not establish a code.

The anatomical model is a "diagnostic planning device", as per your application. It is not primarily medical in nature, and therefore not appropriate for identification using HCPCS Level II codes. Inquires concerning the valuation of CPT procedure codes, and whether anatomical models were considered, should be submitted directly to the American Medical Association. For guidance regarding coverage and coding, contact the insurer in whose jurisdiction a claim would be filed. For Medicare, contact the Director of CMS' Division of Outpatient Care. For private sector insurance systems, contact the individual insurance contractor. For Medicaid systems, contact the Medicaid Agency in the state in which a claim would be filed.

Primary Speaker – Rhonda Jacob, M.D., of the University of Texas MD Anderson Cancer Center, disagreed with the preliminary decision and summarized as follows: The benefits of physical anatomical modeling are independent of the operative/reconstructive techniques preferred by individual surgeons. Physicians do not develop nor manufacture the physical anatomical model. The physician has no oversight over the manufacturing/fabrication process. His/her responsibility is limited to the 2D CT scan request, the surgical planning phase and the operative procedure. If a physician decides to medically follow the patient for some period of time, the model serves as a concrete visualization template of the current anatomy and downstream allows further evaluation and planning.

The application of Stereolithography and 3Dimensional Printing anatomical models provide valuable medical diagnostic information to be used with any surgical technique, permitting the most beneficial options and resolution through utilization of ‘realistic’ anatomical sites. According to Ms. Alexander, a HCPCS code is needed that will enable either a hospital or a manufacturer to bill an insurer and to be (separately) reimbursed for the cost of the physical model.

Meeting Agenda Item #5
June 22, 2005
HCPCS Request #05.90 A-C

Background/Discussion:

Mark Domyahn of Medtronic submitted a request to establish 3 codes for: A) Single array, implantable non-rechargeable neurostimulator pulse generator, B) dual array, implantable non-rechargeable neurostimulator pulse generator, and C) Implantable extension for neurostimulator systems. According to the requester, Neurostimulation is used to aid in the management of movement disorders, chronic intractable pain, and urinary dysfunction, among other disorders associated with nervous function. An implantable neurostimulation system consists of four components, three of which are implanted into a patient's body, a lead, a power source and a tunneled extension that conducts the electrical pulses between the neurostimulator and the lead. The patient programmer is an external device used by the patient to control the therapy. Neurostimulators can be single-array or dual-array.

A single-array neurostimulator is attached to one lead only. Single array neurostimulators are appropriate for disorders that require a single site of stimulation. The Soletra neurostimulator is used in deep brain stimulation therapy to treat patients with advanced Parkinson's disease and essential tremor. Intrel 3 neurostimulator is used to treat chronic intractable pain associated with underlying disorders such as radiculopathy, peripheral neuropathy, arachnoiditis, complex regional pain syndrome, and failed back syndrome. Interstim neurostimulator is used to manage urinary retention and the symptoms of an overactive bladder, including urinary urge incontinence and significant symptoms of urgency-frequency alone.

A dual-array neurostimulator is attached at two leads. For patients who require bilateral stimulation or stimulation at two separate sites, two leads and two extensions are implanted but only one neurostimulator. Kinetra neurostimulator is used in Deep Brain Stimulation therapy to treat patients with advanced Parkinson's disease and patients with essential tremor. Synergy neurostimulator is used to treat chronic intractable pain associated with underlying disorders such as radiculopathy, peripheral neuropathy, arachnoiditis, complex regional pain syndrome and failed back syndrome. Synergy Versitrel neurostimulator is used to treat chronic intractable pain.

The extension is implanted into the patient at the same time that the neurostimulator and leads are implanted. Extensions are insulated conductors, which are tunneled subcutaneously in the patient's body between the neurostimulator and the lead. One extension is required for each lead. Models 7489 and Model 7471 are extensions utilized in spinal cord neurostimulation systems used to treat patients with intractable pain in the trunk or limbs. Model 7482 is used in Deep Brain Stimulation therapy and Model 3095 is used with systems for urinary control.

CMS HCPCS Workgroup Preliminary Decision:

#05.90A & #05.90B
As directed by insurer, use existing code C1767 (generator, neurostimulator (implantable); or E0756 (implantable neurostimulator pulse generator); or appropriate CPT code, based on single or dual array.

Existing codes, C1767 or E0756, adequately describe neurostimulator generators which are functionally similar to the item in this coding request. There are no significant therapeutic distinctions between the category of items described in this code and the item in the coding request. No insurers identified a national program operating need to alter the existing HCPCS Level II code set to differentiate based on single vs. dual array, or rechargeability. For inpatient use, CPT codes should be used for the procedure and C codes for the implantable items. CPT codes distinguish between dual and single array neurostimulator pulse generators. For ASCs, use CPT codes. For ambulatory clinics, use CPT codes.

#05.90C
Use existing code C1883 adaptor/extension, pacing lead or neurostimulator lead (implantable).

An existing code C1883, adequately describes a category of extensions for neurostimulator systems that function similar to the item in this coding request. There are no significant therapeutic distinctions between the category of items described in this code and the item in the coding request.

Primary Speaker – Linda Holtzman, of Clarity Coding speaking as a paid representative of Medtronic and also on behalf of Advanced Bionics, provided a joint presentation for #05.90 A-C and #05.91 A-C. Linda disagrees with the preliminary decision provided for #05.90 A-B and #05.90 C. For #05.90 A-B, CPT codes only distinguish single and dual array for intracranial pulse generators so spinal and peripheral applications cannot be differentiated. Also, therapeutic distinctions exist in that a dual array is less invasive and provides greater ease of programming. For #05.90C, non-hospital facilities cannot use C codes even for Medicare patients. Linda respectfully disagrees with the preliminary decision for #05.91 A-B and agrees with the preliminary decision to create a new code for #05.91C, but disagrees with restricting the code to "replacement only". For #05.91 A-B, the rechargeable pulse generator dramatically extends the life span of the pulse generator, enables more electrodes for broader stimulation and focuses therapy on optimal symptom relief, not managing device or battery life. For #05.91C, payment policy is distinct from code definition for permanent codes such as E codes and "replacement only" restricts usage of the code for all payers. In summary, Linda requested the establishment of 6 new codes; in contrast to Medtronics original request for 3 codes, claiming that: coding enables health system users to identify, track and analyze utilization for unique device types. Specific HCPCS codes are the key:

- Create unique HCPCS II codes for rechargeable and non-rechargeable pulse generators.
- Create a new general E code for external charger.
- Create unique HCPCS II codes for single and dual array pulse generators.
- Create a new E code for extension.

Meeting Agenda Item #6
June 22, 2005
HCPCS Request #05.91 A-C

Background/Discussion:

Tom Walsh of Advanced Bionics Corporation submitted a request to: A) Establish a code for an implantable neurostimulator pulse generator with rechargeable battery, B) Revise code E0756 to read: IMPLANTABLE NEUROSTIMULATOR PULSE GENERATOR WITH NON-RECHARGEABLE BATTERY, currently reads: IMPLANTABLE NEUROSTIMULATOR PULSE GENERATOR and C) Establish a code for an implantable neurostimulator charging system.

According to the requester, Precision rechargeable IPG is an implantable neurostimulator pulse generator that is part of a spinal cord stimulation system used to provide electrical stimulation of the spinal cord for the management of chronic, intractable pain. Precision is designed to deliver current to implanted lead(s) and replace pain sensations with paresthesia, or a cool tingling sensation. It aids in the management of chronic intractable pain of the trunk and/or limbs associated with failed back surgery syndrome, intractable low back pain and leg pain. The Precision is a new generation of neurostimulator that represents an improvement over existing RF generators and non-rechargeable IPGs by providing a rechargeable battery that dramatically increases lifespan of the neurostimulator in clinical practice while allowing for higher power stimulation settings and neurostimulation through multiple independent current sources. According to the requester, the Precision IPG charging system is part of a spinal cord stimulation system used to provide electrical stimulation of the spinal cord for the management of chronic, intractable pain. This external patient charging system is used by the patient to recharge the battery in the Precision rechargeable IPG. The charging system contains a charger with a lithium battery that is recharged in a base station. The charger converts electrical energy to radio frequency energy. The generator converts the RF energy to electrical energy, which recharges its internal battery.

CMS HCPCS Workgroup Preliminary Decision:

#05.91A & B

To use existing code C1767 Generator, neurostimulator (implantable) or E0756 Implantable neurostimulator pulse generator.

Existing codes, C1767 or E0756, adequately describe a category of items which are functionally similar to the item in this coding request. Initial implantation of device should include charging system if provided. There are no significant therapeutic distinctions between the category of items described in this code and the items in the coding request. There is currently no national program operating need to alter the existing code set to differentiate between rechargeable and non-rechargeable systems.

#05.91C
To establish a new “E” code.
E???? External recharging system for implanted neurostimulator, replacement only

Use E???? to identify external recharging system for only for replacement.

Primary Speaker – Linda Holtzman, of Clarity Coding. Please refer to agenda item #5 for speaker summary.

Meeting Agenda Item #7
June 22, 2005
HCPCS Request #05.11

Background/Discussion:
Marc Swartz of Dr. Len's Medical Products, LLC has submitted a request to establish a code for a bi-layer foam sleeve composed of a ¼" layer of foam with a 2lb deflection laminated to a second piece being ½" with a 1lb deflection. It is approximately 11" in length, looking like an elongated, tapered, oval. The bi-layer foam is sewn into a piece of fabric called Optimer® which is comprised of a blend of cotton, nylon, and two micro fibers called dri-release®, and FreshGuard®. The blended fabric is designed to keep the patient cool, dry by absorbing sweat, and odor free. The sleeve when applied to the site is designed to be able to pick up the body's pulse at the site. Product can be used for the prevention of injuries related to repetitive motion, and also used as a sports performance enhancement product.

CMS HCPCS Workgroup Preliminary Decision: Establish a new "A" code.

A???? Tubular dressing with or without elastic, any width, per linear yard

Use existing code K0620 until new "A" code is effective.

Existing code K0620 and new code A???? describe a category of sleeve or tubular dressings that perform a similar function. There are no significant therapeutic distinctions between the item in this request, and other items included in the code. No insurer identified a national program operating need to distinguish this dressing based on material used in fabrication or multi-layer construction.

Primary Speaker – Marc Swartz of Dr. Len's Medical Products, LLC. Dr. Len's Medical Products, LLC does not agree with the present coding recommendation of K0620. Mr. Swartz summarized as follows: "the product uses a patented foam which in the initial review was separated from the product and discarded. The foam is the key to the product's existence in that the foam is what provides the slight pressure necessary to enhance the circulation to the site. As such, we do not agree that this is simply tubular material and further, the price offered in reimbursement of such a product does not cover 1/15 of the cost associated with manufacturing our product."

Meeting Agenda Item #8
June 22, 2005
HCPCS Request #12

Background/Discussion:

Marc Swartz of Dr. Len's Medical Products, LLC has submitted a request to establish a code for a wound care bandage system, Trade Name: Abrams Adjustable All-In-One Foam Wound Care Bandage System with 8% Silver Sodium Hydrogen Zirconium Phosphate. This product is designed to serve as a protective barrier over a wound or burn. The microbisan in the product is designed to keep the site free of infection for up to seven days, while the foam increases and enhances the circulation to the site of treatment, allowing wounds to heal more rapidly. It may also be used in the treatment of pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, and ischemic ulcers.

CMS HCPCS Workgroup Preliminary Decision: Use existing code A6209 foam dressing, wound cover, pad size 16 sq. in. or less, without adhesive border, each dressing.

Existing code A6209 describes a category of foam dressings that perform a similar function to the item in this request. There are no significant therapeutic distinctions between this product and other items described by A6209. No insurer identified a national program operating need to distinguish this dressing based on multi-layer construction or the silver content in the bandage. Since the FDA has not recognized silver as an antimicrobial, a coding distinction based on such a claim would be inappropriate.

Primary Speaker – Dr. Victor Quijano, independent Clinical Researcher contracted to perform clinical efficacy trial of Abrams All-In-One bandage system, spoke on behalf of the applicant for agenda items 8, 9 & 10. Dr. Lens Medical Products, LLC would like to respectfully refute the preliminary recommendation, and ask the workgroup to establish a code for this unique wound care system. Dr. Quijano summarized as follows: "CMS should establish a new code for the Abrams bandage that takes into account the foam properties, such a wound/ulcer protection, exudate absorption, and microcirculatory alterations, in addition to nanocrystallized Silver properties, which include anti-microbial activity, increased granulation tissue and therefore, expedited closure rates."

Meeting Agenda Item #9
June 22, 2005
HCPCS Request #13

Background/Discussion:
Marc Swartz of Dr. Len's Medical Products, LLC has submitted a request to establish a code for a wound care bandage system, Trade Name: Abrams Adjustable All-In-One Foam Wound Care Bandage System. This product is designed to serve as a protective barrier over a wound or a burn, while providing enhancement of circulation to the site. The product is placed over a properly debrided wound in a manner that does not compress the foam which, gently placed against the surface of the wound and skin, is able to pick up the microcirculation of the capillary bed.

CMS HCPCS Workgroup Preliminary Decision: Use existing codes A6209 through A6211 as appropriate, based on dressing size.

A6209 Foam dressing, wound cover, pad size 16 sq. in. or less, without adhesive border, each dressing.

A6210 Foam dressing, wound cover, pad size more than 16 sq. in. but less than or equal to 48 sq. in., without adhesive border, each dressing.

A6211 Foam dressing, wound cover, pad size more than 48 sq. in., without adhesive border, each dressing.

Existing codes A6209, A6210 and A6211 adequately describe a category of foam dressings which perform a function similar to the item that is the subject of this request. There are no significant therapeutic distinctions between the category of items described in these codes, and the item in the code request. No insurer identified a national program operating need to distinguish this dressing based on multi-layer construction. There was not sufficient peer-reviewed clinical evidence provided with the application to support the claim of amplification of venous flow and decongestion of capillary beds as a result of using this product. A coding distinction based on this unsubstantiated claim would be inappropriate.

Primary Speaker – Please refer to agenda item #8 for primary speaker summary.

Meeting Agenda Item #10
June 22, 2005
HCPCS Request #05.155

Background/Discussion:

Marc Swartz of Dr. Len's Medical Products, LLC submitted a request to establish a code for Abrams Wound Care Bandage with 8.5% Silver Sodium Hydrogen Zirconium Phosphate. According to the requester, this wound care bandage is a tri-layer rectangle shaped hydrophilic foam composed of a ¼" layer of foam with a 2lb deflection laminated to a second piece being ½" with a 1lb deflection, followed by a third layer of foam which is one 1/8" thick. The third layer of foam is impregnated with a 8.5% silver sodium hydrogen zirconium phosphate with 1% of the total weight as silver. The applicant makes the following claims: The product was lab tested and proven effective for up to seven days warding off infection. The foam is able to stimulate and enhance the micro circulation to the site. The enhancement of microcirculation in the capillary bed results in increase capillary blood flow to the site. This increased flow results in an expedited time to closure of a wound stemming from the increased nourishment to the site of increased blood flow. The site heals from the inside out minimizing scaring while providing the site of treatment a warm, moist environment. The foam is able to absorb excessive wound exudation, while the added layer of foam with silver hydrogen zirconium phosphate is designed to keep the wound free of infection for up to but not to exceed seven days of use. This product is available in 5 standard sizes, and can be custom ordered in other dimensions.

CMS HCPCS Workgroup Preliminary Decision: Use existing codes A6209 through A6211 as appropriate, based on dressing size.

A6209 Foam dressing, wound cover, pad size 16 sq. in. or less, without adhesive border, each dressing.

A6210 Foam dressing, wound cover, pad size more than 16 sq. in. but less than or equal to 48 sq. in., without adhesive border, each dressing.

A6211 Foam dressing, wound cover, pad size more than 48 sq. in., without adhesive border, each dressing.

Existing codes, A6209-A6211, adequately describe a category of foam dressings which perform a function similar to the item in this coding request. There are no significant therapeutic distinctions between the category of items described in these codes and the item in the coding request. The FDA does not recognize the healing properties of silver. No insurer identified a national program operating need to alter the existing code set to differentiate dressings based on multi-layer construction, silver content, or other differences in material used in fabrication. Evidence has not been provided with the application to support the claim of enhanced micro-circulation and expedited wound

closure as a result of the use of this product. Inquiries regarding pricing of this item should be made to the insurer. For Medicare, please contact CMS' Inherent Reasonableness Authority. For Medicaid systems, please contact the Medicaid Agency in the state in which a claim would be filed. For private insurance systems, please contact the individual insurance contractor.

Primary Speaker – Please refer to agenda item #8 for primary speaker summary.

Meeting Agenda Item #11
June 22, 2005
HCPCS Request #05.150

Background/Discussion:

Frederick Cahn of BioMedical Strategies LLC submitted a request to establish a unique code for multiple sizes of Collagen Glycosaminoglycan Bilayer Matrix (CGBM), Trade Names: Integra Dermal Regeneration Template, Integra Bilayer Matrix Wound Dressing. According to the requester, CGBM is a bilayer system comprising a dermal replacement layer and a temporary epidermal substitute layer. The dermal replacement layer is a porous matrix of fibers consisting of purified undenatured bovine collagen and chondroitin-6-sulfate with an average pore size between 70 and 200 µm and a void volume greater than 99%. The matrix is cross linked with aqueous glutaraldehyde at acetic pH. The temporary epidermal substitute layer is made of silicone 200 to 300 µm thick and it firmly adheres to the dermal replacement layer. According to the requester C9206 is used for HOPPS. The applicant requests a unique code for use in physician's offices and by private insurers. The applicant states that existing code J7343 DERMAL AND EPIDERMAL, TISSUE OF NON-HUMAN ORIGIN, WITH OR WITHOUT OTHER BIOENGINEERED OR PROCESSED ELEMENTS, WITHOUT METABOLICALLY ACTIVE ELEMENTS, PER SQUARE CENTIMETER does not describe the products that are the subject of this request because the codes describe dermal and epidermal tissue, whereas CGBM does not contain dermal or epidermal tissue. The applicant also claims that identifying the amount used based on "per square cm" "will under compensate users of smaller sizes". The product is available in 4 sizes: 2x2, 4x5, 4x10, and 8x10. The applicant suggests the assignment of a unit of "25 square centimeters" to the requested new code to be consistent with the unit of 25 square centimeters associated with CPT codes 15342 and 15343.

CMS HCPCS Workgroup Preliminary Decision:

1) Revise language in codes J7340, J7342, J7343, J7344 and J7350 by adding the word "(SUBSTITUTE)" in front of the word "TISSUE".

2) Use existing code J7343, which will be revised in January 2006 to read: "Dermal and epidermal, (substitute) tissue of non-human origin, with or without other bioengineered or processed elements, without metabolically active elements, per square centimeter". The revised language will make it clearer that the item that is the subject of this request is adequately described by this code.

In the descriptor of J7343 code, "dermal and epidermal" refers to substitute layer and therefore, the products that are the subject of this request are adequately described by this code. J7343 describes a category of products that perform a similar function, and the applicant has not demonstrated a significant therapeutic distinction between the category of products described by this code and the items in this code request. No insurer identified a national program operating need to alter the existing code set to distinguish products in this category based on the variety of sizes of products made available by

manufactures. Appropriate multiples or fractions can be entered in the "units" column on a claim form. Inquiries regarding fees associated with this code, such as those mentioned in this application, should be made to the insurer. For Medicare, contact CMS' Inherent Reasonableness Authority. For private insurance systems, contact the individual contractor. For Medicaid systems, contact the Medicaid Agency in the state which a claim would be filed.

Primary Speaker – Frederick Cahn, of BioMedical Strategies, LLC., respectfully disagreed with the preliminary decision; requested that codes be separated according to ASTM listing (in contrast to original request for unique codes for Bilayer Matrix based on multiple product sizes); and offered the following comments: "adding "substitute" to J7343 is helpful in clarifying that the collagen-GAG bilayer matrix is intended to be included in this code, but adding "substitute" to the HCPCS definitions raises new issues. ASTM Standard F2311-03 defines and categorizes therapeutic distinctions among skin substitutes which are not addressed in the HCPCS classifications. F2311-03 was developed by the AMERICAN Society for Testing and Materials, International, an organization that develops voluntary, full-consensus standards for materials, products, systems and services. F2311-03 was developed by ASTM Committee F04 Division IV, "Tissue Engineered Medical Products."

"According to the CMS Preliminary Decision, "J7343 describes a category of products that perform a similar function, and the applicant has not demonstrated a significant therapeutic distinction between the category of products described by this code and the items in this code request." However, the distinctions in J7340, J7342, J7343, J7344 and J7350 are based on composition and not on therapeutic characteristics. F2311-03 makes important therapeutic distinctions among skin substitutes that are not inherent in J7343."

"We have requested unique coding for the collagen-GAG bilayer matrix because its clinical utility as a substitute for skin autograft in skin replacement surgery is distinct from other skin substitutes: It is applied to clean, excised skin wounds (CPT 15000/15001), provides primary healing, provides immediate physiological wound closure, is engrafted and vascularized, and results in tissue regeneration (not scar tissue). Its ability to achieve these clinical properties is the result of specific design and performance requirements that are addressed in its draft USP monograph. Thus, we are concerned by the possibility that it could share its HCPCS code with other materials that do not share these requirements."

Meeting Agenda Item #12
June 22, 2005
HCPCS Request #05.158

Background/Discussion:
Tom Weaver of the American Optometric Association submitted a request to establish a unique code for solid tint and glass color coating. Presently, solid and gradient tints are both described in existing code V2745 ADDITION TO LENS; TINT, ANY COLOR, SOLID, GRADIENT OR EQUAL, EXCLUDES PHOTOCHROMATIC, ANY LENS MATERIAL, PER LENS. The applicant seeks to separate solid tint from other tints and states in this application that "solid tints are less expensive to manufacture than a gradient tint and usually have a lower reimbursement." According to the requester, solid tint is a treatment that is applied as a coating to a glass or plastic lens or is added to the lens material during the manufacturing process. The tint remains constant throughout the lens. Solid tints reduce light transmission, which improves eye comfort and enhances visual performance. The specific benefits of a tint are its ability to reduce glare, to provide some level of UV protection, to help counteract negative effects of certain lighted environments such as fluorescent lighting in offices. Tints may reduce the effects of certain ocular conditions and enhance the aesthetic appearance of the eyewear.

CMS HCPCS Workgroup Preliminary Decision:
1) Use existing code V2745 (addition to lens; tint, any color, solid, gradient or equal, excludes photochromatic, any lens material, per lens) to identify the tint.

2) Use existing code V2702 (deluxe lens feature) or a "U" modifier, or the "22" modifier if instructed by the insurer, to identify a deluxe lens feature.

Existing code V2745, adequately describes solid or gradient lens tint. Other codes such as V2702, or modifiers, may be specified for used with V2745 by insurers who wish to designate an add-on for a different payment rate. Appropriate code assignment is made by the insurer in whose jurisdiction the claim is filed. For Medicare, please contact the carrier. For private sector health insurance systems, please contact the individual private insurance contractor. For Medicaid systems, please contact the Medicaid Agency in the state in which the claim is being filed. No insurer identified a national program operating need to alter the existing code set to differentiate solid and gradient tints.

There was no Primary Speaker for this item.

Meeting Agenda Item #13
June 22, 2005
HCPCS Request #05.03

Background/Discussion:

Kevin Corcoran of Corcoran Consulting Group submitted a request to establish a code for an artificial cornea, trade name: AlphaCor™. According to the requester, Alphacor is an artificial cornea made of a biocompatible, flexible, hydrogel material similar to a soft contact lens. It contains central clear zone to provide refractive power and a peripheral skirt or rim made of an opaque porous sponge material which allows fibrovascular ingrowth for long term securing of the device into place. The device is available for those with no natural lens and for those with a lens in the eye.

CMS HCPCS Workgroup Preliminary Decision: Use existing CPT code for the procedure, as directed by insurers.

No insurer identified a national program need to alter the existing code set to identify an artificial cornea used in an implant procedure. For guidance regarding appropriate coding of the implant procedure and the implanted device, contact the insurer in whose jurisdiction a claim would be filed. For Medicare OPPS, CPT codes are used and until December 31, 2005, pass-through code C1818 may also be used in APC 1818. After that, the device may be incorporated into the practice expense. For ASC, use appropriate CPT code and L8699 may be billed separately for the device. For physicians office, use appropriate CPT code and either L8699 or CPT 99070. The volume of procedures in ASCs and physician's offices do not justify the administrative burden of adding a unique code for this device. For coding advice for private insurance systems, contact the individual contractor. For Medicaid systems, contact the Medicaid Agency in the state in which a claim would be filed. For guidance regarding appropriate CPT coding and inquiries regarding whether the CPT will be re-valuated, contact the American Medical Association which maintains and copyrights the CPT code set.

Primary Speaker – Kevin Corcoran, of Corcoran Consulting Group, disagreed with the preliminary decision. He suggested that the Workgroup reconsider its decision concerning a new HCPCS code for the following reasons:

- Current experience with high rate of claim rejection.
- Stigma associated with miscellaneous codes.
- Avoid confusion, denials, costly and lengthy appeals.

- Give assurance to physicians and billers about accurate billing—remove paranoia of false claims.
- Improve access to care in ASCs.
- Pass-through code (C1818) initiated July 2003 and will expire before long.

Meeting Agenda Item #14
June 22, 2005
HCPCS Request #05.66

Background/Discussion:

Kevin Corcoran submitted a request to establish a code for intrastromal corneal ring segments, trade name: Intacs. The requester claims that intrastromal corneal ring segments are not included in the ASC facility payment amount as stipulated in MBPM 260.4 (formerly MCM 2265.2), and that the addition of a code is necessary to facilitate Medicare Part B claims in ASCs and also for physician's office and hospital outpatient billing. The requester suggests a new code with the following language "INTRASOMAL CORNEAL RING SEGMENTS". According to the requester, Intacs are intrastromal corneal ring segments designed to reshape the curvature of the cornea to reduce myopia and astigmatism caused by keratoconus. They are clear, thin, psaolymethylmethacrylate (PMMA), crescent shaped, prescription inserts that are surgically implanted in the periphery of the cornea by an ophthalmologist in an outpatient procedure. The placement and dimensions of the Intacs implants help to reshape the cornea to its original, natural shape, thereby normalizing the cornea's architecture. Using proprietary surgical instruments, a small 1.2 millimeter incision is made in the cornea at 70% depth and channels are created for the insertion of the Intacs. Intacs are then threaded into the channels, and the incision is closed using 10-0 suture. Surgical treatment of keratoconus with Intacs is reversible and less invasive than penetrating keratoplasty or corneal transplant.

CMS HCPCS Workgroup Preliminary Decision: Do not establish a HCPCS Level II code. Refer to AMA. Use existing CPT codes as directed by the insurer in whose jurisdiction a claim would be filed.

Your request for a code has not been approved because it is inappropriate for inclusion in the HCPCS Level II code set. This item is not a prosthetic or a replacement. The CMS HCPCS Workgroup suggests that you independently approach the AMA for valuation of intrastromal corneal ring segments and CPT coding guidance, or an inquiry regarding inclusion of your product under category III of the CPT code set for emerging technologies.

Primary Speaker – Kevin Corcoran, of Corcoran Consulting Group, disagreed with the preliminary decision. The intrastromal corneal ring segments (ICRS) is a prosthetic device because it corrects a physical deformity of the cornea, supports a weak or deformed cornea, replaces part of the cornea which does not function properly, and remains in the in the eye as a permanent support device following surgery. The Workgroup should reconsider its decision concerning a new HCPCS code for the following reasons:

- ICRS is a prosthetic device, not a supply
- Economic value of the ICRS varies, so it should be identified discretely on a claim
- Avoid confusion, denials, costly and lengthy appeals

- CMS has a duty to ensure its policies are consistent with law

Meeting Agenda Item #15
June 22, 2005
HCPCS Request #05.68

Background/Discussion:

Kevin Corcoran of Corcoran Consulting Group submitted a request to establish a code for a capsular tensular ring, trade name: Morcher Capsular Tension Ring. The requester claims that capsular tension rings are not included in the ASC facility payment amount as stipulated in MBPM 100-4, 260.4 (formerly MCM 2265.5); however there is a provision for reimbursement for HOPPS as an incidental component of APC 246. Requester is seeking a new HCPCS code to facilitate ASC claims under Medicare Part B, and suggests the following language: "CAPSULAR TENSION RING". According to the requester, capsular tension rings consist of an incomplete loop made out of a flexible polymethyl methacrylate filament with eyelets at each end. The device is indicated for the stabilization of the human crystalline lens capsule in the presence of weak or partially absent zonules in adult patients undergoing cataract extraction with intraocular lens implantation. Conditions associated with weak or partially absent zonules may include primary zonular weakness, secondary zonular weakness, zonulysis, pseudoexfoliation and Marchesani Syndrome.

CMS HCPCS Workgroup Preliminary Decision: Do not establish a HCPCS Level II code. Use existing CPT codes. Refer to AMA for CPT coding guidance.

Your request for a code has not been approved because the item that is the subject of your request is included as part of a surgery and it is not appropriate for inclusion in the HCPCS Level II. The CMS HCPCS Workgroup recommends that the applicant independently approach the AMA for CPT coding guidance. This product does not meet the definition of a prosthetic. ASC payment does not accommodate this item separately.

Primary Speaker – Kevin Corcoran, of Corcoran Consulting Group, disagreed with the preliminary decision and made the following comments: the CTR is a Prosthetic Device not a surgical supply. Its insertion can produce long term stability of the zonule and therefore the IOL. It is designed to replace or buttress a malfunctioning body part i.e. the zonule. It remains in the eye after surgery. It can be used in secondary cases to re-stabilize. A new code is warranted because:

- Lack of reimbursement may and has led to surgeons being discouraged from using the device or the surgery center from providing it.
- From an economic point of view, only represents a small number of surgical procedures.
- May avoid complications, improve quality of care. On a per case basis, complications are amongst the most costly encounters.

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Meeting Agenda Item #16
June 22, 2005
HCPCS Request #05.159

Background/Discussion:

Anne Sather of Hypoguard submitted a request to establish a code for an express blood glucose monitoring system, NewTeK™. According to the requester, NewTek is a self-contained blood glucose monitoring system with 100 pre-loaded, pre-calibrated test strips included in the device. The device is disposed of after 100 uses. NewTek reads a patient's blood glucose level with its pre-loaded, pre-calibrated test strips. The user simply pulls a lever to dispense a test strip, places their capillary blood sample on the strip, and waits 15 seconds for test results. Once the blood glucose level is read, the patient ejects the test strip from the meter by pushing the lever backwards. NewTek is used for persons with diabetes to aid in monitoring the effectiveness of diabetes control by quantitatively measuring the glucose in a fresh capillary whole blood sample. The applicant describes this product as a unique self-contained blood glucose monitor and 100 test strips in one device. Therefore, according to the applicant, codes that separately describing only the test strip or only the monitor do not adequately describe this product. The applicant acknowledges that this product does not meet Medicare's definition of DME and that for Medicare, A9270 is the appropriate code. The applicant, however, is seeking a code for use by state Medicaid agencies and Private Insurers.

CMS HCPCS Workgroup Preliminary Decision: Establish a new "E" code.

E???? Home glucose monitor, includes strips, disposable, each.

Appropriate code assignment is a made by the insurer in whose jurisdiction a claim is filed. For Medicare, A9270 (non-covered item or service) is the appropriate code, and new code E???? will be available for use by non-Medicare insurers if they choose to designate it to describe this item. To confirm appropriate coding for private insurance systems, contact the individual private insurance contractor. For Medicaid systems, contact the Medicaid Agency in the state in which a claim would be filed.

Primary Speaker – Anne Sather of Hypoguard agreed with the preliminary decision for a new code for possible 3rd party use, but expressed an interest in billing the strips to Medicare – suggested that A4253 describes NewTek and asked that a new code be assigned by non-Medicare insurers if the product could not be assigned to A4253.

Meeting Agenda Item #17
June 22, 2005
HCPCS Request #05.160

Background/Discussion:
Patty Curoe of Medtronic Diabetes (MiniMed) has submitted a request to establish 3 separate codes to reflect the 3 components of the Guardian® Telemetered Glucose Monitoring System. The applicant suggests the following language for the 3 requested codes: 1) "Sensors; interstitial continuous glucose monitoring system, per sensor"; 2) "transmitter; interstitial continuous glucose monitoring system"; 3) "monitor; interstitial continuous glucose monitoring system". According to the requestor, the Guardian System is a glucose monitoring system that continuously records glucose values measured in interstitial fluids such as those in subcutaneous tissue. The patient inserts a subcutaneous sensor under the skin which records glucose values every ten seconds and transmits results wirelessly to a small external monitor. The monitor is designed to alert the patient when glucose values go above or below the target ranges prescribed by the physician.

CMS HCPCS Workgroup Preliminary Decision: No new code.

There must be sufficient claims activity or volume, as evidenced by 3 months of marketing activity for non-drug products, so that the adding of a new or modified code enhances the efficiency of the system and justifies the administrative burden of adding or modifying a code. Your application reported used of a very limited number of units on a trial basis, in pilot programs. Appropriate code assignment is made by the insurer in whose jurisdiction the claim is filed. For Medicare, contact the carrier in whose jurisdiction a claim would be filed. For private sector health insurance systems, please contact the individual private insurance contractor. For Medicaid systems, please contact the Medicaid Agency in the state in which the claim is being filed. Use of miscellaneous codes is not appropriate unless directed by the insurer. No insurer identified a national program operating need to alter the existing code set to describe this item at this time. Applicant may wish to submit another request in a subsequent coding cycle if the sales volume increases significantly.

Primary Speaker – Linda Holtzman, of Clarity Coding, respectfully disagreed with the preliminary decision. If data is needed for patient-based continuous glucose monitoring (CGM) systems, suggested that physician-based CGMS data be used as a stand-in since this technology is the predicate and over 6,500 physician-based systems are in use. CGMS is currently an adjunct to fingersticks, and will replace it over time. Data for physician-based systems enable codes to be established for the patient-based application. Otherwise, patients may not have access to the new fingerstick as they do the old. Reiterated request for 3 new HCPCS II codes: one for a sensor; one for a transmitter; and one for a monitor.

Meeting Agenda Item #18
June 22, 2005
HCPCS Request #05.165

Background/Discussion:
Jeffrey A. Hameroff, D.D.S. of BHM Laboratories has submitted a request to establish a code for unit dose Stannous Fluoride Concentrate, Trade Name: MedOral Anti-microbial Fluoride Rinse. According to the requestor, MedOral-Anti-Microbial Fluoride Rinse is a two-part 1oz. dose of 0.63% Stannous Fluoride solution. The rinse acts on gram negative biofilm bacteria colonies in the oral cavity, when used three times daily as a preventative. The applicant claims that daily use diminishes oral pathogens associated with a large variety of systemic diseases and that the therapeutic goal of MedOral Fluoride Rinse is to minimize potential negative influences of oral pathogens in conditions such as cardiovascular disease and diabetes as well as pulmonary disease. It is considered an over the counter drug supplied as a unit-dose, self contained packaging design that can be administered by an attending nurse or nurse's aid.

CMS HCPCS Workgroup Preliminary Decision: Use existing code A9150 (non-prescription drug) or the appropriate NDC code, based on instructions provided by the insurer.

Existing code A9150 and NDC codes are available for assignment as individual insurers deem appropriate. Code assignment and coverage policy is made by the insurer in whose jurisdiction the claim is filed. For Medicare, A9150 is the appropriate code. For private sector health insurance systems, please contact the individual private insurance contractor. For Medicaid systems, please contact the Medicaid Agency in the state in which the claim is being filed. No insurer identified a national program operating need to alter the existing HCPCS code set to specifically identify Stannous Fluoride. Such a code would be redundant of existing NCD codes.

There was no Primary Speaker for this item.

Meeting Agenda Item #19
June 22, 2005
HCPCS Request #05.166

Background/Discussion:

Jeffrey A. Hameroff, D.D.S. of BHM Laboratories has submitted a request to establish a code for MedOral Dry Mouth Treatment, Trade Name: MedOral Dry Mouth Treatment. According to the requestor, MedOral Dry Mouth Treatment is a non-aerosol spray that moistens the oral cavity and helps replenish saliva in the patients with dry mouth symptoms. The product is sprayed in the mouth distributed by the tongue and reapplied, as needed approximately every one to two hours. It is indicated in a broad population of patients, including but not limited to those with medication induced dry mouth, xerostomia, diabetes, cancer treatment patients, and others. It is primarily an oral aid in rewetting the oral mucosa surfaces.

CMS HCPCS Workgroup Preliminary Decision: Use existing code A9150 non-prescription drug.

Existing code A9150 is available for assignment as individual insurers deem appropriate. An NCD code may also be available. Code assignment and coverage policy is made by the insurer in whose jurisdiction a claim is filed. For Medicare, A9150 should be used. For private sector health insurance systems, please contact the Medicaid Agency in the state in which a claim is being filed. No insurer identified a national program operating need to alter the existing HCPCS code set to specifically identify dry mouth treatment.

There was no Primary Speaker for this item.

Meeting Agenda Item #20
June 22, 2005
HCPCS Request #05.181

Background/Discussion:

Rebecca Fancher of Protex Medical Products, Inc. submitted a request to establish a code for a limb cover and torso coverings, trade name: Protex Limb Protectors and Body Covers. According to the requester the Protex product line includes limb protectors that are protective coverings for the arms and legs, and two torso coverings, that help pressure the integrity of a wound, dressing, surgery site, cast, vaccine, IV, PICC line, venous procedures, burns, rashes or any other area of concern that needs to be protected from damaging moisture or other contaminants, especially during a bathing process. These covers fit over and seal off the area of concern to allow the wearer to resume and maintain normal bathing routines or daily activities, using a simple one-step process.

CMS HCPCS Workgroup Preliminary Decision: No new code.

Code assignment and coverage policy is made by the insurer in whose jurisdiction the claim is filed. For Medicare, there is no existing benefit category for this item and A9270 NON-COVERED ITEM OR SERVICE is the appropriate code, and the use of miscellaneous codes for this item is inappropriate. For coding guidance for private sector health insurance systems, please contact the individual private insurance contractor. For Medicaid systems, please contact the Medicaid Agency in the state in which the claim is being filed. No insurer identified a national program operating need to alter the existing code set to describe limb protectors or body covers.

Primary Speaker – Rebecca Fancher, of Protex Medical Products, Inc., disagreed with the preliminary decision. Ms. Fancher offered the following comments: The needs (for the product) are endless; the cost is minimal. Patients using Protex Limb Protectors can:

- Have a better quality of life during recovery.
- Reduce the risk of secondary infection.
- Decrease the incidence of additional problems due to inadequate protection.
- Prevent unnecessary cast or dressing changes.
- Help prevent possible amputations.
- Eliminate the need for additional help from care givers, reducing the length and number of visits.

The need for a specific procedural code is that there is no other product available with identical properties of Protex Medical Products.

Meeting Agenda Item #21
June 22, 2005
HCPCS Request #182

Background/Discussion:
Steve Cooley of Welcon Medical Products submitted a request to establish a code for a pillcrusher, trade name: Welcon Pillcrusher™ Enteral Irrigation Syringe. According to the requester, the PillCrusher is an "all-in-one" system for the crushing, dissolving, and delivery of soluble solid medications in water. It is designated for use with patients using enteral feeding tubes or who have difficulty swallowing. The solid medication is placed into the syringe and then crushed into a powder form by pressing and rotating the syringe piston against the medication. Sterile water is then drawn into the syringe and the syringe is shaken or agitated to completely dissolve the medication powder. This medicated solution is then injected through the enteral feeding tube or administered orally to deliver the proper medication and dosage amount to the patient.

CMS HCPCS Workgroup Preliminary Decision: Use existing code B4034 Enteral feeding supply kit; syringe, per day.

Existing code B4034 adequately describes enteral irrigation syringes. The pill crusher component of this product is considered a convenience item. No insurer identified a national program operating need to alter the existing code set to describe a pill-crushing enteral irrigation syringe. There is no Medicare benefit category for the pill crusher component. For Medicare, use code B4034 to describe the syringe and A9270 (NON-COVERED ITEM OR SERVICE) for the pill crusher. For coding guidance for private insurance systems, please contact the individual insurance contractor. For Medicaid systems, please contact the Medicaid Agency in the state in which a claim would be filed.

There was no Primary Speaker for this item.

Meeting Agenda Item #22
June 22, 2005
HCPCS Request #05.183

Background/Discussion:
Eric Dixon of EProducts, Inc. submitted a request to establish a code for a non-invasive drinking apparatus for measuring and managing fluid intake, trade name: DigiStraw. According to the requestor, DigiStraw is a non-invasive drinking apparatus for measuring and managing fluid intake. It includes a disposable straw for the user to draw fluid. A flow sensor is attached in-line to the straw for measuring the fluid flow rate. An electronic microprocessor is connected to the flow sensor to convert the flow rate to volume. A display enables the patient to view the total amount of liquid consumed and set threshold amounts. A total amount of fluid can be set as an alarm threshold. DigiStraw is powered by two 3 volt batteries. This device is targeted at managing interdialytic fluids for hemodialysis patients, dehydration management in elderly and cardiac patients. DigiStraw can be mounted on most cups, glasses or cans. As the user sucks on the straw, flow sensor measures the flow of fluid through the straw and micro-controller converts the flow signal to volume and adds the measured volume flow to a stored volume, and displays the cumulative volume on display. When turned off, the total volume is stored in the micro-controller unit reset.

CMS HCPCS Workgroup Preliminary Decision: Do not establish a code.

The DigiStraw is not diagnostic or therapeutic and is not primarily medical in nature. Appropriate code assignment is made by the insurer in whose jurisdiction the claim is being filed. For Medicare, there is no existing benefit category and A9270 (NON-COVERED ITEM OR SERVICE) is the appropriate code. For private sector health insurance systems, please contact the individual private insurance contractor. For Medicaid systems, please contact the Medicaid Agency in the state in which the claim is being filed. No insurer identified a national program operating need to alter the existing code set to describe this item.

There was no Primary Speaker for this item.

Meeting Agenda Item #23
June 22, 2005
HCPCS Request #05.25

Background/Discussion:
Linda Brown of In HomeCare Hair Shampooing Co, LLC submitted a request to establish a code for a hair shampooing chair, trade name: In Homecare Hair Shampooing Chair. According to the requestor, In Homecare Hair Shampooing Chair is a shampooing chair that is specifically designed to provide a way to safely, conveniently, and effectively shampoo hair in the home, hospital, nursing homes, health care facilities, or when traveling. The main feature of the chair is the adjustable semi circular neck rest that is designed to support and stabilized the neck while shampooing the hair. The main purpose of the hair-shampooing chair is to protect the eyes, and ears, from suds and water during shampooing and rinsing by allowing water to freely flow away from the face. The main advantage of the chair is that the person would get a relaxing shampooing in the home, hospital, nursing home, or any other healthcare facility. The hair shampooing chair can be placed at the sink to shampoo hair, or placed into the bathtub to bathe the person and shampoo hair at the same time.

CMS HCPCS Workgroup Preliminary Decision: Do not establish a code.

The product is not primarily medical in nature. Code assignment and coverage policies are determined by the insurer in whose jurisdiction a claim is filed. For Medicare, this product does not fit any benefit category, and the item is not covered, therefore the appropriate code is A9270(non-covered item or service). For coding guidance for a private insurance system, please contact the individual private insurance contractor. For Medicaid systems, please contact the Medicaid Agency in the state in which a claim would be filed.

There was no Primary Speaker for this item.

Closing Remarks

In light of new information provided at CMS' HCPCS Public Meetings, the HCPCS workgroup will reconsider its preliminary coding recommendations, CMS staff will reconsider payment methodology recommendations, and the workgroup will formulate its final recommendation. By mid November 2005, the HCPCS workgroup will mail letters to every requestor of its final decision. The 2006 HCPCS Level II Annual Update, including any coding changes, will be effective January 1, 2006, and will be published at: www.cms.hhs.gov/providers/pufdownload/anhcpcdl.asp by mid November, 2005.

Cindy Hake of CMS thanked the participants for their very valuable input at the meeting, and for all the time and effort that was spent on the presentations.

Robin Williams also thanked the audience for their participation, and officially adjourned the meeting.