Centers for Medicare & Medicaid Services (CMS)
Healthcare Common Procedure Coding System (HCPCS)
Public Meeting Summary Report

Supplies & Other – Day 2

Wednesday, May 26, 2010

Introduction and Overview

Approximately 25 people attended. The agenda included 14 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.

Joel Kaiser, Director of the Division of Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Policy, presented an overview of the methods used for setting the payment amount for DME, prosthetics, orthotics and supplies and when the different payment categories are used. The overview was also provided as a written document to the agenda and is attached to this summary. 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:www.cms.gov/DMEPOSFeeSched/.

Prior to the Public Meetings, over the course of several months, the CMS HCPCS Coding Workgroup convene, discuss, and establish preliminary coding recommendations, on all HCPCS code applications. CMS also 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 at http://www.cms.gov/MedHCPCSGenInfo/08_HCPCSPublicMeetings.asp#TopOfPage, as part of the HCPCS public meeting agendas.

Information provided at the CMS HCPCS Public Meetings is considered by the CMS HCPCS Coding Workgroup at a subsequent workgroup meeting. The Workgroup reconvenes after the public meetings and reconsiders its preliminary coding recommendation 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 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 Guidelines for Proceedings at CMS Public Meetings can be found on the CMS HCPCS web site specifically at: http://www.cms.gov/MedHCPCSGenInfo/08_HCPCSPublicMeetings.asp#TopOfPage. In addition, the standard application format for requesting a modification to the HCPCS Level II Code Set, along with instructions for completing the application, and background information regarding the HCPCS Level II coding process is available at: http://www.cms.gov/MedHCPCSGenInfo/01_Overview.asp#TopOfPage . The application form is updated annually and posted on the CMS HCPCS web site sometime in the summer. A decision tree, outlining CMS' decision-making criteria is also available at: http://www.cms.gov/MedHCPCSGenInfo/Downloads/decisiontree/pdf .

Centers for Medicare & Medicaid Services (CMS) Healthcare Common Procedure Coding System (HCPCS) Public Meeting Agenda for Supplies and "Other"
Wednesday, May 26, 2010, 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's preliminary coding decision is provided. An overview of Medicare pricing/payment, methodology is also attached to this agenda. Preliminary decisions are not final or binding upon any payer, and are subject to change. Meeting participants will hear presentations about the agenda item from the registered primary speaker and other speakers (if any). Presentations will be followed by an opportunity for questions regarding that particular agenda item. The public meetings provide an opportunity for the general public to provide additional input related to requests made 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 complete HCPCS code application received by CMS. The information provided in each summary reflects claims made by the applicant and should not be construed as a statement of fact or an endorsement by the federal government.

AGENDA ITEM #1
Attachment# 10.012
Request to establish a single code to identify "No touch" intermittent catheters that have an introducer tip and protective sleeve for insertion, trade names: Apogee Closed System and Advance Plus Intermittent Catheter.

No Primary Speaker

AGENDA ITEM #2
Attachment# 10.011
Request to establish 3 codes for calcium alginate dressings with silver sodium hydrogen zirconium, trade name: Restore Calcium Alginate Dressing Silver.

Attachment# 10.013
Request to establish a code for contact layer silver sulfate, trade name: Restore Contact Layer Silver, with TRIACT technology.

Attachment# 10.014
Request to establish 2 codes for foam dressings with silver sulfate, trade name: Restore Foam Dressing, Silver, non-Adhesive with TRIACT technology.

No Primary Speaker

AGENDA ITEM #3
Attachment# 10.122
Request to establish a code for a Multidirectional Infrared Light Therapy System in a 9 foot Cabinet.

No Primary Speaker

AGENDA ITEM #4
Attachment# 10.133
Request to establish a code for a wool heel protector.

Attachment# 10.126
Request to establish a code for wool slippers, trade name: Bauer Comfort Wool Cast Shoes/Diabetic Slippers.

Attachment# 10.130
Request to establish a single code category that would identify wool trochanter rolls and flexible wool cervical collars used for positioning, trade names: "positioning trochanty roll" and "cervical flexible wool collar".

Attachment# 10.128
Request to establish a code for an elbow/knee belt with padding.

Attachment# 10.129
Request to establish a code for a wool belt with padding.

Attachment# 10.127
Request to establish a code for a 30" x 16" hypoallergenic merino wool pillow.

No Primary Speaker

AGENDA ITEM #5
Attachment# 10.055
Request for a code to identify a merino wool orthopedic pillow.

Attachment# 10.051
Request for a code to describe a Multipurpose Wool Sheet.

Attachment# 10.058
Request for a code to describe a wool chair seat with padding.

No Primary Speaker

AGENDA ITEM #6
Attachment# 10.111
Request to establish a code for a seat with a unique cut-out, designed for retracting prolapsed hemorrhoids, trade name: HemAway Seat.

Primary Speaker: Archie Rosenblum of Hemaway

AGENDA ITEM #7
Attachment# 10.117
Request to establish a code for a walk-in therapeutic tub, trade names: Therapy Tub and Ruby 3052.

Primary Speaker: Jack Gasper of Therapy Tub, Corporation

AGENDA ITEM #8
Attachment# 10.049
Request for a HCPCS code to identify the Madison Oral Strengthening Therapeutic (MOST) Device.

No Primary Speaker

AGENDA ITEM #9
Attachment# 10.031
Request to establish a code for concentrated bioadherent oral gel, trade name: GELCLAIR.

No Primary Speaker

AGENDA ITEM #10
Attachment# 10.009
Request to establish a new HCPCS code for an aerosol hospital grade disinfectant, trade name: Citrace® Hospital Germicide.

No Primary Speaker

AGENDA ITEM #11
Attachment# 10.010
Request to establish 2 codes for a liquid medication dispenser: one for the Medibottle and one for the Medibottle +.

No Primary Speaker

AGENDA ITEM #12
Attachment# 10.069
Request for a HCPCS code for circulating tumor cell enumerations assay, immunomagnetic, trade name: CellSearch® Circulating Tumor Cell Kit.

No Primary Speaker

AGENDA ITEM #13
Attachment# 10.108
Request to establish a code for a transfer and lift device, trade name: Transfer and Lift Control Unit (TLC Unit).

Primary Speaker: Gregory Burkholder of Transitions Industries

AGENDA ITEM #14
Attachment #10.043
Request to establish a code for an external penile support device, trade name: Erektor.

Primary Speaker: Igor Murokh of Global Life Technologies

HCPCS Public Meeting Agenda Item #1
May 26, 2010

Attachment# 10.012

Topic/Issue:

Request to establish a single code to identify "No touch" intermittent catheters that have an introducer tip and protective sleeve for insertion, trade names: Apogee Closed System and Advance Plus Intermittent Catheter. Applicant's suggested language: "Intermittent urinary catheter, no-touch (teflon, silicone, silicone elastomer, or hydrophilic, etc.), each"

Background/Discussion:

According to the requester, the Advanced Plus intermittent catheter and Apogee Closed systems are "sterile, closed, stand-alone catheter systems that have an introducer tip and an attached collection bag which also serves as a no-touch sleeve for insertion." Lubricant for the catheter is contained in the bag. To insert the catheter, the user removes the protective cap from the introducer tip, inserts the introducer tip into the urethra then slides the pre-lubricated, sterile catheter through the introducer tip directly into the urinary tract and into the bladder, while bypassing the critical distal 15mm of the urethra where the most harmful bacteria reside. Once the bladder is drained, the catheter is withdrawn from the body and disposed of with the bag, after the collected urine is emptied. The entire system can be used without the catheter being touched before or during the procedure. These catheters are for use by patients without adequate nerve function to void the bladder (spinal cord injured, spina bifida, multiple sclerosis, etc.) Catheters with introducer tips and no-touch sleeves offer a distinct advantage over straight intermittent catheters without these features, by providing a protective barrier for hygienic catheter insertion. The applicant claims that the incidence of urinary tract infection is decreased upon switching to a "closed intermittent catheter." The applicant also claims that existing codes describe catheters that "must be inserted through the bacterially compromised 15mm zone of the distal urethra," and that require insertion supplies, and therefore existing codes do not describe the systems or the "additional protective benefits" of the catheter systems that are the subject of this application.

CMS HCPCS Workgroup Preliminary Decision:

Existing code A4353 "INTERMITTENT URINARY CATHETER, WITH INSERTION SUPPLIES" adequately describes the product that is the subject of this request. This system is equivalent to a kit. This system includes a catheter, therefore a catheter should not be billed separately or in addition to A4353.

Medicare Payment:

The payment rules associated with the existing code apply to this product. Pricing = 37

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item. The applicant submitted a written comment agreeing with the Workgroup's preliminary decision.

HCPCS Public Meeting Agenda Item #2
May 26, 2010

Attachment# 10.011

Topic/Issue:

Request to establish 3 codes for calcium alginate dressings with silver sodium hydrogen zirconium, trade name: Restore Calcium Alginate Dressing Silver. Applicant's suggested language: Axxx1 " Alginate or other fiber gelling dressing, antimicrobial, pad size 16 sq. in. or less, each dressing" Axxx2 "Alginate or other fiber gelling dressing, antimicrobial, pad size more than 16 sq. in. but less than or equal to 48 sq. in., each dressing" Axxx3 "Alginate or other fiber gelling dressing, antimicrobial filler, per 6 inches"

Background/Discussion:

According to the requester, Restore Calcium Alginate Dressing, Silver is a sterile, non-woven pad composed of a high G (guluronic acid) calcium alginate, carboxymethylcellulose (CMC) and ionic silver complex (Silver Sodium Hydrogen Zirconium Phosphate), which absorbs wound exudates and releases silver ions in the presence of wound fluid, and is clinically indicated for use in the management of moderate to heavily exuding partial to full thickness wounds, including: post-operative wounds, trauma wounds, venous stasis and arterial ulcers, pressure ulcers, diabetic ulcers, graft and donor sites. As wound exudate is absorbed, the alginate forms a gel which assists in maintaining a moist environment for optimal wound healing, and allows intact removal. The silver ions protect the dressing from a broad spectrum of microorganisms over a period of up to seven days, based on in vitro laboratory testing. Odor reduction results from the antibacterial effect in the dressing. The dressing is an effective barrier to penetration by microorganisms. The applicant claims that this dressing kills a wide range of microorganisms which are commonly found in colonized and infected wounds and releases ionic silver for up to 14 days (new claim recently approved by the FDA). The dressing is available in various sizes including a 2x2 inch, a 4x4.75 inch and a rope that is 1x12 inches. According to the requester, codes A6196, A6197 and A6199 describe only the materials with which the dressing is comprised. These codes do not address the antimicrobial role that the dressing plays within the wound bed. The applicant claims that silver ions *protect the dressing* from a broad spectrum of microorganisms. The applicant also claims that the fee schedule for alginate dressings is low compared to the cost of alginate dressing with silver.

CMS HCPCS Preliminary Decision:

Existing code: A6196 “ALGINATE OR OTHER FIBER GELLING DRESSING WOUND COVER, STERILE, PAD SIZE 16 SQ. IN. OR LESS, EACH DRESSING”; A6197 “ALGINATE OR OTHER FIBER GELLING DRESSING, WOUND COVER, STERILE, PAD SIZE MORE THAN 16 SQ.IN. BUT LESS THAN OR EQUAL TO 48 SQ. IN., EACH DRESSING”; or A6199 “ALGINATE OR OTHER FIBER GELLING DRESSING, WOUND

FILLER, STERILE, PER 6 INCHES", (based on product characteristics and size) adequately describes the products that are the subject of this request.

Medicare Payment:

The payment rules associated with the existing codes apply to these products. Pricing = 35

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item #2
May 26, 2010

Attachment# 10.013

Topic/Issue:

Request to establish a code for contact layer silver sulfate, trade name: Restore Contact Layer Silver, with TRIACT technology. Applicant's suggested language: "Antimicrobial contact layer, more than 16 sq. in. but less than or equal to 48 sq. in., each dressing".

Background/Discussion:

According to the requester, Restore Contact Layer Silver is a sterile, non-occlusive, non-adhesive antimicrobial wound contact dressing composed of a polyester mesh impregnated with a matrix comprised of carboxymethylcellulose hydrocolloid particles, cohesion polymers, and vaseline containing silver. The barrier functions of Restore Contact Layer may help reduce infection in low to moderate exuding partial and full thickness wounds, including second degree burns, pressure ulcers, venous stasis ulcers, diabetic ulcers and graft and donor sites. As exudate is absorbed into the dressing, silver is released. *The silver protects the dressing from a broad spectrum of microorganism commonly found in infected and colonized wounds*. This product is used as a primary dressing and requires a secondary dressing to cover it and hold it in place. Restore was shown to be effective against bacteria most frequently associated with wound infections. It continually releases silver for up to seven days. According to the requester, existing code A6207 "CONTACT LAYER, STERILE, MORE THAN 16 SQ. IN. BUT LESS THAN OR EQUAL TO 48 SQ. IN., EACH DRESSING" describes only the materials with which this dressing is comprised. It does not address the antimicrobial role that the dressing plays within the wound bed. The applicant claims that a silver releasing lipidocolloid contact layer promotes a sustained increase of closure rates of venous leg ulcers presenting [inflammatory signs suggesting] a high bacterial load. The applicant also claims that payment associated with code A6207 is not sufficient to cover the cost of products that contain silver.

CMS HCPCS Preliminary Decision:

Existing code A6207 CONTACT LAYER, STERILE, MORE THAN 16 SQ. IN. BUT LESS THAN OR EQUAL TO 48 SQ. IN., EACH DRESSING adequately describes the product that is the subject of this request.

Medicare Payment:

The payment rules associated with the existing code apply to this product. Pricing = 35

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item #2
May 26, 2010

Attachment# 10.014

Topic/Issue:

Request to establish 2 codes for foam dressings with silver sulfate, trade name: Restore Foam Dressing, Silver, non-Adhesive with TRIACT technology. Applicant's suggested language: Axxx1 "Foam dressing, antimicrobial, pad size 16 sq. in. or less, without adhesive border, each dressing" and Axxx2 "Foam dressing, antimicrobial, pad size more than 16 sq. in. but less than or equal to 48 sq. in., without adhesive border, each dressing.

Background/Discussion:

According to the requester, Restore Foam Dressing Silver is a sterile, antimicrobial wound contact dressing with silver sulfate. It is non-occlusive and non-adhesive for painless removal. It is comprised of three layers: a polyester mesh impregnated with a matrix of carboxymethylcellulose hydrocolloid particles, cohesion polymers, and vaseline containing silver; a non-sensitizing, super absorbent polyurethane foam pad; and a protective, semi-permeable polyurethane backing. The barrier functions of Restore Foam Dressing may help to reduce bacterial load in moderately to high exuding partial and full thickness wounds including pressure ulcers, venous stasis ulcers, diabetic ulcers, first and second degree burns, donor and graft sites. The proprietary TRIACT technology specificity lies in the presence of a polymer matrix which ensures cohesion of hydrocolloid particles and petrolatum on a polyester mesh. In contact with exudates, the hydrocolloid particles combine with the matrix to form a lipidocolloidal gel, providing a moist environment that promotes healing. The dressing has also been shown to sustain antibacterial activity for up to 7 days in invitro studies. The super-absorbent foam pad ensures drainage of exudates and helps protect skin around the lesion from any maceration. According to the applicant, existing HCPCS codes A6209 "FOAM DRESSING, WOUND COVER, STERILE, PAD SIZE 16 SQ. IN. OR LESS, WITHOUT ADHESIVE BORDER, EACH DRESSING" and A6210 "FOAM DRESSING, WOUND COVER, STERILE, PAD SIZE MORE THAN 16 SQ. IN. BUT LESS THAN OR EQUAL TO 48 SQ. IN., WITHOUT ADHESIVE BORDER, EACH DRESSING" describe only the materials with which this dressing is comprised. They do not address the antimicrobial role that the dressing plays within the wound bed. The applicant claims that silver protects the dressing from a broad spectrum of microorganisms, including MRSA, and that this is an "alternative function" not described by existing HCPCS codes, that "provides a therapeutic distinction". The applicant also claims that a silver-releasing lipidocolloid contact layer promotes sustained increase in closure rates of venous leg ulcers presenting inflammatory signs suggesting high bacterial load. And the applicant comments that the fee associated with codes A6209 and A6210 is insufficient to cover the cost of products that contain silver.

CMS HCPCS Preliminary Decision:

Existing code A6209 “FOAM DRESSING, WOUND COVER, STERILE, PAD SIZE 16 SQ. IN. OR LESS, WITHOUT ADHESIVE BORDER, EACH DRESSING” or A6210 “FOAM DRESSING, WOUND COVER, STERILE, PAD SIZE MORE THAN 16 SQ. IN. BUT LESS THAN OR EQUAL TO 48 SQ. IN., WITHOUT ADHESIVE BORDER, EACH DRESSING”, depending on size, adequately describes the item that is the subject of this request.

Medicare Payment:

The payment rules associated with the existing codes apply to these products. Pricing = 35

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item #3
May 26, 2010

Attachment# 10.122

Topic/Issue:

Request to establish a code for a Multidirectional Infrared Light Therapy System in a 9 foot Cabinet.

Background/Discussion:

According to the requester, the Multidirectional Infrared Light Therapy System is a portable system that produces infrared rays to treat skin conditions as psoriasis and eczema, as well as, unhealed wounds, skin breakdowns, stasis ulcers, pressure ulcers, diabetic ulcers, stasis dermatitis, temporary relief of minor muscle and joint pain and stiffness, the temporary relief of joint pain associated with arthritis, the temporary increase in local circulation where applied, weight control, heart disease and etc. The 9 foot cabinet provides effective treatment for people suffering from many chronic disease like diabetes, cardiovascular diseases, obesity, cancer, muscle and joint pain and many other health conditions. The Multidirectional Infrared Light Therapy System operates from regular electrical outlet. The system can be used in a physician's office, or by a patient in their home. The patient sits on the chair inside of the reflective cover, turns the timer on the controller box from 5-30 minutes and zips up the cover around his or her body and receives treatment. Infrared rays create healing effect on the entire body, speeding up recovery period for patients with wide variety of health problems. According to the requester, there are no existing codes to describe this product. In treating a variety of conditions, the 9-foot multidirectional system provides a different function from light systems coded at E0694 "ULTRAVIOLET MULTIDIRECTIONAL LIGHT THERAPY SYSTEM IN 6 FOOT CABINET, INCLUDES BULBS/LAMPS, TIMER AND EYE PROTECTION," which only treats skin conditions.

CMS HCPCS Preliminary Decision:

Existing code E0200 "HEAT LAMP, WITHOUT STAND (TABLE MODEL), INCLUDES BULB, OR INFRARED ELEMENT" adequately describes the product that is the subject of this request.

Medicare Payment:

Based on our understanding, we believe there would be no Medicare payment for this item under the existing DME MAC local coverage decision.

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item #4
May 26, 2010

Attachment# 10.133

Topic/Issue:

Request to establish a code for a wool heel protector.

Background/Discussion:

According to the requester, the wool heel protector helps to reduce the pressure on the patient's heel. It is made of 100% merino wool and comes in pairs and in all shoe sizes. The millions of wool fibers help the patient's body to breathe, massages the body, and protects from electrostatic. According to the requester, there are no existing codes to describe this product.

CMS HCPCS Preliminary Decision:

A national program operating need to establish a code for this product was not identified by Medicare, Medicaid or the Private Insurance Sector. For coding guidance, contact the entity in whose jurisdiction a claim would be filed. For private insurers, contact the individual private insurance contractor. For Medicaid, contact the Medicaid Agency in the state in which a claim would be filed. For Medicare, contact the Medicare contractor.

Medicare Payment:

Based on our preliminary benefit category analysis, we believe that there would be no Medicare payment for this item.

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item #4
May 26, 2010

Attachment# 10.126

Topic/Issue:

Request to establish a code for wool slippers, trade name: Bauer Comfort Wool Cast Shoes/Diabetic Slippers.

Background/Discussion:

According to the requester, the wool cast shoes/diabetic slippers are indicated for use by patients who have a cast with partial or full weight bearing and for patients with diabetic stasis ulcers and open wounds, and by patients who are prone to skin breakdown. Without a therapeutic insert, the slippers are "suitable for everyone". They help to regulate the temperature of open toes on a open casted lower extremity and to reduce the pressure on the patient's heel. The cast shoes/diabetic slippers are made of 100% merino wool which is organic and Kosher. The wool fibers are hygroscopic, which means they absorb and evaporate moisture. This wool also contains lanolin, which imparts hypoallergenic and bacteriostatic properties, and water resistance. The millions of wool fibers in these slippers massage the feet and thereby improve blood circulation of the feet. According to the requester, there are no existing codes to describe this product.

CMS HCPCS Preliminary Decision:

A national program operating need to establish a code for this product was not identified by Medicare, Medicaid or the Private Insurance Sector. For coding guidance, contact the entity in whose jurisdiction a claim would be filed. For private insurers, contact the individual private insurance contractor. For Medicaid, contact the Medicaid Agency in the state in which a claim would be filed. For Medicare, contact the Medicare contractor.

Medicare Payment:

Based on our preliminary benefit category analysis, we believe that there would be no Medicare payment for this item.

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item #4
May 26, 2010

Attachment# 10.130

Topic/Issue:

Request to establish a single code category that would identify wool trochanter rolls and flexible wool cervical collars used for positioning, trade names: "positioning trochanty roll" and "cervical flexible wool collar".

Background/Discussion:

According to the requester, the positioning trochanty rolls and cervical flexible wool collars are padding products intended for use by patients with muscle contractures and bone abnormalities. The collar is made of 100% merino wool. The wool fibers are hygroscopic and thereby absorb and evaporate moisture. The collar and roll are used for proper positioning of the upper body, head and trunk support. Side leaning can be corrected by placing the positioning roll around the resident in a chair. According to the requester, there are no existing codes to describe this product.

CMS HCPCS Preliminary Decision:

Existing code E0190 "POSITIONING CUSHION/PILLOW/WEDGE, ANY SHAPE OR SIZE, INCLUDES ALL COMPONENTS AND ACCESSORIES" adequately describes the product that is the subject of this request.

Medicare Payment:

The payment rules associated with the existing code apply to this product. Pricing = 00

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item #4
May 26, 2010

Attachment# 10.128

Topic/Issue:

Request to establish a code for a wool elbow/knee belt with padding.

Background/Discussion:

According to the requester, the elbow/knee belt with padding is useful for patients with arthritis, joint deformities, and pressure ulcers, or patients who are at risk of pressure ulcers at elbow or knee area. The padding is made of 100% merino wool. The wool fibers are hygroscopic and absorb and evaporate moisture. According to the requester, there are no existing codes to describe this product.

CMS HCPCS Preliminary Decision:

A national program operating need to establish a code for this product was not identified by Medicare, Medicaid or the Private Insurance Sector. For coding guidance, contact the entity in whose jurisdiction a claim would be filed. For private insurers, contact the individual private insurance contractor. For Medicaid, contact the Medicaid Agency in the state in which a claim would be filed. For Medicare, contact the Medicare contractor.

Medicare Payment:

Based on our preliminary benefit category analysis, we believe that there would be no Medicare payment for this item.

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item #4
May 26, 2010

Attachment# 10.129

Topic/Issue:

Request to establish a code for a wool belt with padding.

Background/Discussion:

According to the requester, the wool belt with padding is used as a treatment of decubitus ulcers, and skin breakdown on the lower back area. The belts are made of 100% merino wool, pink wool blend wool, and camel blend wool. The wool fibers are hygroscopic and absorb and evaporate moisture. Wool belts with padding can be used as a dry heat for patients with low back pain and are good for patients with scoliosis, herniated disks and low back pain. According to the requester, there are no existing codes to describe this product.

CMS HCPCS Preliminary Decision:

A national program operating need to establish a code for this product was not identified by Medicare, Medicaid or the Private Insurance Sector. For coding guidance, contact the entity in whose jurisdiction a claim would be filed. For private insurers, contact the individual private insurance contractor. For Medicaid, contact the Medicaid Agency in the state in which a claim would be filed. For Medicare, contact the Medicare contractor.

Medicare Payment:

Based on our preliminary benefit category analysis, we believe that there would be no Medicare payment for this item.

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item #4
May 26, 2010

Attachment# 10.127

Topic/Issue:

Request to establish a code for a 30" x 16" hypoallergenic merino wool pillow.

Background/Discussion:

According to the requester, the Merino Wool Pillow is used to reduce pressure on the skin over a bony prominence to reduce the likelihood of the development of decubitus ulcers. It is useful for bed bound patients, patients with pressure ulcers, patients with allergies, patients with temperature instability, asthma patients and patients with COPD. The pillow case is made of 100% merino wool. The millions of wool fibers create free air flow under the entire surface of contact with skin, which protects the patient's skin. The pillow insert is hypoallergenic. According to the requester, there are no existing codes to describe this product.

CMS HCPCS Preliminary Decision:

A national program operating need to establish a code for this product was not identified by Medicare, Medicaid or the Private Insurance Sector. For coding guidance, contact the entity in whose jurisdiction a claim would be filed. For private insurers, contact the individual private insurance contractor. For Medicaid, contact the Medicaid Agency in the state in which a claim would be filed. For Medicare, contact the Medicare contractor.

Medicare Payment:

Based on our preliminary benefit category analysis, we believe that there would be no Medicare payment for this item.

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item #5
May 26, 2010

Attachment# 10.055

Topic/Issue:

Request for a code to identify a merino wool orthopedic pillow.

Background/Discussion:

According to the requester, the merino wool orthopedic pillow (26"x16") is indicated for patients with a history of snoring, sleep apnea, neck and back pain, and severe allergies. This product consists of an upper cover (pillow case) and filling. The pillow case is made from 100% merino wool. The wool is organic, hygroscopic, hypoallergenic, antibacterial and certified Kosher. The latex filling is hypo allergenic. This pillow can be used for proper positioning of the spine and to reduce pressure on the skin over a bony prominence, to reduce the likelihood of developing decubitus ulcers. The wool massages the whole body and it protects from static electricity. Wool is the only product that does not contain dust mites. There are no existing codes that fit the description of an orthopedic pillow from merino wool.

CMS HCPCS Preliminary Decision:

A national program operating need to establish a code for this product was not identified by Medicare, Medicaid or the Private Insurance Sector. For coding guidance, contact the entity in whose jurisdiction a claim would be filed. For private insurers, contact the individual private insurance contractor. For Medicaid, contact the Medicaid Agency in the state in which a claim would be filed. For Medicare, contact the Medicare contractor.

Medicare Payment:

Based on our preliminary benefit category analysis, we believe that there would be no Medicare payment for this item.

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item #5
May 26, 2010

Attachment# 10.051

Topic/Issue:

Request for a code to describe a Multipurpose Wool Sheet.

Background/Discussion:

According to the Requester, Multipurpose Wool Sheet is a medical device that is used to keep a patient's body temperature stable. It hygroscopic, hypoallergenic antibacterial and certified Kosher. The multipurpose wool sheet is safe, wireless, flame resistant and more durable than electric heating pads and blankets. It is indicated for the treatment of burn patients, and patients with temperature instability, open wounds, patients with allergies to dust mites. According to the requester, sheepskin is also useful in preventing pressure ulcers. The Multipurpose Wool Sheet is a durable item. It has a 5 year manufacturer warranty. There are no existing codes that describe this product.

CMS HCPCS Preliminary Decision:

A national program operating need to establish a code for this product was not identified by Medicare, Medicaid or the Private Insurance Sector. For coding guidance, contact the entity in whose jurisdiction a claim would be filed. For private insurers, contact the individual private insurance contractor. For Medicaid, contact the Medicaid Agency in the state in which a claim would be filed. For Medicare, contact the Medicare contractor.

Medicare Payment:

Based on our preliminary benefit category analysis, we believe that there would be no Medicare payment for this item.

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item #5
May 26, 2010

Attachment# 10.058

Topic/Issue:

Request for a code to describe a wool chair seat with padding.

Background/Discussion:

According to the requester, this chair seat cover is made from 100% merino wool. The wool is hygroscopic, hypoallergenic, antibacterial, and certified Kosher. The chair seat (16" by 16") is intended to reduce pressure on the skin over a bony prominence. The filling gives a cushion effect. It is also useful for prevention of hemorrhoids.

CMS HCPCS Preliminary Decision:

A national program operating need to establish a code for this product was not identified by Medicare, Medicaid or the Private Insurance Sector. For coding guidance, contact the entity in whose jurisdiction a claim would be filed. For private insurers, contact the individual private insurance contractor. For Medicaid, contact the Medicaid Agency in the state in which a claim would be filed. For Medicare, contact the Medicare contractor.

Medicare Payment:

Based on our preliminary benefit category analysis, we believe that there would be no Medicare payment for this item.

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item #6
May 26, 2010

Attachment# 10.111

Topic/Issue:

Request to establish a code for a seat with a unique cut-out, designed for retracting prolapsed hemorrhoids, trade name: HemAway Seat. Applicant's suggested language: "Pressure reducing seat, for use with prolapsed hemorrhoids, each."

Background/Discussion:

According to the requester, the HemAway Seat is a "medical treatment" to relieve the pain and pressure of prolapsed hemorrhoids, and reduce or eliminate the need for surgery. It is designed to fit on any raised flat or slightly curved surface such as a non-cushioned chair or toilet. This portable seat is a shaped plastic disc with a unique cutout for pressure relief. It operates by causing a simultaneous increase in hydrostatic forces around the anus externally and a corresponding decrease in hydrostatic pressures internally around the rectal area. This combination allows the blood trapped in the prolapsed hemorrhoids to gently be returned to the normal circulation pathways. The resulting decrease in size allows the hemorrhoids to slip naturally and without manipulation into the rectal vault. According to the requester, there are no other products that perform this function and there are no codes to describe it.

CMS HCPCS Preliminary Decision:

A national program operating need to establish a code for this product was not identified by Medicare, Medicaid or the Private Insurance Sector. For coding guidance, contact the entity in whose jurisdiction a claim would be filed. For Medicaid, contact the Medicaid Agency in the state in which a claim would be filed. For private insurance, contact the individual insurance contractor. For Medicare, contact the Medicare contractor.

Medicare Payment:

Based on our preliminary benefit category analysis, we believe that there would be no Medicare payment for this item.

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with the Workgroup's preliminary decision. The speaker stated that the HemAway Seat actively treats complications of hemorrhoids. The HemAway Seat is a portable Seat that fits non-cushioned chair, flat tabletop, or any style toilet. Also, the speaker stated that the seat treats hemorrhoids by using natural body physics to enable a prolapsed hemorrhoid to retract. Specifically, the HemAway Seat reduces or delays doctor or hospital

visits and surgery. The speaker believed that a new HCPCS code should be established for the HemAway Seat.

HCPCS Public Meeting Agenda Item #7
May 26, 2010

Attachment# 10.117

Topic/Issue:

Request to establish a code for a walk-in therapeutic tub, trade names: Therapy Tub and Ruby 3052.

Background/Discussion:

According to the requester, the Therapy Tub is a walk-in tub with hydro and air message therapy jets used to promote better health by easing aches, pains and symptoms of many diseases or conditions. Therapy Tub was designed for individuals with medical and/or mobility issues who have a hard time getting in and out of a standard bath tub. A walk-in tub promotes independence by enabling an individual to bathe while reducing the risk of falls and fractures, and the need for in-home or institutional care. The tub is constructed of fiberglass. According to the requester, there are no existing codes to describe this product.

CMS HCPCS Preliminary Decision:

A national program operating need to establish a code for this product was not identified by Medicare, Medicaid or the Private Insurance Sector. For coding guidance, contact the entity in whose jurisdiction a claim would be filed. For private insurers, contact the individual private insurance contractor. For Medicaid, contact the Medicaid Agency in the state in which a claim would be filed. For Medicare, contact the Medicare contractor.

Medicare Payment:

Based on our preliminary benefit category analysis, we believe that there would be no Medicare payment for this item.

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with the Workgroup's preliminary decision. The speaker stated that the Therapy Tub is designed to be placed in a patient's home to eliminate the expense and time needed for transportation to a facility when hydrotherapy is prescribed by a physician. The tub is designed to fit into a standard bathtub area. Also, the speaker stated that the tub has an anti-scalding valve that protects the patient from potential hot water scalding. Further, the speaker claimed that the Therapy Tub prevents falls and injuries. The speaker also stated that the Therapy Tub allows the patient to return home to complete their rehabilitation, which will reduce recovery time and ultimately reduce Medicare reimbursement costs.

HCPCS Public Meeting Agenda Item #8
May 26, 2010

Attachment# 10.049

Topic/Issue:

Request for a HCPCS code to identify the Madison Oral Strengthening Therapeutic (MOST) Device.

Background/Discussion:

According to the Requester, the Madison Oral Strengthening Therapeutic (MOST) device 1) used by physicians as a screening tool to identify risk for dysphagia, and 2) used by patients to perform progressive resistance lingual press exercises to strengthen the muscles of the tongue and oropharynx. The device consists of a single-patient use, pliable mouthpiece component that incorporates sensors to measure tongue pressure, and a portable, DC battery powered hand-held device that measures and records manometric readings from the sensors imbedded in the mouthpiece. The physician/diagnostic component involves fitting the oral component's sensory receptors against the patient's hard palate, instructing the patient, and evaluating the lingual press measurements. After a patient has used the MOST device at home, they return to the physician who downloads the lingual press measures from the device, analyzes them, and uses the information to recommend lingual strengthening exercise regimen, and monitor patient compliance and progress. Patients who may benefit from the use of this device are those diagnosed with dysphagia secondary to stroke or other neuromuscular condition, those who have had prolonged endotracheal intubation after cardiac surgery, those demonstrating difficulty swallowing after chemotherapy, or patients presenting with age-related changes. According to the Requester, there are no HCPCS Level II codes that describe this device and no CPT codes that specifically describe a device with 5 sensors that are placed against the hard palate and intended to diagnose and evaluate swallowing function.

CMS HCPCS Preliminary Decision:

A national program operating need to establish a code for this product was not identified by Medicare, Medicaid or the Private Insurance Sector. For coding guidance, contact the entity in whose jurisdiction a claim would be filed. For private insurers, contact the individual private insurance contractor. For Medicaid, contact the Medicaid Agency in the state in which a claim would be filed. For Medicare, contact the Medicare contractor.

Medicare Payment:

Based on our preliminary benefit category analysis, we believe that there would be no Medicare payment for this item.

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item #9
May 26, 2010

Attachment# 10.031

Topic/Issue:

Request to establish a code for concentrated bioadherent oral gel, trade name: GELCLAIR.

Background/Discussion:

According to the Requester, GELCLAIR offers pain relief by means of mechanical protection provided by an adherent film which coats the mucosal surfaces of the mouth, lubricating, and hydrating the damaged tissues, soothing irritation and improving the patient's ability to eat and drink. The patient population who would benefit from the use of GELCLAIR are those who experience pain from oral lesions of various etiologies, including oral mucositis/stomatitis (frequently occurring after radiation and chemotherapy), irritation due to oral surgery, traumatic ulcers caused by braces or ill-fitting dentures, or disease. It is also indicated for diffuse aphthous ulcers. It is formulated with purified water, maltodextrin, propylene glycol, PEG-40, hydrogenated castor oil, potassium sorbate, sodium benzoate, hydroxyethylcellulos, benzalkonium chloride, disodium edetate, saccharin sodium, polyvinylpyrrolidone, sodium hyaluronate, glycyrrhetinic acid and flavoring. GELCLAIR is available by prescription and can be administered up to three times per day. It is supplied in boxes containing 15 single-use sachets. Each sachet contains a single 15 mL dose. The entire contents of one sachet are added to 15-45 mL of water. The patient rinses or gargles with the solution for at least one minute. If water is not available, concentrated GELCLAIR gel can be used undiluted straight from the sachet. The requester states that Rincinol is a diluted, non-prescription version of GELCLAIR that is available over the counter and has additional ingredients such as aloe vera and a flavoring agent methylcyclopentenolone. Differences in function/treatment provided to the patient and clinical outcomes are unknown as the products have not been compared head to head. Claims for GELCLAIR are frequently denied due to the lack of a billing code specific to the product. In some cases, the pharmacy may use the product NDC as the billing code, but GELCLAIR is not universally recognized as a pharmacy benefit by all prescription drug plans. There are no existing HCPCS codes that describe a this product, and a code and price is necessary in order for patients to have access to the product and to "accommodate payment" for it.

CMS HCPCS Preliminary Decision:

A national program operating need to establish a code for this product was not identified by Medicare, Medicaid or the Private Insurance Sector. For coding guidance, contact the entity in whose jurisdiction a claim would be filed. For private insurers, contact the individual private insurance contractor. For Medicaid, contact the Medicaid Agency in the state in which a claim would be filed. For Medicare, contact the Medicare contractor.

Medicare Payment:

Based on our preliminary benefit category analysis , we believe that there would be no Medicare payment for this item.

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item #10
May 26, 2010

Attachment# 10.009

Topic/Issue:

Request to establish a new HCPCS code for an aerosol hospital grade disinfectant, trade name: Citrace® Hospital Germicide.

Background/Discussion:

According to the requester, Citrace® is an aerosol disinfectant used to disinfect surfaces, devices, and equipment. It accomplishes broad-spectrum disinfection, including effectiveness against MDRO microorganism of concern. The primary use of this product is to disinfect surfaces which have become contaminated with blood borne pathogens, and to prevent the spread of disease. This product is needed to disinfect high touch surfaces of home dialysis and or ESRD facilities (and other medical) equipment. Product is used by spraying the potentially infected surface and allowing to sit for up to five minutes. According to the requester, in establishing new active infection control program requirements for ESRD facilities, CMS recognizes the need for infection control procedures and products. CMS covers necessary supplies for home dialysis; one of those supplies would be an approved disinfectant to help prevent the spread of infection among this immunosuppressed group of patients. There are no existing HCPCS codes to describe this product or other surface disinfectants.

CMS HCPCS Preliminary Decision:

A national program operating need to establish a code for this product was not identified by Medicare, Medicaid or the Private Insurance Sector. For coding guidance, contact the entity in whose jurisdiction a claim would be filed. For private insurers, contact the individual private insurance contractor. For Medicaid, contact the Medicaid Agency in the state in which a claim would be filed. For Medicare, contact the Medicare contractor.

Medicare Payment:

Based on our preliminary benefit category analysis, we believe that there would be no Medicare payment for these items.

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item #11
May 26, 2010

Attachment# 10.010

Topic/Issue:

Request to establish 2 codes for a liquid medication dispenser: one for the Medibottle and one for the Medibottle +.

Background/Discussion:

According to the requester, the Medibottle is a pediatric medication delivery system designed for infants. A care-giver measures an accurate dose of oral, liquid medication, loads an oral dispenser with the medicine, fills the medibottle like a regular baby bottle, and attaches a nipple. The caregiver inserts the loaded oral dispenser into the inner sleeve of the bottle. The sleeve's tip has a very precise tolerance that restricts the flow of medicine, creating a small and powerful jet or "little squirt" each time the dispenser plunger is pressed. These small amounts of medicine displace the liquid in the very tip of the nipple. According to the requester, it is this functionality that offers a "significant therapeutic distinction" over other means of delivering oral medication to an infant, and it is clinically proven "superior" by top-level researchers. The most recent study involved 76 hospitalized infants and a bitter-tasting medication. The medibottle was found to be 85% more likely to deliver 100% of the prescribed dosages than its closest competitor, the industry standard oral syringe. The requester comments that the difference in successful delivery of the full dose results in improved compliance and a decrease in the effects and cost of non-compliance, which makes this medication delivery system more than a matter of convenience. The requester asks for a code to identify the medibottle, which is not identified in the existing code set.

CMS HCPCS Preliminary Decision:

A national program operating need to establish a code for this product was not identified by Medicare, Medicaid or the Private Insurance Sector. For coding guidance, contact the entity in whose jurisdiction a claim would be filed. For private insurers, contact the individual private insurance contractor. For Medicaid, contact the Medicaid Agency in the state in which a claim would be filed. For Medicare, contact the Medicare contractor.

Medicare Payment:

Based on our preliminary benefit category analysis, we believe that there would be no Medicare payment for these items.

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item #12
May 26, 2010

Attachment# 10.069

Topic/Issue:

Request for HCPCS code for circulating tumor cell enumerations assay, immunomagnetic. Trade Name: CellSearch® Circulating Tumor Cell Kit.

Background/Discussion:

According to the Requester, the CellSearch® Circulating Tumor Cell Kit contains a ferrofluid-based capture reagent and immunofluorescent reagents. The ferrofluid reagent consists of nanoparticles with a magnetic core surrounded by a polymeric layer coated with antibodies targeting the EpCAM antigen for capturing CTC. The Cell Search® Circulating Tumor Cell Kit is intended for the enumeration of circulating tumor cells of epithelial origin (CD45-, EpCAM+, and cytokeratins 8, 18+, and/or 19+) in whole blood. The presence of CTC in the peripheral blood, as detected by the CellSearch® Circulating Tumor Cell Kit, is associated with decreased progression free survival and decreased overall survival in patients treated for metastatic breast, colorectal or prostate* cancer. The test is to be used as an aid in the monitoring of patients with metastatic breast, colorectal or prostate cancer. Serial testing for CTC should be used in conjunction with other clinical methods for monitoring metastatic breast, colorectal and prostate cancer*. Evaluation of CTC at any time during the course of the disease allows assessment of patient prognosis and is predictive of progression free survival and overall survival. Immunomagnetic-based circulating tumor cell enumeration assay is used in the physician office, hospital outpatient and hospital inpatient setting to monitor prognosis during the course of treatment in patients with metastic breast, prostate and colon cancer. Immunomagnetic-based circulating tumor cell enumeration assay is prescribed by health care professionals.

CMS HCPCS Preliminary Decision:

A national program operating need to establish a code was not identified by Medicare, Medicaid or the Private Insurance Sector. CMS suggests that the applicant contact the American Medical Association (AMA) for CPT coding guidance.

Medicare Payment:

Based on our preliminary benefit category analysis, we believe that there would be no separate Medicare payment under a DMEPOS benefit category for this item.

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item #13
May 26, 2010

Attachment# 10.108

Topic/Issue:

Request to establish a code for a transfer and lift device, trade name: Transfer and Lift Control Unit (TLC Unit). Applicant's suggested language: "Combination supine to stand patient lift-hospital bed system, with integrated even weight distribution frame, counter weight/balance assembly, actuator, electronic logic controller, integrated weight-bearing footplate, protective safety barriers and patient accessible controls."

Background/Discussion:

According to the requester, the TLC unit is a patient lift and transfer device that also functions as a sleep surface. This device replaces a multipositional patient support system, a patient seat lift, and a hospital bed. It supports the patient so they can transfer independently and safely to a mobile device. The TLC unit is used by patients with numerous medical issues such as Parkinson's disease, orthopedic issues, neurological ailments, and bariatric patients. This manufacturer's device is supplied in several models, respectively accommodating patient weights up to 350; 600; and 1000 pounds. The device includes a tilting mechanism supported by a base assembly that equally distributes weight to create stability. The deck rotates between a supine position and an upright position using patient accessible hand operated electronic, programmable controls. A foot plate/footboard assembly allows full weight bearing when deck is in the full upright position, accommodating full or partial weight bearing transfers and providing a patient support surface while the patient is being lifted from a supine to a standing upright position. The TLC unit also aids in blood circulation and decreasing events of pressure sores as the unit serves as a sleeping surface. Using actuators, the upper deck tilts up to 65 degrees, and the entire deck assembly tilts up to 87 degrees to support safe transfers and lifting. It reduces and/or eliminates injuries from falling or unsafe transfers. According to the requester, the TLC unit is described by a combination of codes E0636 "MULTIPOSITIONAL PATIENT SUPPORT SYSTEM, WITH INTEGRATED LIFT, PATIENT ACCESSIBLE CONTROLS", E0640 "PATIENT LIFT, FIXED SYSTEM, INCLUDES ALL COMPONENTS AND ACCESSORIES" and E0250 "HOSPITAL BED, FIXED HEIGHT, WITH ANY TYPE SIDE RAILS, WITH MATTRESS".

CMS HCPCS Preliminary Decision:

A national program operating need to establish a code for this product was not identified by Medicare, Medicaid or the Private Insurance Sector. For coding guidance, contact the entity in whose jurisdiction a claim would be filed. For Medicaid, contact the Medicaid Agency in the state in which a claim would be filed. For private insurance, contact the individual insurance contractor. For Medicare, contact the Medicare contractor.

Medicare Payment:

Based on our preliminary benefit category analysis, we believe that there would be no Medicare payment for this item.

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with the Workgroup's preliminary decision. The speaker believed that the Transfer & Lift Control Unit (TLC Unit) should be evaluated under the DME benefit category because it meets the Medicare definition of a DME. The speaker stated that the TLC Unit is a combination product that combines a patient lift and transfer device with the function of a hospital bed into one system. The TLC would only be used to provide assistance to a patient who cannot get out of the bed to ambulate or use a mobility device. The speaker believed that a new HCPCS code should be created to identify a combination product and eliminate billing confusion with the existing codes for hospital beds and patients lifts. According to the speaker, both product categories (hospital beds and patient lifts) are part of the DME benefit category and are coded separately and reimbursed by Medicare, Medicaid, and private payers.

HCPCS Public Meeting Agenda Item #14
May 26, 2010

Attachment# 10.043

Topic/Issue:

Request to establish a code for an external penile support device, trade name: Erektor. Applicant's suggested language: "External penile support device".

Background/Discussion:

According to the Requester, Erektor is a custom made external penile support device for men with erectile dysfunction and premature ejaculation problems. The Erektor stretches the penis to the correct angle when applied on a flaccid penis, providing sufficient support and rigidity to the penis enabling the wearer to engage in intercourse with a weak erection or no erection at all. The Erektor is a super-lightweight (less than 0.2 ounce) device designed to provide the wearer just enough direct penile support and flexibility for immediate sexual penetration. The structural base of the device is made from thin stainless steel tempered wire encapsulated by tubing and over-molded with hypoallergenic silicon rubber. The latch, slider lock and base rings are injection molded Polypropylene Homopolymer. Each device is custom made based on personal measurements. The requester comments that Erektor is a totally unique non-drug, non-surgical and non-invasive treatment for ED and premature ejaculation, and claims that the device is a male genitourinary prosthetic that is not described in the existing HCPCS code set.

CMS HCPCS Preliminary Decision:

A national program operating need to establish a code for this product was not identified by Medicare, Medicaid or the Private Insurance Sector. For coding guidance, contact the entity in whose jurisdiction a claim would be filed. For private insurers, contact the individual private insurance contractor. For Medicaid, contact the Medicaid Agency in the state in which a claim would be filed. For Medicare, contact the Medicare contractor.

Medicare Payment:

Based on our preliminary benefit category analysis, we believe that there would be no separate Medicare payment for this item.

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with the Workgroup's preliminary decision. The speaker stated that the Erektor is a revolutionary penile support device for men with erectile dysfunction that involves no medications, no surgeries, and no side effects. The speaker also stated that the newly designed flexible manufacturing system allows for a precise and comfortable fit based on each specific patient measurement. The speaker believed that a unique HCPCS code should be established for the Erektor based on its effectiveness, no side effects, and increased demand.

PAYMENT FOR DMEPOS

DMEPOS

The term DMEPOS, which stands for durable medical equipment (DME), prosthetics, orthotics and supplies, is used in the Medicare program to describe a set of Medicare Part B device and supply benefits for which claims are processed by four DME Medicare Administrative Contractors (DME MACs). The Part B device benefits covered by this term include:

- DME – equipment used in the home which can withstand repeated use, is primarily and customarily used to serve a medical purpose, and is generally not useful in the absence of an illness or injury;
- Prosthetic Devices – devices that replace all or part of an internal body organ, including ostomy, tracheostomy and urological supplies, parenteral and enteral nutrients, equipment and supplies (PEN), intraocular lenses (IOLs), and one pair of conventional eyeglasses or contact lenses after each cataract surgery;
- Prosthetics – artificial legs, arms, and eyes;
- Orthotics – rigid or semi-rigid leg, arm, back, and neck braces;
- Home Dialysis Supplies and Equipment
- Surgical Dressings
- Therapeutic Shoes and Inserts

Depending on the item or the setting in which the item is furnished, Medicare claims for some of these items may also be processed by local carriers, fiscal intermediaries and A/B MACs(e.g., claims for DME implanted in an ambulatory surgical center are processed by local carriers). Claims for DME and ostomy, tracheostomy and urological supplies furnished by a home health agency are processed by Regional Home Health Intermediaries (RHHIs)and A/B MACs.

Fee Schedule Payments

Prior to January 1, 1989, payment for most DMEPOS items and services was made on the basis of the reasonable charge methodology. Reasonable charges are calculated using suppliers' charges and are limited by an inflation adjustment factor. Payment is still made on a reasonable charge basis for home dialysis supplies and equipment and for IOLs inserted in a physician's office. There is a monthly limit per beneficiary on payments for home dialysis supplies and equipment. Payment for most of the other DMEPOS items and services is based on the lower of the actual charge for the item or a fee schedule amount. The Part B deductible and 20 percent coinsurance both apply to the DMEPOS items and services described above.

The Social Security Act requires that the DMEPOS fee schedule amounts be established based on average reasonable charges made during a base period (e.g., July 1, 1986 thru June 30, 1987 for prosthetic devices, prosthetics and orthotics). The fee schedule amounts are increased by annual update factors. Because the reasonable charge data required by the law in establishing fee schedule amounts does not exist for new DMEPOS items, the fee schedule amounts for new DMEPOS items are "gap-filled" using fees for comparable items, supplier price lists, manufacturer suggested retail prices, or wholesale prices plus a markup. The gap-filling methodology is used to estimate the average reasonable charge for the item from the base period.

DMEPOS Payment Categories/HCPCS Pricing Indicators

The Social Security Act separates DMEPOS into different Medicare payment categories, each with its own unique payment rules. The pricing indicators in the HCPCS identify which major payment category a code falls under. The pricing indicators applicable to DMEPOS are as follows:

- **Pricing = 00 Service Not Separately Priced**
  Items or services described by the HCPCS codes that are either not covered under Medicare Part B or for which payment is bundled into the payment some other Medicare service or procedure.

- **Pricing = 31 Frequently Serviced Items**
  Payment is generally made on a monthly rental fee schedule basis for items such as ventilators that require frequent and substantial servicing in order to avoid risk to the patient's health.

- **Pricing = 32 Inexpensive and Other Routinely Purchased Items**
  Payment is made on a purchase or rental fee schedule basis. This category includes items that have a purchase price of $150 or less, are generally purchased 75 percent of the time or more, or which are accessories used in conjunction with a nebulizer, aspirator, continuous airway pressure device, or intermittent assist device with continuous airway pressure device. The beneficiary has the option to acquire the item on a purchase or monthly rental basis. Total payments for the item cannot exceed the purchase fee schedule amount for the item.

- **Pricing = 33 Oxygen and Oxygen Equipment**
  Monthly fee schedule payments are made for furnishing oxygen and oxygen equipment. This monthly payment includes payment for all stationary oxygen equipment, supplies, and accessories and delivery of oxygen contents (stationary and portable). A monthly add-on to this payment is made for portable oxygen equipment only for those beneficiaries who require portable oxygen. The monthly payments for oxygen equipment cap after the 36th monthly payment is made, after

which payment for the ongoing delivery of contents continues for patient owned gaseous or liquid systems.

- **Pricing = 34 Supplies Necessary for the Effective Use of DME**
  Payment is made on a purchase fee schedule basis for supplies necessary for the effective use of DME (e.g., lancets that draw blood for use in blood glucose monitor).

- **Pricing = 35 Surgical Dressings**
  Payment is made on a purchase fee schedule basis for surgical dressings.

- **Pricing = 36 Capped Rental Items**
  Payment is made on a monthly rental fee schedule basis. For items furnished on or after January 1, 2006, the beneficiary takes over ownership of the item after the 13th rental payment is made. The rental fee for capped rental items other than power wheelchairs for each of the first 3 months of rental is equal to 10 percent of the purchase fee for the item. The rental fee for months 4 through 13 is equal to 7.5 percent of the purchase fee for the item. Effective for items furnished on or after January 1, 2011, the rental fee for power wheelchairs for each of the first 3 months of rental is equal to 15 percent of the purchase fee for the item. The rental fee for power wheelchairs for months 4 through 13 is equal to 6 percent of the purchase fee for the item. Effective for items furnished on or after January 1, 2011, only complex rehabilitative power wheelchairs can be purchased in the first month.

- **Pricing = 37 Ostomy, Tracheostomy and Urological Supplies**
  Payment is made on a purchase fee schedule basis for ostomy, tracheostomy and urological supplies.

- **Pricing = 38 Orthotics, Prosthetics, Prosthetic Devices, and Vision Services (Prosthetic Lenses)**
  Payment is made on a purchase fee schedule basis for orthotics, prosthetics, and prosthetic devices & lenses.

- **Pricing = 39 Parenteral and Enteral Nutrition (PEN)**
  Payment is made on a purchase fee schedule basis for parenteral and enteral nutrients and supplies. Payment is made on a purchase or rental fee schedule basis for parenteral and enteral equipment. The beneficiary has the option to acquire the item on a purchase or monthly rental basis.

- **Pricing = 45 Customized DME**
  Payment is made for lump-sum purchase of DME that meets the Medicare regulatory definition of customized DME at 42 CFR 414.224. The payment amount is based on the carrier's individual consideration of the item.

- **Pricing = 46 Carrier Priced Item**
  For items falling under codes for miscellaneous or not otherwise classified items, the fee schedule or reasonable charge payment amount, whichever is applicable, is based on the carrier's individual consideration of the item.

- **Pricing = 52 Reasonable Charges**
  Payment continues to be made on a reasonable charge basis in accordance with Medicare regulations at 42 CFR 405.500 for blood products, transfusion medicine, splints, casts, and other devices used to reduce a fracture or dislocation, and intraocular lenses (IOLs) inserted in physician's offices.