Centers for Medicare & Medicaid Services (CMS)
Healthcare Common Procedure Coding System (HCPCS)
Public Meeting Summary Report
Durable Medical Equipment (DME) and Accessories
Tuesday, June 8, 2010

Introduction and Overview

Approximately 41 people attended. The agenda included 18 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.

Karen Jacobs, Health Insurance Specialist in the Division of Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Policy, provided background information on the DMEPOS payment system and the payment categories utilized by Medicare for DME, prosthetics, orthotics and supplies. The overview was also provided as a written document to the agenda and is attached to this summary.

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 and make preliminary coding recommendations. CMS assigns preliminary recommendations regarding the applicable Medicare payment category and methodology that will be used to set a payment amount for the items on the agenda. The preliminary coding and payment recommendations are posted on the CMS HCPCS web site, specifically at 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 recommendations in light of any new information provided, and formulates its final coding decisions.

CMS maintains the permanent HCPCS Level II codes, and reserves final decision making authority concerning requests for permanent HCPCS codes. Final decisions regarding Medicare payment are made by CMS and must comply with the Statute and Regulations. Payment determinations for non-Medicare insurers, (e.g., state Medicaid Agencies or Private Insurers) are made by the individual state or insurer.

In November, all requestors will be notified in writing of the final decision regarding the HCPCS code modification request(s) they submitted. At about the same time, the HCPCS Annual Update is published at: www.cms.hhs.gov/HCPCSReleaseCodeSets/ANHCPCS/itemdetail.asp.

The latest information on the process for developing agendas and speaker lists for the public meetings, as well as the Guidelines for Proceedings at these CMS Public Meetings can be found on the CMS HCPCS web site, specifically at: http://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 Durable Medical Equipment (DME) and Accessories
Tuesday, June 8, 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 to modify the HCPCS code set. Final decisions are not made at the public meetings. Applicants will be notified of final decisions in November.

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

AGENDA ITEM #1

Attachment# 10.004
Request to establish a new code for a humidification delivery system for treatment of tracheostomy patients, trade name: The Wright Face & Tracheostomy Nebulizing Mask.

Primary Speaker: Vivian Wright of Wright Solutions LLC

AGENDA ITEM #2

Attachment# 10.105
Request to establish 2 codes: (1) one code for a nebulizer system for use with a specific drug, trade name: Altera Nebulizer System; and 2) one code for a handset for use with this nebulizer system, trade name: Altera handset.

Primary Speaker: Dr. Gerald Rogan of Rogan Consulting, Inc.

AGENDA ITEM #3

Attachment# 10.005
Request to establish 3 "J" codes: 1 for the Tyvaso Inhalation System Starter Kit, 1 for the Tyvaso Inhalation System Refill Kit, and 1 for the 4-pack short-term refill kit. Applicant's suggested language:

XXXX1 "Treprostinil, inhalation solution, 48.72 mg, with inhalation systems and accessories;"
XXXX2 "Treprostinil, inhalation solution, 48.72 mg, with accessories;"
XXXX3 "Treprostinil, inhalation solution, 6.96 mg"

Note: The Optineb-ir nebulizer and accessories component of this application is discussed in Request #10.005B, and the preliminary coding decision for the system appears in this agenda. The (Tyvaso) drug component of this application is discussed in Request #10.005A. The preliminary decision that correlates with Request #10.005A was posted in the May 4, 2010 Drugs, Biologicals, and Radiopharmaceuticals HCPCS Public Meeting Agenda.

Primary Speaker: Tom Gustafson of Arnold & Porter LLP

AGENDA ITEM #4

Attachment# 10.107
Request to distinguish "standard" head rest devices that merely provide a place for resting the head from devices that provide the same type of support, but can accommodate additional pads for intimate head support, including lateral facial, lateral neck or forehead.

Primary Speaker: Tom Whelan of Sunrise Medical

AGENDA ITEM #5

Attachment# 10.054
Request for a new HCPCS code to identify an integrated, ergonomic wheelchair hand rim assembly, trade name: Natural Fit.

No Primary Speaker

AGENDA ITEM #6

Attachment# 10.047
Request to separate 2-point and 4-point padded, adjustable positioning belts from existing code E0978 by establishing 2 new codes to identify positioning belts, and omitting the words "positioning belt" from the text of existing code E0978.

Primary Speaker: Allen Siekman of Allen Siekman Consulting

AGENDA ITEM #7
Attachment# 10.109
Request to establish 2 codes for an upgraded proportional remote joystick, trade names: Q-Logic Joystick & Remote+ Joystick.

Primary Speaker: Jill Kolczynski of Pride Mobility Products, Corporation

AGENDA ITEM #8
Attachment# 10.124
Request to establish a code for Merino Wool Skin Protection Wheelchair Seat Cushion.

Attachment# 10.131
Request to establish a code for a positioning wheelchair back cushion.

Attachment# 10.123
Request to establish a code for an orthopedic mattress, trade name: Bauer Comfort Orthopedic Mattress.

Attachment# 10.125
Request to establish a code for a merino wool mattress cover with padding.

Attachment# 10.132
Request to establish a code to identify multipurpose sheep skin.

No Primary Speaker

AGENDA ITEM #9

Attachment# 10.102
Request to establish a code for a dynamic splinting device, trade name: Hallux Varus/Valgus Dynasplint® (HVD) System.

Attachment# 10.103
Request to establish a code for a dynamic splinting device designed to treat carpal tunnel syndrome (CTS), trade name: Carpal Tunnel Dynasplint® System (CTD).

No Primary Speaker

AGENDA ITEM #10

Attachment# 10.104
Request to establish a unique code for a portable knee extension device, trade name: Elite Seat.

Primary Speaker: Annette Sullivan of Kneebourne Therapeutic, LLC

AGENDA ITEM #11

Attachment#10.098
Request to establish a code for a knee/ankle flexionater, trade name: Knee/Ankle Flexionater.

Attachment# 10.099
Request to establish a code for metatarsophalangeal joint (MPJ), trade name: MPJ Extensionater.

Primary Speaker: Dr. Thomas Branch of ERMI, Inc.

AGENDA ITEM #12

Attachment# 10.037
Request for a code to identify a tunnel dressing for use with Negative Pressure Wound Therapy, trade names: Engenex® Tunnel Dressing 1x15cm and Engenex® Tunnel Dressing 1.5x15 cm.

Primary Speaker: Joseph Rolley of ConvaTec, Inc.

AGENDA ITEM #13

Attachment# 10.100
Request to establish a code for an external insulin infusion pump for diabetes, trade name: Personal Diabetes Manager (PDM).

Primary Speaker: Thomas Scully of Alston & Bird LLP

AGENDA ITEM #14

Attachment# 10.101
Request to establish a code for a personal therapy manager, trade name: myPTM.

No Primary Speaker

AGENDA ITEM #15

Attachment# 10.106
Request to establish a code for an acoustic airway clearance device, trade name: The Frequencer™.

No Primary Speaker

AGENDA ITEM #16

Attachment# 10.086
Request to establish a code for replacement patient breathing circuits used in cough stimulating devices, trade names: CoughAssist™ and Patient Circuit for the Cough Assist™.

No Primary Speaker

AGENDA ITEM #17

Attachment #10.119
Request to establish a code for an electrochemical low-dose tissue oxygenation system, trade name: TransCu O_2.

Primary Speaker: Dr. Michael Howard of University of Chicago Pritzker School of Medicine

AGENDA ITEM #18

Attachment# 10.007
Request to have a new code assigned to a heat therapy system, trade name: Xtreme-Relief Heat Therapy System.

Primary Speaker: Dr. Doug Duncan

HCPCS Public Meeting Agenda Item #1

June 8, 2010

Attachment# 10.004

Topic/Issue:

Request to establish a new code for a humidification delivery system for treatment of tracheostomy patients, trade name: The Wright Face & Tracheostomy Nebulizing Mask. Applicant's suggested language: "Upper airway and tracheostomy humidification mask delivery system for simultaneous moisturizing of the nose, mouth, sinus cavity & tracheostomy tissues. This all-in-one upper and lower airway humidification delivery system is used in conjunction with a nebulizer container and an air compressor."

Background/Discussion:

According to the requester, the Wright Face & Tracheostomy Nebulizing Mask is a humidification delivery system for treatment of tracheostomy patients' upper airway and tracheostomy. As a humidification delivery system, moisture droplets are delivered through the Wright Mask into patients' upper airway and tracheostomy in the form of a fine mist thereby moisturizing the tissues and membranes of the nose, mouth, tracheostomy, sinus cavity, and throat. This double-face/trach mask delivery system is placed over the nose/mouth and tracheostomy and a nebulizer holding medicant/saline is attached. The air compressor is attached to the nebulizer. The Wright Face & Tracheostomy Nebulizing Mask is indicated for patients with traumatic brain injury, spinal cord injuries, gunshot chest/head and neck wounds, burns, paralysis and etc. According to the requester, there is no similar humidification delivery system. Other humidification masks are not systems, but individual masks that are used independently of one another. They are stand-alone masks that moisturize the immediate area they were designed to address. Currently, two separate Aerosol masks are used (one for the tracheostomy, the other for the nose/mouth) for humidification treatment. The Wright Mask combines the mechanism of operation of both conventional masks; and its function of simultaneous moisturizing is unlike the function of any other masks. According to the applicant, the "Wright Mask delivery system's therapeutic distinction is that it simultaneously humidifies the nose, mouth, sinus cavity, throat and tracheostomy thus treatment is carried out in half the time of conventional aerosol masks, while using half the medication of the conventional aerosol facemask and tracheostomy masks." The convenience of use of the Wright Mask encourages patient compliance. Existing codes A7015 "NEBULIZER AEROSOL MASK", K0533 COMBINATION ORAL/NASAL MASK," A4621 "TRACHEOSTOMY MASK OR COLLAR" and/or K0180 "AEROSOL MASK," are inadequate as these codes describe individual products and not the entire Wright Mask system.

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. Existing code A9999 "MISCELLANEOUS DME SUPPLY OR ACCESSORY, NOT OTHERWISE SPECIFIED" is available for assignment by all payers, if they deem appropriate, to identify the Wright Face Mask. 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. CMS would be happy to review a subsequent application when the Wright Face Mask has been sold on the U.S. Market and there is an experience base that can be considered when formulating a coding decision.

Medicare Payment:

The payment rules associated with the existing code apply to this product if covered.

Pricing = 46

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with the Workgroup's preliminary decision. The speaker claimed that the Wright Face & Teacheostomy Nebulizing Mask simultaneously humidifies upper airway and tracheostomy and encourages treatment compliance. Also, the speaker reported that this all-in-one upper and lower airway humidification delivery system may reduce other potentially preventable complications and thereby reduce hospital re-admissions and create healthier patients. The speaker stated that other devices are separately coded and requested the establishment of a unique code to enable appropriate reimbursement for this item.

HCPCS Public Meeting Agenda Item #2

June 8, 2010

Attachment# 10.105

Topic/Issue:

Request to establish 2 codes: (1) one code for a nebulizer system for use with a specific drug, trade name: Altera Nebulizer System. Applicant's suggested language: Exxxx "Electric aerosol nebulizer system with perforated, vibrating membrane and aerosol holding chamber with valves cleared for use only with specific drugs; including administration handset; and 2) one code for a handset for use with this nebulizer system, trade name: Altera handset. Applicant's suggested language: Axxxx "Nebulizer administration handset with perforated, vibrating membrane and aerosol holding chamber with valves for Exxxx used only to administer aztreonam for inhalation solution"

Background/Discussion:

According to the requester, Altera is a nebulizer system that is designed specifically to deliver aztreonam solution for inhalation. It is indicated for the treatment of Pseudomonas aeruginosa infection complicating chronic pulmonary disease in patients with Cystic Fibrosis (CF) and bronchiectasis. The durable component of Altera is a platform consisting of the controller, nebulizer connection cord, and AC power supply. The handset is a vibrating, perforated membrane and an aerosol holding chamber with 2 one-way valves. It generates an aerosol cloud of specific particle sizes with narrow variance. The cloud passes into the aerosol holding chamber where it accumulates pending the next inhalation. Aerosol holding chambers and valves are designed with flow dynamics to deliver in aerosolized drug bolus with normal breathing. This combination delivers a specific and consistent dose of drug which is retained in the lung, called the respirable dose. When additional drugs are made available for the eFlow Technology devices, the starter kit will have the same platform, but the handset will be specific to the new drug. According to the requester, current nebulizer codes do not accurately describe the platform or handset because the nebulizers specified under existing codes will not meet the specifications of the Altera System or the FDA label requirements for AZLI. Specifically, code E0570 "NEBULIZER, WITH COMPRESSOR" describes a nebulizer with compressor. Altera does not use a compressor. Code E0574 "ULTRASONIC/ELECTRONIC AEROSOL GENERATOR WITH SMALL VOLUME NEBULIZER" is not appropriate because the “Altera is not ultrasonic”. Code K0730 "CONTROLLED DOSE INHALATION DRUG DELIVERY SYSTEM" is not appropriate because (the applicant believes) this code is specifically for use to identify a nebulizer used with Iloprost.

CMS HCPCS Preliminary Decision:

Existing code E0574 "ULTRASONIC/ELECTRONIC AEROSOL GENERATOR WITH SMALL VOLUME NEBULIZER" 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 if covered.

Pricing = 36

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with the Workgroup's preliminary decision and claimed there is a significant therapeutic distinction for Altera® compared to current products described by HCPCS code E0574. Specifically, Altera was approved by the FDA with the indication to be used only with the inhalation drug Cayston®, and that the FDA approved the use of Cayston® only via Altera® and not any general purpose nebulizer that are currently reported with HCPCS code E0574 or E0570 . Further, the speaker clarified that the Altera® Nebulizer System has not been approved by the FDA for any other drug, nor is it indicated as a general purpose nebulizer. The speaker also stated that the Workgroup has already established a drug-specific nebulizer HCPCS code, specifically K0730 (Controlled dose inhalation drug delivery system), that is used to report I-neb for inhalation of Iloprost. The speaker recommended the Workgroup either create a new code for each drug-specific nebulizer, except for I-neb for Iloprost, or establish a new code for all drug-specific nebulizers.

HCPCS Public Meeting Agenda Item# 3

June 8, 2010

Attachment# **10.005B**

Topic/Issue:

Request to establish 3 "J" codes: 1 for the Tyvaso Inhalation System Starter Kit, 1 for the Tyvaso Inhalation System Refill Kit, and 1 for the 4-pack short-term refill kit. Applicant's suggested language:
XXXX1 "Treprostinil, inhalation solution, 48.72 mg, with inhalation systems and accessories;"
XXXX2 "Treprostinil, inhalation solution, 48.72 mg, with accessories;"
XXXX3 "Treprostinil, inhalation solution, 6.96 mg"

Note: The Optineb-ir nebulizer and accessories component of this application is discussed in Request #10.005B, and the preliminary coding decision for the system appears in this agenda. The (Tyvaso) drug component of this application is discussed in Request #10.005A. The preliminary decision that correlates with Request #10.005A was posted in the May 4, 2010 Drugs, Biologicals, and Radiopharmaceuticals HCPCS Public Meeting Agenda.

Background/Discussion:

According to the requester, Tyvaso (treprostinil) inhalation solution is a prostacyclin analogue indicated for the treatment of pulmonary arterial hypertension (WHO Group I) in patients with NYHA Class III symptoms, to increase walk distance. The major pharmacologic actions of treprostinil are direct vasodilation of pulmonary and systemic arterial vascular beds and inhibition of platelet aggregation. Initial dosage of Tyvaso is 3 breaths (6 mcg of treprostinil delivered per breath) per treatment session, with the dose increasing by an additional 3 breaths at approximately 1-2 week intervals up to the target maintenance dosage of 9 breaths per treatment session as tolerated.

Treprostinil inhalation solution is cleared by the FDA in combination with the Tyvaso inhalation system Optineb-ir Model On-100/7, an ultrasonic, pulsed-delivery inhalation system. Treprostinil is administered in four separate treatment sessions each day. Only one ampule of treprostinil is required to deliver the four daily treatment sessions. Treprostinil inhalation solution is supplied in 2.9 ml ampules, packaged as four ampules in a foil pouch. Each 2.9 mL contains 1.74 mg treprostinil (a concentration of 0.6 mg/ml).

Tyvaso is supplied as three different products:

NDC 66302-206-01: Tyvaso inhalation system starter kit, which contains a carton of 28 ampules (1 month supply) of treprostinil; two Tyvaso inhalation systems (the second system provides back-up capacity); and disposable supplies [(1) Tyvaso inhalation system instruction manual, (1) tyvaso inhalation system warranty card, [((2) sets of dome assembly, inhalation piece, mouthpiece, and 2 filter shells), (32) medicine cups, (65) filters, (1) measuring cup, (1) nose clip, (2) plugs for storage between treatments, (2) AC wall plugs, (1) rechargeable battery, (1) 12V DC car adaptor, (1) storage box, (1) carrying case.]

NDC 66302-206-02: Tyvaso inhalation system refill kit, which contains a carton of 28 ampules (1 month supply) of treprostinil and disposable supplies [((1) set of dome assembly, inhalation piece, mouthpiece, and 2 filter shells), (32) medicine cups, (65) filters, (2) plugs for storage between treatment sessions.]

NDC 66302-206-03: A 4-pack short-term refill kit that contains four ampules of treprostinil that is intended for inpatient use.

According to the requester, the Optineb-ir Model ON-100/7 is an ultrasonic, pulsed-delivery inhalation system device intended for single patient use in the administration of Treprostinil for inhalation. The Optineb-ir operates ultrasonically by energizing a piezoelectric transducer at 2.4 MHz. This action collimates distilled water stored in the water reservoir ergizing liquid medicine stored in the medicine cup creating an aerosol above the liquid medicine and appears as a cloud. The proprietary dome (with baffle) is designed to control the size of the particles that are emitted from the device. The Optineb's software controls the aerolization process to occur during expiration and then responds by providing visual and audible signals to the patient requiring the patient to inhale the vapor. Optineb-ir is available only as a part of the Tyvaso Inhalation System Starter Kit and is not sold separately. The starter kit contains two nebulizers, one of which is a back-up n case nebulizer #1 fails or breaks. Depending on the source of a problem, it may be replaced under warranty. Replacement nebulizers not under warranty can only be obtained by purchasing a Tyvaso starter kit. Optineb-ir is designed for repeated uses for up to two years. According to the requester, use of the Optineb-ir with other products is unknown since this device has not been studied with other drugs. As such, use of Optineb-ir Model ON-100/7 with a drug other than treprostinil would be an off-label use.

According to the requester, nebulizers described by HCPCS codes E0570 NEBULIZER, WITH COMPRESSOR, E0580 NEBULIZER, DURABLE, GLASS OR AUTOCLAVABLE PLASTIC, BOTTLE TYPE, FOR USE WITH REGULATOR OR FLOWMETER and E0585 NEBULIZER, WITH COMPRESSOR AND HEATER are not ultrasonic nebulizers and therefore do not describe the Optineb-ir Model ON-100/7 nebulizer. HCPCS codes E0574 ULTRASONIC/ELECTRONIC AEROSOL GENERATOR WITH SMALL VOLUME

NEBULIZER and E0575 NEBULIZER, ULTRASONIC, LARGE VOLUME, although described as ultrasonic nebulizers, are not "controlled dose inhalation delivery systems" (K0730). The Optineb uses a baffle plate to determine the particle size of the aerosol. The design that includes the baffle inside a dome is unique to the Optineb-ir Model ON 100/7, and makes this system different from other controlled dose inhalers coded at K0730. While traditional nebulizers generate droplets in a wide range of sizes, the Optineb technology generates droplets that are "monodisperse" and the particles are almost all the same size. There are no specific HCPCS codes for the three Tyvaso products.

CMS HCPCS Preliminary Decision:

1) Existing code E0574 "ULTRASONIC/ELECTRONIC AEROSOL GENERATOR WITH SMALL VOLUME NEBULIZER" adequately describes the nebulizer that is the subject of this request, including the battery and wall plug.
2) Existing code A7016 “DOME AND MOUTHPIECE, USED WITH SMALL VOLUME ULTRASONIC NEBULIZER” adequately describes the inhaler/mouthpiece portion of the handset, and dome.
3) Revise existing code A7013 which currently reads: FILTER, DISPOSABLE, USED WITH AEROSOL COMPRESSOR to instead read “FILTER, DISPOSABLE, USED WITH AEROSOL COMPRESSOR OR ULTRASONIC GENERATOR”. Revised code A7013 adequately describes the filters.
4) A national program operating need to establish separate HCPCS codes for the filter shell, medicine cups, measuring cups, nose clip, plugs for storage, car adapter, and storage and carrying cases was not identified by Medicare, Medicaid or the Private Insurance sector.

Medicare Payment:

The payment rules associated with the existing codes apply to these products if covered.

For E0574, Pricing = 36

For A7016, Pricing = 32

For A7013, Pricing = 32

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker supported the Workgroup’s preliminary coding decision but expressed concern about the consequences of the preliminary Medicare payment decision. Specifically, the speaker believed that the most appropriate payment category for the nebulizer should be payment category number 32 (Inexpensive and Other Routinely Purchased Items), rather than payment category number 36 (Capped Rental Items). The speaker stated that if a change to the payment category from number 36 to 32 is approved, the coding would be adequate to permit the use of

the category for the nebulizer. If the change in payment category cannot be accommodated using the code E0574, then separate coding maybe needed.

HCPCS Public Meeting Agenda Item #4

June 8, 2010

Attachment# 10.107

Topic/Issue:

Request to distinguish "standard" head rest devices that merely provide a place for resting the head from devices that provide the same type of support, but can accommodate additional pads for intimate head support, including lateral facial, lateral neck or forehead. Applicant's suggested language: "Wheelchair accessory, posterior adjustable head support, contoured, cushioned, single pad with adjustable, detachable hardware."

Background/Discussion:

According to the requester, the Whitmyer Biomechanix Plush and Contour Cradle line of head support pads combined with the appropriate hardware provide head support for individuals with little or no voluntary head movement. They are designed to prevent the patient's head from falling posterior or to the side. These products provide a contoured and angle adjustable pad that specifically meets the contour of an individual's head to provide upright positioning of the head and to provide lateral support. The dimensions are routinely determined by the ATP during a technology assessment; however, the pad has a minimal depth of contour of 25mm. These products also have a minimum of 0.5" of a conforming or pressure relieving material when measured at the thinnest point of the midline of the pad. They utilize a structural base made of steel, aluminum, plastic or plywood that supports the padding and has a means of attaching the pad to the hardware. They are upholstered/covered or coated with a neoprene, lycra or vinyl. The hardware for mounting this support is adjustable in height, depth and angle, and provides a means for detachment without the use of tools. An adjustable pad with a contour can be positioned at the suboccipital shelf to provide support and lift for the weight of the head as the patient does not have the muscle control to accomplish this independently. These head supports are intended to be used by patients with muscle weakness or who fatigue rapidly and cannot support their own head during the normal use of a wheelchair. According to the requester, existing code E0955 "WHEELCHAIR ACCESSORY, HEADREST, CUSHIONED, ANY TYPE, INCLUDING FIXED MOUNTING HARDWARE, EACH" does not adequately describe these products because it groups technologically disparate products, and the associated fee does not reflect the cost of adjustable head support. The requester is seeking to differentiate "Standard DME" from "Complex Rehab Technology" via HCPCS coding and comments that the lack of such segmentation negatively impacts manufacturers, patients and payers; stifles innovation; and has “caused suppliers and payers to develop schemes to work around the HCPCS code set”.

CMS HCPCS Preliminary Decision:

Existing code E0955 "WHEELCHAIR ACCESSORY, HEADREST, CUSHIONED, ANY TYPE, INCLUDING FIXED MOUNTING HARDWARE, EACH" adequately describes the product that is the subject of this request.

Medicare Payment:

The payment rules associated with the existing code applies to this product if covered.

Pricing = 32

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with the Workgroup's preliminary decision and indicated that HCPCS code E0955 describes head supports and not headrests. The speaker listed the differences between headrests and head supports. In particular, headrests are single pads that require vertical or no adjustment, whereas head supports require multiple pad systems and require either vertical, horizontal, or multiple angle adjustments that must be specific to the user. In addition, the speaker believed that the words "any type" in the HCPCS code descriptor for E0955 is inclusive and therefore inadequate. The speaker claimed that the terms "any type" sets several limitations, including access to more complex technologies, inappropriate reimbursement, inability for competitive bidding, and hinder payers ability to develop coverage policies that acknowledge technological differences and clinical application. The speaker urged the Workgroup to reconsider its decision. Alternatively, if the Workgroup is unable to establish a new HCPCS code, the speaker recommended a change to the descriptor for HCPCS code E0955 by adding the terms "single pad" and suggested the long descriptor to read "WHEELCHAIR ACCESORY, SINGLE PAD HEADREST, CUSHIONED, ANY TYPE, INCLUDING FIXED MOUNTING HARDWARE, EACH."

HCPCS Public Meeting Agenda Item #5

June 8, 2010

Attachment# 10.054

Topic/Issue:

Request for a new HCPCS code to identify an integrated, ergonomic wheelchair handrim assembly, trade name: Natural Fit. Applicant's Suggested Language: Exxxx"Manual wheelchair accessory, integrated two-piece handrim system; contoured thumb slot and contoured oval and multi-friction surfaces."

Background/Discussion:

According to the Requester, the Natural-Fit is ergonomically designed to relieve stress on the hands and wrist during the repetitive strain of manual wheelchair propulsion, and to reduce pain associated with Carpal Tunnel Syndrome (CTS). The Natural-Fit is an "assembly" because it has two separately coated components, a smooth oval surface for the palm of the hand and a higher friction contoured slot for the thumb. The assembly of these two components creates an ergonomic grip for the hand and provides separate surfaces for propulsion and braking. The Natural-Fit allows the user to brake without having to tightly grip or "pinch" the Natural-fit. The enlarged overall surface area removes the need to push on wheelchair tires. The high friction coating surface only on the contoured component for propulsion enhances propulsion efficiency and reduces the gripping force necessary for propulsion. Reduced stress through increased propulsion efficiency and lower grip forces relieves pain associated with carpal tunnel syndrome. According to the requester, existing code E2205 MANUAL WHEELCHAIR ACCESSORY, HANDRIM WITHOUT PROJECTIONS (INCLUDES ERGONOMIC OR CONTOURED), ANY TYPE, REPLACEMENT ONLY, EACH (to which the words "ergonomic and contoured" have been added), is insufficient to cover the unique features, functions, and manufacturing process of the Natural Fit handrim. Inclusion of the Natural-Fit under the E2205 code ignores 1) "the needs of wheelchair users experiencing CTS-related hand and wrist pain not addressed by standard hand rims"; 2) research "demonstrating the importance of ergonomics in the management and treatment of CTS"; 3) " the importance of ergonomics in the management of upper limb pain and injury; and 4) direct, published evidence documenting the therapeutic benefits of the Natural Fit as compared with standard E2205 handrims. It also denies access to Medicare beneficiaries experiencing upper limb pain who would benefit from a

"non-invasive, inexpensive treatment option (in contrast to surgery or a power chair) for treating their pain."

CMS HCPCS Preliminary Decision:

Existing code E2205 "MANUAL WHEELCHAIR ACCESSORY, HANDRIM WITHOUT PROJECTIONS (INCLUDES ERGONOMIC OR CONTOURED), ANY TYPE, REPLACEMENT ONLY, EACH" 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 if covered.

Pricing = 32

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item but written comments were submitted to the Workgroup. The commenter disagreed with the Workgroup's preliminary decision because E2205 does not adequately describe Natural-Fit The commenter indicated that HCPCS code E2205, which describes both standard round-tube handrims and ergonomic/contoured handrims, such as the Natural-Fit, puts dissimilar items into the same category. The commenter suggested that the Natural-Fit is technologically and therapeutically different from the existing products currently described with HCPCS code E2205. Further, the commenter argued that placing dissimilar items in the same HCPCS code defeats the purpose of the coding system and make appropriate pricing for the HCPCS code impossible. The primary speaker recommended the establishment of a new E-code to appropriately describe Natural-Fit, and proposed the long descriptor to read "MANUAL WHEELCHAIR ACCESSORY, INTEGRATED TWO-PIECE HANDRIM SYSTEM; CONTOURED THUMB SLOT AND CONTOURED OVAL AND MULTI-FRICTION SURFACES."

HCPCS Public Meeting Agenda Item #6

June 8, 2010

Attachment# 10.047

Topic/Issue:

Request to separate 2-point and 4-point padded, adjustable positioning belts from existing code E0978 by establishing 2 new codes to identify positioning belts, and omitting the words "positioning belt" from the text of existing code E0978. Requester's suggested language: revise existing code with currently reads: WHEELCHAIR ACCESSORY, POSITIONING BELT/SAFETY BELT/PELVIC STRAP, EACH to instead read: "Wheelchair accessory, general use safety belt/pelvic strap, each." Establish 2 new codes: Exxx1 Wheelchair accessory, padded, two-point positioning belt, any buckle, with angle and length-adjustable hardware; and Exxx2 Wheelchair accessory, padded, four-point positioning belt, any buckle, with angle and length-adjustable hardware.

Background/Discussion:

According to the Requester, a pelvic positioning belt is designed to be placed anterior to the pelvis as a part of a wheelchair seating system to maintain the pelvis in an anatomically correct posture and to provide client stability and allow isolated movement of distal extremities for increased function. By maintaining upright, neutral seated postures, positioning belts are also used to improve respiration, digestion and other organ functions. Pelvic positioning belts are indicated for clients with decreased muscle strength or paralysis and for muscular dystrophy, spinal cord injury, multiple sclerosis and ALS. According to the requester, a distinction should be made between automobile style safety straps and medically necessary positioning belts, and the language of existing code E0978 does not reflect the complexity of a true wheelchair positioning device as it is applied in complex rehab. The Requester claims that there are substantial differences in features, function and price between an unpadded safety belts and 2- or 4-point padded belts, and that the 2-point and 4-point padded belts are currently identified on claims using codes E0978 "WHEELCHAIR ACCESSORY, POSITIONING BELT/SAFETY BELT/PELVIC STRAP, EACH", E0944 “PELVIC BELT/HARNESS/BOOT” and K0108 “WHEELCHAIR COMPONENT OR ACCESSORY, NOT OTHERWISE SPECIFIED”.

CMS HCPCS Preliminary Decision:

A national program operating need to distinguish 2 and 4-point positioning belts from other belts currently coded E0978 was not identified by Medicare, Medicaid and private insurers. Existing code E0978 "WHEELCHAIR ACCESSORY, POSITIONING BELT/SAFETY BELT/PELVIC STRAP, EACH" adequately describes the products that are the subject of this request.

Medicare Payment:

The payment rules associated with the existing code apply to this product if covered.

Pricing = 32

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with the Workgroup's preliminary decision and reiterated the need to separately identify safety belt/pelvic straps from positioning belts. The speaker stated that positioning belts differ significantly from safety belts/pelvic straps in therapeutic applications and functional needs. Safety belts/pelvic straps are used in short term post-surgeries and prevent users from falling out of wheelchairs, whereas positioning belts are used to maintain pelvic position in wheelchairs and come in 2-point or 4-point styles. The speaker outlined the need to modify HCPCS code E0978 and proposed three options to address the issues with the current HCPCS code.

HCPCS Public Meeting Agenda Item #7

June 8, 2010

Attachment# 10.109

Topic/Issue:

Request to establish 2 codes for an upgraded proportional remote joystick, trade names: Q-Logic Joystick & Remote+ Joystick. Applicant's suggested language: XXXX1 "Power wheelchair accessory, hand control interface, upgraded proportional remote joystick (not including expandable controller), proportional, including fixed mounting hardware;" and XXXX2 "Power wheelchair accessory, hand control interface, upgraded proportional remote joystick (not including expandable controller), proportional, including fixed mounting hardware, replacement only."

Background/Discussion:

According to the requester, an upgraded proportional remote joystick offers actuator control for 3 or more power options and can transition to secondary input devices with plug and play interfacing and minimal expense. This remote also offers exponentially more programmability for individuals with disabilities to create the best opportunity for success in gaining independence through power mobility. An upgraded proportional joystick, working in combination with an expandable controller, will allow the user to operate a combination of medically necessary power seating. The upgraded proportional remote joystick can be programmed to operate with a low deflection force and/or limited excursion. It can also be programmed for alternative directions such that movement of the gimble to the left could direct the power module to drive the chair forward via the communication from the expandable controller to the motors via the wire harness. In addition, the upgraded proportional remote joystick can allow for the operation of other necessary devices, such as augmentative and alternative communication systems, electronic aids to daily living and/or a computer. According to the requester, existing codes E2377 "POWER WHEELCHAIR ACCESSORY, EXPANDABLE CONTROLLER, INCLUDING ALL RELATED ELECTRONICS AND MOUNTING HARDWARE, UPGRADE PROVIDED AT INITIAL ISSUE" and E2313 "POWER WHEELCHAIR ACCESSORY, HARNESS FOR UPGRADE TO EXPANDABLE CONTROLLER, INCLUDING ALL FASTENERS, CONNECTORS AND MOUNTING HARDWARE, EACH" do not describe these devices because the products currently coded in these code categories are not expandable controllers or wiring harnesses. The Q-Logic Joystick

and Remote is similar in function to other drive input devices but is not accurately described by the HCPCS codes for these devices.

CMS HCPCS Preliminary Decision:

Existing code E2377 "POWER WHEELCHAIR ACCESSORY, EXPANDABLE CONTROLLER, INCLUDING ALL RELATED ELECTRONICS AND MOUNTING HARDWARE, UPGRADE PROVIDED AT INITIAL ISSUE" together with E2313 "POWER WHEELCHAIR ACCESSORY, HARNESS FOR UPGRADE TO EXPANDABLE CONTROLLER, INCLUDING ALL FASTENERS, CONNECTORS AND MOUNTING HARDWARE, EACH" describes the entire system on initial issue. Existing code E2376 "POWER WHEELCHAIR ACCESSORY, EXPANDABLE CONTROLLER, INCLUDING ALL RELATED ELECTRONICS AND MOUNTING HARDWARE, REPLACEMENT ONLY" together with E2313 describes a replacement system. Existing code E2376 alone describes a replacement controller. Existing code E2313 plus the KC modifier "REPLACEMENT OF SPECIAL POWER WHEELCHAIR INTERFACE" describes a replacement harness.

Medicare Payment:

The payment rules associated with the existing codes apply to this product if covered.

Pricing = 32

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with the Workgroup's preliminary decision that the entire system on initial issue is described by HCPCS codes E2377 and E2313; however, the speaker agreed that the replacement harness is described by existing HCPCS codes E2376 and E2313 when reported with a KC modifier. In addition, the speaker indicated that separate HCPCS codes are still needed to accurately describe the joystick for initial issue and for replacement. Specifically, the speaker requested the establishment of two new HCPCS: one to describe an upgraded/expandable, proportional remote joystick at initial issue, and another as a replacement. The speaker clarified that a complete system consists of multiple components. A complete system may include either a controller with harness and a joystick, or a controller with harness, and a specialty control device. The speaker noted that current HCPCS code exists for the controller, harness, and the specialty control device, but not for the joystick. The speaker stated that the establishment of new HCPCS codes for the joystick would ensure uniform reporting for the product and allow for meaningful data collection.

HCPCS Public Meeting Agenda Item #8

June 8, 2010

Attachment# 10.124

Topic/Issue:

Request to establish a code for Merino Wool Skin Protection Wheelchair Seat Cushion.

Background/Discussion:

According to the requester, the Merino Wool Skin Protection Wheelchair Seat Cushion is a 100% wool cushion intended to reduce pressure on the skin over a bony prominence, to reduce the likelihood of decubitus ulcer development. The cushion is made of 3 layers (2 layers of sheepskin and a middle layer of "hypoallergenic pressure reduction material." It measures 35" x 20" and includes seat and back. It is used by wheelchair bound patients, patients with pressure ulcers, patients with allergies, and patients with temperature instability. Millions of wool fibers create free air flow under entire surface of contact with skin, which protects skin of the patient. It contains lanolin, the natural antiseptic and antibacterial agent. The wool protects from electricity and is the only product that does not contain the dust mites that cause allergies.

CMS HCPCS Preliminary Decision:

A national program operating need to establish a code to identify 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:

Payment for any covered items will be based on the carrier's individual consideration of the claim since no specific code or fee schedule has been established for this item.

Summary of Primary Speaker Comments at the Public Meeting:

No primary speaker for this item.

HCPCS Public Meeting Agenda Item #8

June 8, 2010

Attachment# 10.131

Topic/Issue:

Request to establish a code for a positioning wheelchair back cushion.

Background/Discussion:

According to the requester, the positioning wheelchair back cushion is intended to reduce pressure on the skin over a bony prominence to reduce the likelihood of the development of decubitus ulcers. The 30"x30" cushion consists of a hypoallergenic insert, and a pillow cover made of 100% Merino wool. The pillow size is suitable for a standard and oversized wheelchair. The cushion keeps the body in the upright position and was specifically designed for patients with significant postural asymmetries. It is useful for bed bound patients, patients with pressure ulcers, patients with allergies, and patients with temperature instability. 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 to identify 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:

Payment for any covered items will be based on the carrier's individual consideration of the claim since no specific code or fee schedule has been established for this item.

Summary of Primary Speaker Comments at the Public Meeting:

No primary speaker for this item.

HCPCS Public Meeting Agenda Item #8

June 8, 2010

Attachment# 10.123

Topic/Issue:

Request to establish a code for an orthopedic mattress, trade name: Bauer Comfort Orthopedic Mattress.

Background/Discussion:

According to the requester, the Bauer Comfort Orthopedic Mattress is a device intended to reduce pressure on the skin over a bony prominence to reduce the likelihood of decubitus ulcer development. The mattress is made from latex and the latex layers are surrounded by wool material, which is hypoallergenic and provides additional cushioning. The latex has special openings for ventilation of the body. Latex foam conforms instantly to each contour of the body for outstanding pressure relief and orthopedic support. This alleviates pressure and helps bring nutrients and much needed oxygen to muscles, so that the patient can awake feeling rejuvenated. The mattress also helps to support the body in natural physiological position during the sleep, and it flexes to meet any hospital bed position. It arrives in a special vacuum package in shrink roll form and takes 48 hours to absorb the air and be ready for use. According to the requester, existing codes do not describe this mattress because it has 7 pressure zones, which makes it Orthopedic. The mattress is available in different sizes for standard and hospital beds.

CMS HCPCS Preliminary Decision:

Existing code E0184 "DRY PRESSURE MATTRESS" 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 if covered.

Pricing = 32

Summary of Primary Speaker Comments at the Public Meeting:

No primary speaker for this item.

HCPCS Public Meeting Agenda Item #8

June 8, 2010

Attachment# 10.125

Topic/Issue:

Request to establish a code for a merino wool mattress cover with padding.

Background/Discussion:

According to the requester, the merino wool mattress cover with padding is a device intended to reduce pressure on the skin over a bony prominence to reduce the likelihood of the patient developing decubitus ulcers. The mattress cover is a support surface designed for bed bound patients, patients who are completely immobile, patients with limited mobility and patients with impaired nutritional status, altered sensory perception and compromised circulatory status. This mattress cover is also useful for prevention of chronic anxiety and sleep disturbance. It is made of 100% merino wool and has adjustable straps. It consists of 3 layers: the upper layer is 100% merino wool, the middle layer is wool felt and the third layer is flannel. The upper layer helps to reduce the pressure on bony prominence; the middle layer adds a cushion to help reduce the pressure; and the third layer protects from the particles of dust from the mattress. The millions of fibers from the wool help the whole body to breathe. It also massages the entire body and protects from static electricity. This mattress cover is available in different sizes for standard and hospital beds. According to the requester, this mattress overlay exceeds the benefits of mattress pads made of other materials that are billed using existing codes, because this overlay offers an ecologically clean, natural product that prevents pressure ulcers.

CMS HCPCS Preliminary Decision:

Existing code E0189 "LAMBSWOOL SHEEPSKIN PAD, ANY SIZE" adequately describe the product that is the subject of this request.

Medicare Payment:

The payment rules associated with the existing code apply to this product if covered.

Pricing = 32

Summary of Primary Speaker Comments at the Public Meeting:

No primary speaker for this item.

HCPCS Public Meeting Agenda Item #8

June 8, 2010

Attachment# 10.132

Topic/Issue:

Request to establish a code to identify multipurpose sheep skin.

Background/Discussion:

According to the requester, this multipurpose sheep skin product (40"x24") is intended to reduce pressure on the skin over a bony prominence to reduce the likelihood of the development of decubitus ulcers. It is made of 100% merino wool. The millions of fibers from the wool help the whole body to breathe, massage the body, and protect the body from static electricity. Multipurpose sheep skin is useful for bed bound patients, patients with pressure ulcers, patients with allergies, patients with temperature instability, asthma patients, and patients with COPD. According to the requester, there are no existing codes to describe this product.

CMS HCPCS Preliminary Decision:

Existing code E0189 "LAMBSWOOL SHEEPSKIN PAD, ANY SIZE" 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 if covered.
Pricing = 32

Summary of Primary Speaker Comments at the Public Meeting:

No primary speaker for this item.

HCPCS Public Meeting Agenda Item #9

June 8, 2010

Attachment# 10.102

Topic/Issue:

Request to establish a code for a dynamic splinting device, trade name: Hallux Varus/Valgus Dynaspint® (HVD) System. Applicant's suggested language: "Dynamic adjustable toe varus or valgus (medial or lateral) stretching device includes soft interface material."

Background/Discussion:

According to the requester, the HVD is a dynamic splinting device designed to restore proper alignment and range of motion in a patient's hallux (big toe) that is affected by either a varus (medial) or valgus (lateral) deformity (Hallux Varus or Hallux Valgus). It applies the total end range time (TERT) principle that there is a direct correlation between the amount of time that a joint spends at its end range of motion and subsequent gains in that joint's end range of motion. The HVD includes a strut that contains an adjustable spring-loaded tensioning system that allows the device to stretch the metatarsophalangeal joint (MPJ) to its end range of motion 100% of the time that a patient is at rest. The patient easily dons and doffs the HVD by opening two straps, placing the device on the intended joint and then closing the straps around the foot. When worn it applies a low-load, prolonged duration stretch (LLPS) to the MPJ. The LLPS permanently lengthens the connective tissue surrounding the joint, thus moving the hallux back into correct alignment and eliminating the deformity. The HVD is commonly worn three times per day for up to an hour during each treatment session. The HVD is constructed of a stainless steel strut, a thermoplastic toe piece, and straps. According to the requester, codes that identify similar dynamic splinting devices are in the E1800 - E1840 range. This request is to establish a similar code to specifically identify a dynamic splinting device intended for the treatment of the MPJ by stretching the toe medially and laterally, depending upon the patient's condition.

CMS HCPCS Preliminary Decision:

Existing code E1830 "DYNAMIC ADJUSTABLE TOE EXTENSION/FLEXION DEVICE, INCLUDES SOFT INTERFACE MATERIAL" 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 if covered.

Pricing = 36

Summary of Primary Speaker Comments at the Public Meeting:

No primary speaker for this item.

HCPCS Public Meeting Agenda Item #9

June 8, 2010

Attachment# 10.103

Topic/Issue:

Request to establish a code for a dynamic splinting device designed to treat carpal tunnel syndrome (CTS), trade name: Carpal Tunnel Dynasplint® System (CTD). Applicant's suggested language: "Dynamic adjustable carpal tunnel stretching device."

Background/Discussion:

According to the requester, the CTD is a dynamic splinting device designed to treat carpal tunnel syndrome. The CTD applies a dynamic low-load, prolonged duration stretch to the carpal tunnel in order to stretch the transverse carpal ligament and other connective tissue surrounding the carpal tunnel. The applied stretch permanently lengthens the tissue, eliminating the compression of the median nerve within the carpal tunnel. The internal tensioning system of the CTD is comprised of multiple components which work in unison to deliver a fully reproducible dynamic tension which can be adjusted by the patient to enable them to comfortably advance throughout their therapeutic process. The CTD is bio-mechanically designed to be highly adjustable and fit a wide variety of hand sizes and accommodate unique hand characteristics. CTD is indicated for: 1) early intervention for patients who have been diagnosed with light to moderate CTS; 2) patients who do not want injections or have had reoccurrences after injection; 3) patients who do not want to have surgery; and 4) patients who are not surgical candidates. The CTD is constructed of stainless steel. According to the requester, there are no other dynamic splinting devices on the market for the treatment of CTS and there is no code to describe such a device.

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:

Payment for any covered items will be based on the carrier's individual consideration of the claim since no specific code or fee schedule has been established for this item.

Summary of Primary Speaker Comments at the Public Meeting:

No primary speaker for this item.

HCPCS Public Meeting Agenda Item #10

June 8, 2010

Attachment# 10.104

Topic/Issue:

Request to establish a unique code to describe a portable knee extension device, trade name: Elite Seat. Applicant's suggested language: "Terminal-extension knee device: non-custom, supine, portable, patient controlled ratcheted tension knee device that is designed to restore terminal-extension."

Background/Discussion:

According to the requester, Elite Seat is a portable, non-custom, patient controlled, ratcheted tension knee device that provides a progressive stretch above and below the knee joint to allow complete relaxation of the hamstring muscle. The Elite Seat is designed to stretch the knee joint to its normal state of HYPER-extension. This rehabilitation device can be used for non-operative and pre/post operative indications. It is specifically used to treat any and all knee injuries that result in a loss of normal or full terminal extension. Elite Seat is portable and can easily be used by a patient in a clinical setting or at home. It is also exclusively "patient controlled" which allows the patient to be in control of their own rehabilitation processes thus eliminating the added expense associated with a nurse or physical therapist. Elite Seat is used 3 to 5 times per day for a period of 10 minutes each session. This device is designed to replace serial casting; Arthroscopy and scar resection; and manual manipulation under anesthesia. It is indicated for patients with joint stiffness and loss of full, terminal extension due to osteoarthritis, Arthrofibrosis, Total Knee Arthroplasty (pre- and post-operatively), acute knee ligament injury, and post-op ACL reconstruction. The requester claims a significant functional and therapeutic distinction offered by the Elite Seat as compared to other products coded at E1811 STATIC PROGRESSIVE STRETCH KNEE DEVICE, EXTESNION AND/OR FLEXION, WITH OR WITHOUT RANGE OF MOTION ADJUSTMENT, INCLUDES ALL COMPONENTS AND ACCESSORIES". Specifically, only the Elite Seat is intended to and able to restore terminal-extension, whereas the intended use of other products is "to work toward" increasing extension. Elite Seat, on the other hand, is used to obtain the critical goal of achieving terminal-extension and to treat the underlying pathology of full terminal extension loss.

CMS HCPCS Preliminary Decision:

Existing code E1811 "STATIC PROGRESSIVE STRETCH KNEE DEVICE, EXTENSION AND/OR FLEXION, WITH OR WITHOUT RANGE OF MOTION ADJUSTMENT, INCLUDES ALL COMPONENTS AND ACCESSORIES" adequately describes this product.

Medicare Payment:

The payment rules associated with the existing code apply to this product if covered.

Pricing = 36

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with the Workgroup's preliminary decision and reiterated the need for a unique code for Elite Seat. The applicant claimed (1) a functional difference in structure and style usage, (2) therapeutic distinction that Elite Seat has seven indications whereas other similar products have no indications, and (3) Elite Seat will save Medicare billions of dollars in unnecessary knee replacement surgeries.

HCPCS Public Meeting Agenda Item #11

June 8, 2010

Attachment#10.098

Topic/Issue:

Request to establish a code for a knee/ankle flexionater, trade name: Knee/Ankle Flexionater. Applicant's suggested language: "High intensity, patient actuated serial stretch knee/ankle machine, variable load/variable position, patient controlled, with hydraulic pump".

Background/Discussion:

According to the requester, the ERMI knee/ankle flexionater is a self-contained machine that facilitates and accelerates recovery from decreased range of motion of the knee and/or ankle joints. It is designed to address the needs of patients with arthrofibrosis, a complication of surgery where an excessive scar tissue response leads to painful restriction of knee flexion and/or ankle dorsiflexion. The knee/ankle flexionater is fully patient-controlled, variable load/variable position medical device that utilizes a hydraulic pump and quick-release mechanism which allows patients to perform stretching therapy sessions, alternately stretching and relaxing the scar tissue surrounding the affected joints. To use this device, the patient sits in the chair, puts his/her foot in the cradle, and pulls a lever. This knee/ankle flexionater is constructed of aluminum extrusion, hydraulic cylinders, and various valves/fittings/tubing. The average patient use is 6-7 weeks. According to the requester, existing codes E1810 "DYNAMIC ADJUSTABLE KNEE EXTENSION/FLEXION DEVICE, INCLUDES SOFT INTERFACE MATERIAL" and E1812 "DYNAMIC KNEE, EXTENSION/FLEXION DEVICE WITH ACTIVE RESISTANCE CONTROL" do not adequately describe this device because: 1) these codes describe orthotic-like devices permitting passive stretching through the use of spring mechanisms; and 2) the torque levels are low and are not patient-applied or controlled and fall into the low load prolonged duration stretch (LLPS) category. Existing code E1811 "STATIC PROGRESSIVE STRETCH KNEE DEVICE, EXTENSION AND/OR FLEXION, WITH OR WITHOUT RANGE OF MOTION ADJUSTMENT, INCLUDES ALL COMPONENTS AND ACCESSORIES" does not adequately describe this code because: 1) it describes orthotic-like devices permitting passive stretching through the use of ratchet mechanisms; and 2) devices coded under E1811 cannot exert the high levels of torque to break the cross-links of the periarticular connective tissue and elongate the actual collagen bundles according to the TERT protocol.

CMS HCPCS Preliminary Decision:

A national program operating need was identified to differentiate this product from other similar products based on higher levels of torque. Existing code E1811 "STATIC PROGRESSIVE STRETCH KNEE DEVICE, EXTENSION AND/OR FLEXION, WITH OR WITHOUT RANGE OF MOTION ADJUSTMENT, 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 if covered.

Pricing = 36

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with the Workgroup's preliminary decision and stated that the ERMI Knee/Ankle Flexionater® operates differently than the products described by HCPCS code E1811. Specifically, the speaker claimed that the ERMI Knee/Ankle Flexionater® demonstrates better outcomes based on operating differences in mechanism, materials, and measurement based on a higher intensity patient controlled torque/load, different materials and design.

HCPCS Public Meeting Agenda Item #11

June 8, 2010

Attachment# 10.099

Topic/Issue:

Request to establish a code for metatarsophalangeal joint (MPJ), trade name: MPJ Extensionater. Applicant's suggested language: "High intensity, patient actuated serial stretch MPJ extension/flexion device, variable load/variable position, patient controlled, with pneumatic pump."

Background/Discussion:

According to the requester, the MPJ extensionater is a self-contained machine that facilitates and accelerates recovery from decreased range of motion of the first metatarsophalangeal joint. It is designed to treat patients with decreased range of motion due to arthrofibrosis of the MPJ, a complication of injury or surgery where an excessive scar tissue response leads to painful restriction of motion. The MPJ extensionater is fully patient controlled, variable load/variable position medical device that utilizes a pneumatic hand pump, air bladder and quick-release mechanism to allow patients to perform stretching therapy sessions, alternately stretching and relaxing the scar tissue and adhesions surrounding the affected joints. Functionally, the MPJ extensionater is designed to provide a gentle though forceful plantarly-directed load to the metatarsal segment while the hallux is stabilized against a passive, freely rotating restraint. This effectively recreates the gliding J-axis seen normally at the first MPJ, allowing for maximal stretch on contracted tissues. The patient fits the device and operates the hand pump moving air into the bladder. As the bladder inflates, it places an increasing force on the patient's metatarsal imparting a torque on the MPJ and stretching forces to the motion-restricting tissues surrounding the joint. The expected duration of use for the MPJ extensionater is 6-8 weeks, though the actual duration for a specific patient depends on many variables including volume and maturity of scar tissue, the patient's pain threshold, and, in post-operative cases, the post-operative time interval. According to the requester, existing code E1830 does not adequately describe this product because: 1) this code describes orthotic-like devices permitting passive stretching through the use of spring mechanisms; 2) the products identified by this code are not patient-applied or controlled and fall into the Low Load Prolonged Duration Stretch (LLPS) category; 3) the products are light weight spring-loaded, brace or splint-like devices; and 4) the axis of rotation for these devices is a fixed, hinge-like axis which does not match the normal, moving "J" axis of

the MPJ. Static progressive stretch (SPS) and low-load progressive stretch (LLPS) devices cannot exert the high levels of torque that the extensionater can to break the cross-links of the periarticular connective tissue and elongate the collagen bundles according to the TERT protocol. In addition, devices described by code E1830 “DYNAMIC ADJUSTABLE TOE EXTENSION /FLEXION DEVICE, INCLUDES SOFT INTERFACE MATERIAL” do not have a rotational component and apply the load to the phalanx rather than the metatarsal. "In sum, the MPJ extensionater described by HCPCS code E1830 are very different devices."

CMS HCPCS Preliminary Decision:

Establish Exxxx STATIC PROGRESSIVE STRETCH TOE DEVICE, EXTENSION AND/OR FLEXION, WITH OR WITHOUT RANGE OF MOTION ADJUSTMENT, INCLUDES ALL COMPONENTS AND ACCESSORIES

Medicare Payment:

Based on our preliminary benefit category analysis, we believe that the item would be paid in accordance with the payment rules that apply to capped rental items if covered.

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker agreed with the Workgroup’s preliminary decision.

HCPCS Public Meeting Agenda Item #12

June 8, 2010

Attachment# 10.037

Topic/Issue:

Request for a code to identify a tunnel dressing for use with Negative Pressure Wound Therapy, trade names: Engenex® Tunnel Dressing 1x15 cm and Engenex® Tunnel Dressing 1.5x15 cm. Applicant's suggested language: "Tunnel Dressing with applicator, to be inserted into a wound with a tunnel or sinus tract, for use with a Negative Pressure Wound Therapy System."

Background/Discussion:

According to the Requester, Engenex® Tunnel Dressing is recommended for use in wounds with tunnels or sinus tracts, and is used to maintain a flow passage for Negative Pressure Wound Therapy administration. The dressing is used until the distal portion of the tunnel has closed. The Engenex® Tunnel Dressing is inserted into the wound tunnel or sinus tract to within 0.5 - 1.0 cm from the distal portion of the tunnel, using an applicator. The Engenex® Tunnel Dressing is made with a proprietary Bio-Dome Technology which prevents the collapse of the dressing upon itself unlike other gauze or foam based dressings. By facilitating the maintenance of the flow passage the wound should heal from distal to proximal. Other dressings may close proximally before they heal distally creating an abscess which may lead to complications. The Local Coverage Determination for Negative Pressure Wound Therapy provides specific HCPCS Codes for other components, including the pump (E2402), dressing kit (A6550) and canister (A7000). The Requester is asking for a specific HCPCS code for a tunnel dressing to be consistent with the LCD, provide accountability for all components of the NPWT system, and to aid in the processing of billing claims that contain a tunnel dressing along with other components of the NPWT system. The tunnel dressing is a component of the Negative Pressure wound Therapy system that serves a specific function in addition the standard dressing kit for use in wounds with tunnels or sinus tracts.

CMS HCPCS Preliminary Decision:

Existing code A6550 “WOUND CARE SET, FOR NEGATIVE PRESSURE WOUND THERAPY ELECTRICAL PUMP, INCLUDES ALL SUPPLIES AND ACCESSORIES” adequately describes the product that is the subject of this request.

Medicare Payment:

The payment rules associated with the existing code applies to this product if covered.

Pricing = 34

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with the Workgroup's preliminary decision and stated that HCPCS code A6550 does not adequately describe the Engenex® Tunnel Dressing. The speaker clarified that the Engenex® Tunnel Dressing is used in addition to the NPWT wound dressing and not in place of it. The speaker claimed that the Engenex® Tunnel Dressing is recommended for use in wound with tunnels or sinus tracts and is used to maintain a flow passage for NPWT administration until the distal portion of the tunnel has closed. In addition, the speaker reported that the Local Coverage Determination (LCD) for NPWT provides specific HCPCS codes for other components, including the pump (E2402), dressing kit (A6550) and canister (A7000). The speaker requested the establishment of a new HCPCS code for the Engenex® Tunnel Dressing to appropriately identify the product, and thereby aid in the processing of billing claims that contain a tunnel dressing along with other components of the NPWT system. The speaker urged the Workgroup to reconsider its decision and grant a new HCPCS code to appropriately describe the Engenex® Tunnel Dressing.

HCPCS Public Meeting Agenda Item #13

June 8, 2010

Attachment# 10.100

Topic/Issue:

Request to establish a code for an external insulin infusion pump for diabetes, trade name: Personal Diabetes Danager (PDM). Applicant's suggested language: "External ambulatory insulin delivery and monitoring system, controller for programming, regulating and monitoring insulin infusions with integrated home blood glucose monitor."

Background/Discussion:

According to the requester, the PDM is a wireless, menu-driven, hand-held device used to regulate the infusion of insulin, program the OmniPod with personalized insulin delivery instructions or individualized bolus directions, and to check blood glucose levels using common blood glucose test strips. The PDM facilitates disease management by integrating blood glucose results into suggested bolus calculations, integrating a food reference library with over 1,000 common food items, and storing up to 5,400 carbohydrate, insulin delivery and blood glucose records. The PDM also features a large display, large font and a backlight to enhance readability for people with all levels of vision acuity in any setting. The PDM is one component of the OmniPod Insulin Management System (OIMS). The OIMS provides exactly the same functionality as a conventional pump in a different architecture to make the overall system more user friendly and less expensive up-front. The user interface and much of the system intelligence reside on the PDM. According to the requester, existing code E0607 HOME BLOOD GLUCOSE MONITOR does not accurately describe the PDM's primary functionality. The primary function of the PDM is to program, regulate and monitor infusion of insulin by the Omnipod supply component of the OIMS, and as such, the PDM has the same function as insulin pumps included in code E0784 EXTERNAL AMBULATORY INFUSION PUMP, INSULIN. The OMIS is an integrated unit, composed of two parts. CMS codes each separately, preventing the OIMS from being recognized for what it is: an integrated system to deliver, regulate and monitor insulin infusions.

CMS HCPCS Preliminary Decision:

Existing code A9274 "EXTERNAL AMBULATORY INSULIN DELIVERY SYSTEM, DISPOSABLE, EACH, INCLUDES ALL SUPPLIES AND ACCESSORIES" adequately describes the Omnipod; and code E0607 "HOME BLOOD GLUCOSE MONITOR" adequately describes the glucose monitor feature. A national program operating need to separately code the controller/programming function of the Omnipod was not identified by Medicare, Medicaid, or the Private Insurance Sector.

Medicare Payment:

For E0607, the payment rules associated with the existing code apply to this product if covered.
Pricing = 32

For A9274, the payment rules associated with the existing code apply to this product.

Pricing = 00

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with the Workgroup's preliminary decision and stated that HCPCS code E0607 does not accurately describe the Personal Diabetes Manager's (PDM's) primary functionality, which is to control insulin delivery. The speaker recommended the establishment of a new "E" code to accurately describe the PDM.

HCPCS Public Meeting Agenda Item #14

June 8, 2010

Attachment# 10.101

Topic/Issue:

Request to establish a code for a personal therapy manager, trade name: myPTM.

Background/Discussion:

According to the requester, the PTM is a patient-operated, hand-held, battery-powered device that communicates with the Medtronic SynchroMed®II Programmable Infusion System via telemetry. It is an accessory to the implantable infusion system. The PTM enables patients to direct the implanted pump to deliver supplemental doses of physician-prescribed medication to the intrathecal space (area in the spine through which pain signals travel). The amount and frequency of the supplemental dose is limited to a maximum, pre-programmed by the patient's physician. The PTM uses a touch-screen interface, graphics and audible tones that direct patient interaction. When the patient presses the activator button, a message is sent by telemetry to the implanted pump which releases a preprogrammed dose of drug. The PTM includes a patient diary to record information like delivery times and self pain ratings that physicians review at the next routine, follow-up appointment, as they consider whether dosage adjustment is appropriate. The PTM is intended for patients with implantable programmable infusion pumps with chronic intractable pain who experience: uncontrolled, intermittent pain of varying intensity; an unpredictable need for varying doses of medication; and inadequate pain relief or intolerable side effects from supplemental pain medications. According to the requester, there are concerns about the usage of existing code E0783 "INFUSION PUMP SYSTEM, IMPLANTABLE, PROGRAMMABLE (INCLUDES ALL COMPONENTS, E.G., PUMP, CATHETER, CONNECTORS, ETC.)" to bill for this product because hospitals or physicians will often provide the initial PTM many months after the SynchroMed II implantable infusion system is implanted, and not all patients require a PTM. In this instance it would be inappropriate for a hospital to bill code E0783 again or use C1772 "INFUSION PUMP, PROGRAMMABLE (IMPLANTABLE)" under HOPPS, since these codes represent an entire pump system. Additionally, in this instance, hospitals or physicians also cannot use A9900 since they are providing the initial PTM, not a replacement.

CMS HCPCS Preliminary Decision:

A national program operating need to establish a code to separately identify the PTM was not identified by Medicare, Medicaid or the Private Insurance Sector. This component is included in existing code E0783 “INFUSION PUMP SYSTEM, IMPLANTABLE, PROGRAMMABLE (INCLUDES ALL COMPONENTS, E.G., PUMP, CATHETER, CONNECTORS, ETC.).

Medicare Payment:

The payment rules associated with the existing code apply to this product if covered.
Pricing = 32

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item #15

June 8, 2010

Attachment# 10.106

Topic/Issue:

Request to establish a code for an acoustic airway clearance device, trade name: The Frequencer™. Applicant's suggested language: "Electro-Acoustic Airway Clearance Device."

Background/Discussion:

According to the requester, the Frequencer™ device provides airway clearance by inducing oscillatory sound waves in the chest by means of an electro-acoustical transducer placed externally on the patient's chest. The transducer is connected to a frequency generator which is capable of producing frequencies between 20 and 100Hz. The vibrations in the patient's chest are effective in loosening mucus deposits and promoting bronchial drainage. The Frequencer consists of two parts, a control unit and a transducer. The user places the transducer on the chest. The frequency (adjustable between 20 and 100HZ) and the volume are adjusted in the control unit to create sympathetic resonance that can be felt in the lungs. According to the requester, there are significant differences between devices coded at E0480 "PERCUSSOR, ELECTRIC OR PNEUMATIC, HOME MODEL" and the Frequencer. Specifically: (1) Devices coded at E0480 deliver a frequency pounding or striking action, similar to clapping, to a patient's chest to loosen mucus. The Frequencer does not use mechanical action. It uses higher frequency acoustic waves to excite resonance in the chest. This is much gentler. (2) Devices coded at E0480 are not self-contained and require a source of regulated compressed air, whereas, the Frequencer is self-contained. (3) Compared to other electro-mechanical and sonic percussors coded at E0480, the Frequencer has the unique capability of changing the rheological properties of mucus to make it flow more readily. Existing code E0483 "HIGH FREQUENCY CHEST WALL OSCILLATION AIR-PULSE GENERATOR SYSTEM, (INCLUDES HOSES AND VEST), EACH" also does not describe the Frequencer, because the Frequencer does not use an air pulse generator. The requester states within the application that "all of these devices have the identical clinical indication.... for Postural Drainage Therapy..." and "As far as efficacy is concerned, these devices are comparable." "... The most logical basis of comparison is the amount of sputum expelled." Studies comparing the clinical results of the various devices coded at E0480 are not provided.

CMS HCPCS Preliminary Decision:

Existing code E0480 “PERCUSSOR, ELECTRIC OR PNEUMATIC, HOME MODEL” adequately describes the frequencer device.

Medicare Payment:

The payment rules associated with the existing code applies to this product if covered.

Pricing = 36

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item #16

June 8, 2010

Attachment# 10.086

Topic/Issue:

Request to establish a code for replacement patient breathing circuits used in cough stimulating devices, trade names: CoughAssist™ and Patient Circuit for the Cough Assist™. Applicant's suggested language: Breathing circuit for cough stimulating device, including flexible tubing, bacterial filter and patient interface (face mask, mouthpiece or tracheal adapter)."

Background/Discussion:

According to the requester, the patient breathing circuit functions to create an effective, filtered conduit for air exchange between the patient and the cough stimulating device. Cough stimulating devices are indicated for individuals who lack the ability to perform an unassisted cough of sufficient strength to remove secretions from the lungs secondary to amyotrophic lateral sclerosis, spinal muscular atrophy, muscular dystrophy, myasthenia gravis or spinal cord injuries. This patient breathing circuit is an essential accessory for cough stimulating devices. It consists of three components: a flexible breathing tube; a bacterial filter; and a patient interface (face mask, mouthpiece or tracheal adapter for patients with endotracheal or tracheostomy tubes). The flexible tubing provides a conduit for the air to flow between the device and the patient. The disposable bacterial filter serves to remove microbiological and particulate matter from the gases in the breathing circuit. The patient interface consists of a face mask, mouthpiece or tracheal adapter. The CoughAssist™ Patient Circuit is available in a wide range of options and sizes to ensure effective interface with the patient and to promote adherence to therapy. It is packaged as follows: large, medium, small, toddler, or infant patient circuit with a face mask, flexible breathing hose and bacterial filter; a trach with a tracheal adapter (airway connector), flexible breathing hose and bacterial filter; and a patient circuit with a mouthpiece, flexible breathing hose and bacterial filter. According to the requester, there are no codes to describe the patient breathing circuit used in cough stimulating devices. While it is typically provided as part of initial rental or purchase of a cough stimulating device, a separate code is necessary for patients to obtain replacement breathing circuits, especially after completion of Medicare's 13-month capped rental period when the patient owns the device. All of the components of the patient breathing circuit must be replaced approximately every two months, as a unit, to reduce the risk of infection, to account for predictable degradation under daily use, and to ensure proper functioning.

CMS HCPCS Preliminary Decision:

Establish Axxxx INTERFACE FOR COUGH STIMULATING DEVICE, INCLUDES ALL COMPONENTS, REPLACEMENT ONLY

Medicare Payment:

Based on our preliminary benefit category analysis, we believe that the item would be paid for use with beneficiary-owned equipment in accordance with the payment rules that apply to inexpensive and other routinely purchased items if covered.

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item #17

June 8, 2010

Attachment #10.119

Topic/Issue:

Request to establish a code for an electrochemical low-dose tissue oxygenation system, trade name: TransCu O_2.

Background/Discussion:

According to the requester, the TransCu O_2 is a microprocessor controlled electrochemical oxygen concentrator and wound monitoring system. This non-invasive therapy is used to treat difficult-to-heal wounds and is intended for use with lower cost wound dressings as a simple-to-use and easy-to-administer adjunctive therapy to feed an oxygen-compromised wound a continuous supply of supplemental low-dose pure oxygen directly to the wound site. TransCu O_2 works by extracting oxygen from room air; concentrating the oxygen to 99.9% through the Proton Exchange Membrane (PEM); and then creating an oxygen rich environment of up to 99% oxygen under the dressing at the wound site. The device can be worn discretely in a pocket, fanny pack or attached to a belt clip like a cell phone. It can provide continuous treatment 24 hours a day, 7 days a week. The duration of therapy is projected to be 6 to 8 weeks. The device is rented to the hospital, long-term care facility, or if used at home, the patients' insurance company. The micro bore oxygen delivery tube is sold as a disposable supply. In addition to the device and cannula, a two part moist wound dressing system is required. The dressings are sold separately and/or provided by the facility, doctors' offices, nursing agency or local medical supply house. TransCu O_2 is an advanced wound care technology viewed as the last line of defense in treating difficult-to-heal wounds such as diabetic foot ulcers, venous stasis ulcers, pressure ulcers, infected residual limbs, skin grafts, burns, and frostbite. The system consists of a battery operated microprocessor controlled electrochemical oxygen concentrator device weighing only 9 ounces, a 60-inch oxygen delivery extension set and 12-inch wound site oxygen delivery cannula. The five basic components of the system are the low dose tissue oxygenation system, the battery charger, the protective covering, the oxygen delivery extension set, and the wound oxygen delivery cannula. According to the requester, there are no existing codes to describe this product. A new code would ensure Medicare beneficiaries access to this innovative new wound care therapy.

CMS HCPCS Preliminary Decision:

Establish code Exxxx TOPICAL OXYGEN DELIVERY SYSTEM

Medicare Payment:

Based on guidance contained in Chapter 1, Part 1, Section 20.29 of the Medicare National Coverage Determinations manual, we believe 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 to establish a new HCPCS code that describes a topical oxygen delivery system, and requested the Workgroup to create a HCPCS code that describes an electrochemical low-dose tissue oxygenation system. The speaker explained the differences in characteristics and risks associated with low-dose tissue oxygen therapy, topical oxygen therapy, and hyperbaric oxygen therapy. The speaker urged the Workgroup to establish a unique HCPCS code for low-dose tissue oxygenation, which would appropriately describe TransCu O_2.

HCPCS Public Meeting Agenda Item #18

June 8, 2010

Attachment# 10.007

Topic/Issue:

Request to have a new code assigned to a heat therapy system, trade name: Xtreme-Relief Heat Therapy System.

Background/Discussion:

According to the requester, the Xtreme-Relief Heat Therapy System is a mobile heat therapy system that is computer driven. A control unit is worn on the belt or in a pocket. Computerized heaters are placed in an orthotic support. The heater control unit provides a consistent, safe moist, centralized heat for treatment of chronic and acute pain. The system allows site specific heat and can be worn while the patient is performing activities. The temperature can be controlled. This product is indicated for patients with injury, arthritis or pain. The Extreme Heat Therapy System is rechargeable and easily cleaned for repeated use. Patient usage has been tested and the battery lasts for over 400 charges. The product package includes a control unit, charger, heaters, carrying case, instructions and a warranty. According to the requester, this product is very similar to the J-Stim 1000 coded at existing HCPCS code E0762 TRANSCUTANEOUS ELECTRICAL JOINT STIMULATION DEVICE SYSTEM, INCLUDES ALL ACCESSORIES. However, J-Stim uses infrared light while the Xtreme Heat Therapy System provides controllable heat.

CMS HCPCS Preliminary Decision:

Existing code E0210 "ELECTRIC HEAT PAD, STANDARD" is available for assignment by all payers to identify the garment, if they deem appropriate. A national program operating need to establish a code for the heating unit was not identified by Medicare, Medicaid or private insurers.

Medicare Payment:

The payment rules associated with the existing code apply to this product if covered.

Pricing = 32

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with the Workgroup's preliminary decision and stated that the Xtreme-Relief Heat Therapy System is significantly different than the devices currently described by HCPCS code E0210. In particular, the Xtreme-Relief Heat Therapy System has its own generator and is worn with a belt. Also, the speaker claimed this item is the only computerized, totally mobile, heat therapy system available on the market today. The speaker indicated this product was given an E1399 HCPCS code; however, a miscellaneous code is not desired. The speaker requested the establishment of a new HCPCS code to appropriately identify the "XTREME-RELIEF Heat Therapy System."

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.