Centers for Medicare & Medicaid Services (CMS)
Healthcare Common Procedure Coding System (HCPCS)
Public Meeting Summary Report
Durable Medical Equipment
Thursday, May 28, 2009

Introduction and Overview

Approximately 50 people attended. The agenda included 15 items.

Cindy Hake provided an overview of the HCPCS public meeting process as it relates to the overall HCPCS coding process.

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

Prior to the Public Meetings, CMS HCPCS workgroup meets to review all HCPCS code applications and makes preliminary coding recommendations. CMS also makes 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 HCPCS world-wide web site at www.cms.hhs.gov/medhcpcsgeninfo, as part of the HCPCS public meeting agendas.

Following the public meetings, CMS HCPCS workgroup reconvenes, and considers all the input provided at the Public Meetings regarding its preliminary coding recommendations. CMS also reconsiders its Medicare payment recommendations. CMS maintains the permanent HCPCS Level II codes, and reserves final decision making authority concerning requests for permanent HCPCS codes. Final decisions regarding Medicare payment are made by CMS and must comply with the Statute and Regulations. Payment determinations for non-Medicare insurers, (e.g., state Medicaid Agencies or Private Insurers) are made by the individual state or insurer.

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

The process for developing agendas and speaker lists for the public meetings, and Guidelines for Proceedings at CMS' Public Meetings are posted on the official HCPCS world wide web site at: http://cms.hhs.gov/medhcpcsgeninfo/downloads/2008guidelines.pdf . The standard application format for requesting a modification to the HCPCS Level II Coding System, along with

instructions for completion and background information regarding the HCPCS Level II coding process is available at: http://cms.hhs.gov/medhcpcsgeninfo/downloads/2009_alpha.pdf. A decision tree, outlining CMS' decision-making criteria is also available at: http://cms.hhs.gov/medhcpcsgeninfo/downloads/decisiontree.pdf.

Centers for Medicare & Medicaid Services (CMS) Healthcare Common Procedure Coding System (HCPCS) Public Meeting Agenda
for Durable Medical Equipment (DME) and Accessories
Thursday, May 28, 2009, 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 #09.112
Request to establish a code to describe wheelchair headrests that have "highly adjustable supports" for the head and other features, such as detachable hardware and contoured, cushioned, single pad.

Attachment #09.087
Request to modify the descriptor of code E0955 to more specifically describe the Freedom Designs adjustable headrest - model number 7755-std pad with 7700 hardware.

Primary Speaker: Tom Whelan of Sunrise Medical

AGENDA ITEM #2
Attachment #09.069
Request to establish a code for an integrated wheelchair handrim assembly, trade name: Natural Fit®.

Primary Speaker: David Boninger of Three Rivers Holdings, LLC

AGENDA ITEM #3
Attachment #09.040
Request to establish 2 codes for an upgraded proportional remote joystick, trade names: Q-Logic Joystick & Remote + Joystick.

Primary Speaker: Julie Piriano of Pride Mobility Products Corporation

AGENDA ITEM #4
Attachment #09.088
Request to establish a code for an automatic wheelchair brake or lock, trade name: "Safer Automatic Wheelchair Wheel Lock"

Primary Speaker: Mark Golubow of Safer Automatic Wheelchair Wheel Locks

AGENDA ITEM #5
Attachment #09.116
Request to establish a code for an automatic pneumatic seating system, trade name: iPUPc, (Intelligent Pressure Ulcer Prevention Cushion).

Primary Speaker: Stephen Wasko of Medical Technology Systems, Inc.

AGENDA ITEM #6
Attachment #09.071
Request to establish a code to describe the bariatric version of the Barton Positioning and Transfer System, trade name: Extra-wide Barton Positioning and Transfer System (PTS).

Primary Speaker: Natalie Wood of Barton Medical Corporation

AGENDA ITEM #7
Attachment #09.012
Request to "attain Medicare approval by the establishment of a new HCPCS code" for a Cane Leg Support (CLS).

No Primary Speaker

AGENDA ITEM #8
Attachment #09.067
Request to establish a code for a portable knee hyper-extension device, trade name: Elite Seat.

Primary Speaker: Edward Dietrich of Kneebourne Therapeutic, LLC

AGENDA ITEM #9
Attachment #09.039
Request to establish 3 new codes for the turnbuckle ankle, elbow, and knee orthoses. Trade names: (respectively), Turnbuckle Ankle Orthosis; Turnbuckle Elbow Contracture Orthosis; and Turnbuckle Knee Contracture Orthosis.

Attachment #09.059
Request to establish a code for a dynamic dorsal night splint, trade name: D2 Night Splint.

Primary Speaker: Alan Bingham of AliMed, Inc.

AGENDA ITEM #10
Attachment #09.060
Request to establish a code for a dynamic splint, trade name: Ankle Dorsiflexion Dynasplint® (ADFD) Type IV System.

Attachment #09.061
Request to establish a code for a dynamic splint, trade name: Elbow Extension Dynasplint® (EED) Type III System.

Attachment #09.062
Request to establish a code for a dynamic splint, trade name: Knee Extension Dynasplint® (KED) Type III System.

Primary Speaker: Sean Murphy of Dynasplint Systems, Inc.

AGENDA ITEM #11
Attachment #09.081
Request to establish a code for a patient-operated, hand-held, battery-powered device, trade name: Personal Therapy Manager (myPTM).

Primary Speaker: Linda Holtzman of Clarity Coding

AGENDA ITEM #12
Attachment #09.055
Request to establish a new code for a percutaneous electrode array (PEA), trade name: Deepwave® Percutaneous Electrode Array (PEA).

Primary Speaker: Brad Siff of Biowave Corporation

AGENDA ITEM #13
Attachment #09.065
Request to establish a code for an ultraviolet light panel containing 6' 6-lamp UVB-Narrowband, trade name: Panosol II.

No Primary Speaker

AGENDA ITEM #14
Attachment #09.049
Request to either establish a new code for portable liquid oxygen systems, trade name: HomeLox Portable Liquid Oxygen System, or modify existing code K0738.

Primary Speaker: Samuel Nebiolo of Philips Home Healthcare Solutions

AGENDA ITEM #15
Attachment #09.068
Request to establish a code for home oxygen liquefier and portables, trade names: VIAspire Personal Oxygen System: Model 300D VIAspire Liquefier; and Models 300P, 600P, 1200P VIAspire Oxygen Portables.

No Primary Speaker

HCPCS Public Meeting Agenda Item #1
May 28, 2009

Attachment: #09.112

Topic/Issue:
Request to establish a code to describe highly adjustable supports for the head. Applicant's suggested language: "Wheelchair accessory, posterior adjustable head support, contoured, cushioned, single pad with adjustable, detachable hardware."

Background/Discussion:
According to the requester, these head support systems have a single, adjustable contoured pad and provide posterior and mild lateral head support designed to prevent the patient's head from falling posteriorly or to the side. The hardware for mounting this support is adjustable in height, depth, and angle, and provides a means for detachment without the use of tools. These head supports have a contoured pad made of foam or gel, covered or coated and mounted on a base made of steel, aluminum, plastic or plywood. The contours of the pads are designed to fit the contours of the head to provide upright positioning of the head and are shaped to cradle the head to provide lateral support. The hardware is designed to allow the contoured pad to be attached to a wheelchair or wheelchair seatback and adjusted to a specific position relative to the head. These head supports are indicated for patients who have weakness or fatigue rapidly and cannot support their own head during the normal use of a wheelchair, such as a client with a spinal cord injury at cervical level, C-1 through 4 who have little to no voluntary movement below their level of injury. According to the requester, codes K0108 and E0955 are inadequate to describe this product because the code descriptions are too broad, causing a wide range of technologies to be grouped into a single code. The lack of appropriate distinction causes problems for coverage policy development and payment policy issues.

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

Medicare Payment:
The payment rules associated with the existing code apply to this product. Pricing = 32

Summary of Primary Speaker Comments at the Public Meeting:
The primary speaker disagreed with the workgroup's preliminary decision. He stated that there is a wide range of headrest products bundled into one code, including simple to

complex. The speaker stated that a program operating need for differential coding exists: 1) for tracking (traceability of the product); 2) to allow access to more complex technologies; 3) to support differential coverage policy; 4) to encourage innovation in support and positioning technologies; and 5) to support appropriate payment for headrests of vary complexity.

HCPCS Public Meeting Agenda Item #1
May 28, 2009

Attachment: #09.087

Topic/Issue:
Request to modify the descriptor of code E0955 to more specifically describe the Freedom Designs adjustable headrest - model number 7755-std pad with 7700 hardware. Current language: WHEELCHAIR ACCESSORY, HEADREST, CUSHIONED, ANY TYPE, INCLUDING FIXED MOUNTING HARDWARE, EACH Applicant's suggested language: "Wheelchair Accessory, Posterior Adjustable Headrest, Cushioned, Single Pad with Fixed Mounting Hardware".

Background/Discussion:
According to the requester, the descriptor of code E0955 causes inappropriate grouping of existing technologies. Grouping technologies that address varied clinical issues causes a number of issues, such as: 1) difficulty developing differential coverage policy; 2) "inappropriate payment policies"; 3) inability to track utilization of different technologies; 4) stifled innovation of complex support and positioning technologies; and 5) limitations of access to more complex technologies. Additional codes are needed to appropriately segment distinct technologies. The applicant believes that code E0955 should encompass only products designed with a single cushioned pad, with a means of attaching to the wheelchair, that meet the following suggested criteria to the exclusion of all others. "The pad is generally flat, but may be mildly contoured. The pad must have anterior/posterior and inferior/superior adjustments, meaning the pad can be up/down and in/out in order to achieve appropriate head and neck location for the intended patient. The attaching hardware is fixed, meaning it does not remove or swing-away. This technology is designed primarily to keep the patient's head from moving or falling posterior to the backrest. The patient's head position is limited, but not controlled, by this type of headrest. It is used by patients at risk of falling into neck extension. This may be due to mild strength or endurance limitations, and/or for patients that require a surface to rest his/her head during tilt and/or recline. Examples of these types of patients might be, but not limited to: patients with spinal cord injuries lower on the cervical spine (C-5 to C- 7) may require power mobility with powered seating for pressure relief resulting in the need for an adjustable posterior headrest to properly support the head, preventing posterior extension while in the tilt or recline position. The adjustment is needed as these patients often have fusion to the affected vertebrae and have range of motion limitations in the area of their spine due to the stabilization surgery."

CMS HCPCS Preliminary Decision:
A national program operating need was not identified by Medicare, Medicaid or the Private Insurance sector to revise the verbiage of code E0955. The existing code language “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 apply to this product. Pricing = 32

Summary of Primary Speaker Comments at the Public Meeting:
The primary speaker disagreed with the workgroup's preliminary decision. He stated that there is a wide range of headrest products bundled into one code, including simple to complex. The speaker stated that a program operating need for differential coding exists: 1) for tracking (traceability of the product); 2) to allow access to more complex technologies; 3) to support differential coverage policy; 4) to encourage innovation in support and positioning technologies; and 5) to support appropriate payment for headrests of vary complexity.

HCPCS Public Meeting Agenda Item #2
May 28, 2009

Attachment: #09.069

Topic/Issue:
Request to establish a code for an integrated wheelchair handrim assembly, trade name: Natural Fit®. Applicant's suggested language: "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 wheelchair handrim is ergonomically designed to relieve stress on the hands and wrist during the repetitive strain of manual wheelchair propulsion, and to improve clinical outcomes associated with Carpal Tunnel Syndrome (CTS)." The Natural Fit 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 is designed to create an ergonomic grip for the hand and to provide separate surfaces for propulsion and braking. The contoured trough provides a surface area between the rim and tire to increase the contact area for the thumb to apply propulsion forces. By adding the trough, the gap between the tire and standard handrims is eliminated which enhances safety. For the treatment of CTS, that space can now be used to contribute towards forward propulsion under the pressure of the thumb. The ergonomic grip provided by the combination of the contoured trough and the oval component of the Natural-Fit reduces finger tip loading, pinch gripping, and excessive activation of the finger flexors during wheelchair propulsion. This will in turn reduce pressure on the carpal tunnel and relieve pain associated with CTS. The oval component is now available in a reduced weight, smaller profile. The HCPCS Workgroup revised the descriptor of the E2205 code to include ergonomic and contoured handrims within the same code as standard round-tube handrims. It currently reads: "MANUAL WHEELCHAIR ACCESSORY, HANDRIM WITHOUT PROJECTIONS (INCLUDES ERGONOMIC OR CONTOURED), ANY TYPE, REPLACEMENT ONLY, EACH." The requester claims that the Natural-Fit is significantly different from other handrims coded at E2205 in terms of function, components, manufacturing, and cost. According to the requester, the Natural Fit does not belong in code E2205 because it (1) has a unique function that targets a specific subpopulation not addressed by handrims in existing codes, and (2) meaningfully reduces hand and wrist pain in manual wheelchair users.

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. Pricing = 32

Summary of Primary Speaker Comments at the Public Meeting:
The primary speaker disagreed with the workgroup's preliminary decision and claimed that code E2205 puts disparate, dissimilar items into the same category. According to the speaker, the Natural-fit handrim is differentiated from other products in existing code E2205 because: 1) it has a unique ergonomic design and function that targets wheelchair users who experience pain in the hands and wrists; and 2) it confers a significant therapeutic distinction as evidenced in published documentation of improved clinical outcomes that set the Natural-fit apart from standard round-tube handrims. The speaker claimed that CMS' preliminary decision disregards distinctions already made, as evidenced by expert reviewers, federal agencies and professional consortiums, and published scientific evidence.

HCPCS Public Meeting Agenda Item #3
May 28, 2009

Attachment: #09.040

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 or chin control interface, upgrade proportional remote joystick (not including controller), proportional, including fixed mounting hardware" xxxx2 "Power wheelchair accessory, hand or chin control interface, upgrade proportional remote joystick (not including 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 functions. The joystick can be configured to limit or expand the "stick" direction, range, and/or exursion, setting it up as a switch or using it for single touch operation rather than requiring sustained contact. It can also allow for the operation of other necessary devices, such as augmentative and alternative communication systems, electronic aids to daily living and/or a computer. Individuals who would benefit most from using an upgraded, proportional joystick are among the most severely disabled, yet still have the capability of using a joystick drive input device to operate their power wheelchair. There are certain cases where there can be a therapeutic advantage for a client using an upgraded proportional joystick. However, it would need to be justified based on the client function (or lack thereof). According to the applicant, the upgraded proportional joystick should be assigned a code as are other drive control interfaces that are components of complete expandable controller systems.

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. Pricing = 32

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with the workgroup's preliminary decision that codes E2377 and E2313 describe the entire system on initial issue. The speaker also disagreed that codes E2376 and E2313 describe a replacement system. The speaker claimed that the remote proportional upgraded joystick was "left out of the formula" when the decision was made to combine codes E2377 with E2313. The speaker reiterated the original request to establish two codes to describe this product, to support uniform reporting and data collection.

HCPCS Public Meeting Agenda Item #4
May 28, 2009

Attachment: #09.088

Topic/Issue:
Request to establish a code for an automatic wheelchair brake or lock, trade name: "Safer Automatic Wheelchair Wheel Lock"

Background/Discussion:
According to the requester, the Safer Automatic Wheelchair Wheel Lock is a patented, fall prevention product for a manual wheelchair. This product will automatically lock when a person rises out of the chair and remains locked until someone re-enters the chair. This will greatly reduce the amount falls for the people who do not or cannot remember to use the manual brake. The Safer Locks have been in the field protecting people since 1998 and have become a product that Nursing Homes and Long-term care hospitals have come to rely on for patients that are at risk of falls. This product the chair from rolling out from underneath a patient, of regardless of whether the manual brake is applied. Existing codes are non-specific. Existing codes for toggle locks that come standard on wheelchairs do not allow enough money to pay for the Safer Locks.

CMS HCPCS Preliminary Decision:
Existing code E2206 "MANUAL WHEELCHAIR ACCESSORY, WHEEL LOCK ASSEMBLY, COMPLETE, 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. Pricing = 32

Summary of Primary Speaker Comments at the Public Meeting:
The primary speaker disagreed with the workgroup's preliminary decision and payment. The speaker stated that the Medicare fee does not cover the features and benefits or the retail price of the product. The speaker also claimed that falls could be prevented and lives saved if this wheelchair lock is used on the wheelchairs of patients who have Alzheimers or Dementia or who are heavily medicated.

HCPCS Public Meeting Agenda Item #5
May 28, 2009

Attachment: #09.116

Topic/Issue:
Request to establish a code for an automatic pneumatic seating system, trade name: iPUPc, (Intelligent Pressure Ulcer Prevention Cushion).

Background/Discussion:
According to the requester, iPUPc is a light-weight, battery powered, automated, pneumatic seating system, designed for use with both manual and power wheelchairs. Its intended use is to aid in pressure relief, specifically: to reduce the risk of developing pressure ulcers; to accelerate healing of existing pressure ulcers; and to promote comfort for individuals who use a wheelchair as their major means of mobility. The dynamic seating system includes a lumbar support, a split seat and a control system, (including an air control manifold, air valves and fittings, compressor, circuit board and battery). The system measures seating contact pressure and automatically adjusts the user's weight distribution by raising or lowering the back part of the seat (BPS). As such, the system offers 2 seating positions (with and without "BPS") which are automatically adjusted and alternated to reduce pressure on the ischial tuberosities, coccyx and sacrum. iPUPc is designed to fit onto a wide range of standard manually operated and motorized wheelchairs and is indicated for use by individuals who sit for prolonged time during the day. According to the requester, existing codes do not describe a seating system designed specifically for pressure relief and skin integrity, and to prevent and cure pressure ulcers.

CMS HCPCS Preliminary Decision:
Existing code E2610 "WHEELCHAIR SEAT CUSHION, POWERED" adequately describes the product that is the subject of this request.

Medicare Payment:
The payment rules associated with the existing code apply to this product. Pricing = 32

Summary of Primary Speaker Comments at the Public Meeting:
The primary speaker disagreed with CMS' preliminary decision. The speaker believes that the iPuPc is not adequately described by existing code E2610. According to the speaker, code E2610 does not describe the features of iPuPc that other powered cushions in this code do not have, specifically; 1) full segmentation of the seating pan; 2) lumbar support to promote positioning: and 3) micro-computer and multi-sensor controlled optimization of pressure relief. The speaker claimed that clinical data shows that patients using the iPuPc have significantly faster healing rates for pressure ulcers. The speaker also stated that the iPuPc is a seating system, and not just a cushion. And the speaker also requested reconsideration of the BETOS indicator of 32 as assigned to code E2610.

HCPCS Public Meeting Agenda Item #6
May 28, 2009

Attachment: #09.071

Topic/Issue:
Request to establish a code to describe the bariatric version of the Barton Positioning and Transfer System, trade name: Extra-wide Barton Positioning and Transfer System (PTS). Applicant's suggested language "EXTRA-WIDE MULTI-POSITIONAL PATIENT TRANSFER SYSTEM, WITH INTEGRATED SEAT, OPERATED BY CARE GIVER"

Background/Discussion:
According to the requester, the Barton is a care-giver operated multi-positional Patient Transfer System (PTS). The PTS, which "received the E1035 HCPCS code", has a maximum weight capacity of 250 pounds and therefore is not medically appropriate for bariatric patients. Barton Medical Corporation has manufactured the FDA approved I-400 model which can safely accommodate transfers for patients up to 400 pounds. Because bariatric equipment requires more materials and is more costly to the manufacturer, the current fee schedule for the E1035 HCPCS code does not provide sufficient reimbursement for Home Medical Equipment (HME) providers to feasibly distribute this Extra-Wide version, which is why a coding recommendation is being made. By introducing a new HCPCS code and fee schedule for the Extra-wide Barton PTS, HME providers would be able to distribute the product in-home which would ultimately allow many more bariatric bed-bound patients to be transferred in and out of bed. The obese population is continuing to rise which correlates with a rise in the need for Bariatric medical equipment. There are currently no 3rd party payers for this product specifically; however, the PDAC allows E1035 code to be used for reimbursement of this product. This product is typically provided to institutional facilities which are direct payers.

CMS HCPCS Preliminary Decision:
1)Revise code E1035 which currently reads: "MULTI-POSITIONAL PATIENT TRANSFER SYSTEM, WITH INTEGRATED SEAT, OPERATED BY CARE GIVER" to instead read "MULTI-POSITIONAL PATIENT TRANSFER SYSTEM, WITH INTEGRATED SEAT, OPERATED BY CARE GIVER, PATIENT WEIGHT CAPACITY UP TO AND INCLUDING 300 LBS";
2) Establish Exxxx "MULTI-POSITIONAL PATIENT TRANSFER SYSTEM, EXTRA-WIDE, WITH INTEGRATED SEAT, OPERATED BY CAREGIVER, PATIENT WEIGHT CAPACITY GREATER THAN 300 LBS.

Medicare Payment:
Based on guidance contained in an informal benefit category determination, we believe that the item would be paid in accordance with the payment rules that apply to capped rental items.

Summary of Primary Speaker Comments at the Public Meeting:
The primary speaker supported the workgroup's preliminary decision to revise code E1035 and establish a new code, but requested a revision to the proposed verbiage. According to the speaker, the weight capacity of the product that is the subject of this request is 250lbs, and the speaker would like this to be the prescribed weight limit for the new code. The speaker claimed that a 250lb limit ensures that appropriate population receives the appropriate Barton transfer system, based on weight specifications and width.

HCPCS Public Meeting Agenda Item #7
May 28, 2009

Attachment: #09.012

Topic/Issue:
Request to "attain Medicare approval by the establishment of a new HCPCS code" for a Cane Leg Support (CLS).

Background/Discussion:
According to the requester, the Cane Leg Support is a dual-use product that consists of a leg support attached to the shaft of a walking cane. There are 2 soft pads on the leg support; one to support the calf and the other to support the side of the leg. The leg support section swings up and snaps into a horizontal position, providing a portable leg rest for use while seated. When not in use, the support can be pushed back down against the cane shaft, converting this product to a standard care to assist when walking. According to the requester, this medical device will aid persons suffering from a permanent injury or recovering from a leg, knee or foot operation. Existing code E0100 as assigned by the SADMERC, does not describe a walking cane that is modified to include a permanently attached leg support.

CMS HCPCS Preliminary Decision:
Existing code E0100 "CANE, INCLUDES CANES OF ALL MATERIALS, ADJUSTABLE OR FIXED, WITH TIP" adequately describes the product that is the subject of this request.

Medicare Payment:
The payment rules associated with the existing code apply to this product. Pricing = 32

Summary of Primary Speaker Comments at the Public Meeting:
There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item #8
May 28, 2009

Attachment: #09.067

Topic/Issue:
Request to establish a code for a portable knee hyper-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. This device is designed to replace serial casting; Arthroscopy and scar resection; and manual manipulation under anesthesia. It is indicated for Arthrofibrosis, Total Knee Arthroplasty, Arthritic knee joint with flexion contracture or reconditioned knee with flexion contracture. The applicant claims a significant functional and therapeutic distinction offered by the Elite Seat as compared to other products coded at E1811. Only the Elite Seat can restore terminal-extension. 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. Pricing = 36

Summary of Primary Speaker Comments at the Public Meeting:
There was no primary speaker for this item, however the applicant submitted a written comment in disagreement with CMS' preliminary coding decision. The applicant stated that code E1811 does not adequately describe the Elite-Seat, and that the Elite-Seat

differs from other products in code E1811. Specifically, the Elite-Seat restores full terminal extension, whereas other products in this code category do not. The applicant also claims a significant therapeutic distinction in that use of the Elite-Seat prevents the need for Total Knee Replacement, Serial Casting and Arthroscopy.

HCPCS Public Meeting Agenda Item #9
May 28, 2009

Attachment: #09.039

Topic/Issue:
Request to establish 3 new codes for the turnbuckle ankle, elbow, and knee orthoses. Applicant's suggested language:
Lxxx1 "Ankle orthosis, includes one or more nontorsion joint(s), turnbuckles, elastic bands/springs, may include soft interface material, straps, prefabricated, includes fitting and adjustment;"
Lxxx2 "Elbow orthosis, includes one or more nontorsion joint(s), turnbuckles, elastic bands/springs, may include soft interface material, straps, prefabricated, includes fitting and adjustment;"
Lxxx3 "Knee orthosis, includes one or more nontorsion joint(s), turnbuckles, elastic bands/springs, may include soft interface material, straps, prefabricated, includes fitting and adjustment". Trade names: (respectively), Turnbuckle Ankle Orthosis; Turnbuckle Elbow Contracture Orthosis; and Turnbuckle Knee Contracture Orthosis.

Background/Discussion:
According to the requester these turnbuckle orthoses were previously assigned to "E" codes by the SADMERC. The applicant disagrees with this coding decision, stating that these products are orthotics and should be coded with "L" codes, similar to the L3931 code for the wrist. These turnbuckles are not only for short periods of therapy, but are considered dynamic-assist joint orthotics. The ankle, elbow, and knee turnbuckle splints provide adjustable, incremental low-load force to gradually reduce contracture while controlling muscle imbalance. While these splints provide treatment for contractures, they also provide a rigid support for the joint. Patients who are functionally using their joint to perform activities during a recovery period can also use the splints. After undergoing their tolerated amount of low-load stretch, the turnbuckle can be loosened and the patient can wear the splint full time to maintain the range of motion that was gained. The ankle turnbuckle is used to apply progressive low-load force at the ankle joint to control muscle imbalance and reduce contracture. The splint has bilateral turnbuckles to control dorsiflexion/plantar flexion and eversion/inversion simultaneously. The turnbuckle is adjusted to the angle at the ankle joint that will facilitate standing and walking. It is indicated for any post operative management of ankle contractures, conservative treatment of contracture or any condition where there is unbalanced muscle strength. The elbow turnbuckle is used to apply a dynamic low-load force to the elbow. It can be used for any elbow flexion or extension contracture. The elbow turnbuckle also treats muscle imbalance. It can be used postoperatively in the functional recovery phase. The knee turnbuckle applies a low-load dynamic force to the knee. The force can be adjusted in small increments to treat flexion and extension contractures. The knee turnbuckle is indicated for conservative or post-operative management. According to the requester, there are no other braces that can be used for low-load force while being

functional. The products coded at E1801, E1811 and E1816 are all therapy devices. The turnbuckle devices are considered dynamic splinting devices that would be worn 8 - 12 hours per day, replacing serial casting.

CMS HCPCS Preliminary Decision:

These are static devices, and as such: existing code E1801 "STATIC PROGRESSIVE STRETCH ELBOW DEVICE, EXTENSION AND/OR FLEXION, WITH OR WITHOUT RANGE OF MOTION ADJUSTMENT, INCLUDES ALL COMPONENTS AND ACCESSORIES" describes the elbow orthoses; existing code E1811 "STATIC PROGRESSIVE STRETCH KNEE DEVICE, EXTENSION AND/OR FLEXION, WITH OR WITHOUT RANGE OF MOTION ADJUSTMENT, INCLUDES ALL COMPONENTS AND ACCESSORIES" describes the knee orthosis; and existing code E1816 "STATIC PROGRESSIVE STRETCH ANKLE DEVICE, FLEXION AND/OR EXTENSION, WITH OR WITHOUT RANGE OF MOTION ADJUSTMENT, INCLUDES ALL COMPONENTS AND ACCESSORIES" describes the ankle orthosis that is the subject of this request.

Medicare Payment:

The payment rules associated with the existing codes apply to these products.
Pricing = 36

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with the workgroup's preliminary decision that turnbuckle devices are static progressive stretch devices. According to the speaker, the pressure on the turnbuckle can continually be adjusted up, which makes the device dynamic. The turnbuckle provides a constant dynamic stretch to the joint, while providing protection to the joint during functional activity. The speaker claimed that this product is used for contractures, is intended for single patient use, and is not refurbished or re-rented. The speaker requested that CMS reconsider the original request to establish 3 new "L" codes for these turnbuckle devices.

HCPCS Public Meeting Agenda Item #9
May 28, 2009

Attachment: #09.059

Topic/Issue:
Request to establish a code for a dynamic dorsal night splint, trade name: D2 Night Splint. Applicant's suggested language: Lxxxx "Dynamic ankle foot orthosis, including soft interface material, adjustable for fit, for positioning, may be used for minimal ambulation/maintaining ROM, prefabricated, includes fitting and adjustment"

Background/Discussion:
According to the requester, D2 night splints are intended to stretch the plantar fascia and foot/calf musculature while the patient rests or sleeps. However, the D2 night splint allows a more gradual stretch, and allows the patient to progress as their tolerance in increased. The low-load stretching also allows the patient to maintain their gains in range of motion. An adjustable dynamic cord and an articulating dorsal shell control the degree of stretch. There are multiple cord hooks on the anterior side of the splint to allow adjustment of the cord tension. The cord hooks are numbered, allowing the patient to follow their progress. The range of motion indicator (markings on the hinge) allows the patient to monitor and the physician to document progress. The D2 is intended for patients with plantar fasciitis, achilles tendonitis, post-operative immobilization of the ankle, plantar flexion contractures, tendon repair, stroke/foot drop, tibial tendonitis, etc. The D2 night splint is made of foam, Primaflex, HTH 745, binding, elastic shock cord, zipper pull, rigid shell, and mesh. According to the requester, code L4396 "STATIC ANKLE FOOT ORTHOSIS, INCLUDING SOFT INTERFACE MATERIAL, ADJUSTABLE FOR FIT, FOR POSITIONING, PRESSURE REDUCTION, MAY BE USED FOR MINIMAL AMBULATION, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT" describes a static night splint, however; no code exists to describe a dynamic night splint that provides a progressive stretching of the muscles, maintains range of motion, and has a range of motion indicator.

CMS HCPCS Preliminary Decision:
Revise code L4396 which currently reads: "STATIC ANKLE FOOT ORTHOSIS, INCLUDING SOFT INTERFACE MATERIAL, ADJUSTABLE FOR FIT, FOR POSITIONING, PRESSURE REDUCTION, MAY BE USED FOR MINIMAL AMBULATION, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT" to instead read “STATIC OR DYNAMIC ANKLE FOOT ORTHOSIS, INCLUDING SOFT INTERFACE MATERIAL, ADJUSTABLE FOR FIT, FOR POSITIONING, MAY BE USED FOR MINIMAL AMBULATION, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT”. This revision is intended to clarify that this code is also intended for use for dynamic devices. In fact, the predicate product for this code is a dynamic device. Revised code L4396 adequately describes this product.

Medicare Payment:
The payment rules associated with the existing code apply to this product. Pricing = 38

Summary of Primary Speaker Comments at the Public Meeting:
The primary speaker agreed with CMS' preliminary decision.

HCPCS Public Meeting Agenda Item #10
May 28, 2009

Attachment: #09.060

Topic/Issue:
Request to establish a code for a dynamic splint, trade name: Ankle Dorsiflexion Dynasplint® (ADFD) Type IV System. Applicant's suggested language: "Dynamic ankle dorsiflexion device, bilateral length and tension adjustable struts, custom fitted, includes soft interface material."

Background/Discussion:
According to the requester, the Ankle Dorsiflexion Dynasplint (ADFD) system is a dynamic splint designed to restore range of motion (ROM) in a contracted ankle. It is indicated for orthopedically or neurologically caused dorsiflexion deficit in ankle ROM. The ADFD Type IV is commonly worn at night while the wearer is asleep. According to the applicant, existing HCPCS code E1815 "DYNAMIC ADJUSTABLE ANKLE EXTENSION/FLEXION DEVICE, INCLUDES SOFT INTERFACE MATERIAL" does not adequately describe this product because it does not describe bilateral stainless steel struts, and limb length accommodations during the fitting and dynamic tension adjustment. The ADFD Type IV is vastly different than other devices currently coded at E1815 including the ADFD Type III system. The ADFD Type IV system provides a clinical advantage based on advanced design and technology in at least one of 4 key areas that provide a "significantly superior level of care". Specifically: (1) The ADFD Type IV uses welded stainless steel bilateral struts with pull-button technology for length and rotational stability and a circular tension control read out window that enables a patient to easily stay within recommended tension guidelines. This promotes constant, even force across the ankle joint, avoiding torsion, shearing and deterioration of the connective tissue. Proper positioning along the midline and sides of the leg is achieved through cuff and foot plate adjustment. Other devices employ a unilateral strut and tensioning system that can shift out of position during wear and risk causing further damage to connective tissue. (2) The ADFD Type IV uses two industrial strength compression springs, (one in each strut). These quality springs generate greater range of force and maintain better consistency of stretch when compared with coil springs used in other devices, which are weaker and degenerate over time. (3) The ADFD Type IV uses telescoping, length adjustable struts that permit the maximum lever arm available to apply stretch. Devices without length adjustable struts do not enable individualized maximization of stretch and thereby reduce clinical outcomes, by comparison. (4) The ADFD Type IV soft interface is custom-fit to provide even stretch, displace pressure and protect skin integrity. This increases safety, efficacy, comfort and compliance. Use of devices that do not include custom-fitting or "high-level" custom-fitting could result in adverse effects such as sores, and do not ensure precise application of stretch. And finally, "there exists a national program operating need to establish this new code due to the fact that reimbursement rates tied to existing codes are insufficient to reimburse for the Ankle Dorsiflexion

Dynasplint Type IV System." The advanced technologies and extensive custom fitting of the system are not inadequately covered by the reimbursement without a coding change.

CMS HCPCS Preliminary Decision:
Existing code E1815 "DYNAMIC ADJUSTABLE ANKLE 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. Pricing = 36

Summary of Primary Speaker Comments at the Public Meeting:
The primary speaker disagreed with the workgroup's preliminary coding decision and also commented that Medicare reimbursement is insufficient. According to the speaker, the existing codes are general and do not describe the specific device features/components (e.g., adjustable length, custom fitting) of the Dynasplint systems that are the subject of this request. Therefore, the existing codes do not allow for differentiation of dynamic splint devices that lead to a significantly different treatment outcome (ref. Article in Journal of Sports Rehabilitation not yet published). The speaker also stated that the Medicare fee associated with the existing code is so low that the reimbursement fails to cover expenses associated with providing the products and services. The speaker claimed that a national program operating need for unique codes exists based on a claim that "insurers are unable/unwilling to reimburse properly for the Dynasplint System based upon the current coding and corresponding Medicare fee schedule."

HCPCS Public Meeting Agenda Item #10
May 28, 2009

Attachment: #09.061

Topic/Issue:
Request to establish a code for a dynamic splint, trade name: Elbow Extension Dynasplint® (EED) Type III System. Applicant's suggested language: "Dynamic elbow extension device, bilateral length and tension adjustable struts, custom fitted, includes soft interface material"

Background/Discussion:
According to the requester, the Elbow Extension Dynasplint® (EED) Type III System is a dynamic splint designed to restore range of motion in a contracted elbow. It is indicated for patients with an orthopedic or neurologically caused extension deficit in the elbow range of motion. The EED system is commonly worn at night while a patient is asleep. According to the applicant, none of the dynamic splinting devices currently coded at E1800 "Dynamic adjustable elbow extension/flexion device, includes soft interface material", including the EED Type II System are designed with all the facets of the EED Type III System. The EED Type III provides a clinical advantage based on advanced design and technology in at least one of 4 key areas that provide a "significantly, superior level of care". Specifically: 1) The EED Type III uses welded stainless steel bilateral struts with pull-button technology for length and rotational stability and a circular tension control readout window that enables a patient to easily stay within recommended tension guidelines. This promotes consistent force, and tension directly in line with the plane of motion of the joint. Other devices employ a unilateral strut and tensioning system which can easily shift out of position and risk causing further damage to connective tissue. 2) The EED Type III uses two industrial strength compression springs (one in each strut). These quality springs generate a greater range of force and maintain better consistency of stretch when compared with coil springs used in other devices, which are weaker and degenerate over time. 3) The EED Type II uses telescoping, length adjustable struts that permit the maximum lever arm available to apply stretch. Devices without length adjustable struts do not enable individualized maximization of stretch and thereby reduce clinical outcomes, by comparison. 4) The EED Type III soft interface is custom-fit to provide even stretch, displace pressure and protect skin integrity. This increases safety, efficacy, comfort and compliance. Use of devices that do not include custom fitting or "high-level" custom fitting could result in adverse effects such as sores, and do not ensure precise application of stretch. And finally, "there exists a national program operating need to establish this new code due to the fact that reimbursement rates tied to existing codes are insufficient to reimburse for the Elbow Extension Dynasplint Type III System." The advanced technologies and extensive custom fitting of the system are not inadequately covered by the reimbursement without a coding change.

CMS HCPCS Preliminary Decision:
Existing code E1800 "DYNAMIC ADJUSTABLE ELBOW EXTENSION/FLEXION, INCLUDES SOFT INTERFACE MATERIAL" 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. Pricing = 36

Summary of Primary Speaker Comments at the Public Meeting:
The primary speaker disagreed with the workgroup's preliminary coding decision and also commented that Medicare reimbursement is insufficient. According to the speaker, the existing codes are general and do not describe the specific device features/components (e.g., adjustable length, custom fitting) of the Dynasplint systems that are the subject of this request. Therefore, the existing codes do not allow for differentiation of dynamic splint devices that lead to a significantly different treatment outcome (ref. Article in Journal of Sports Rehabilitation not yet published). The speaker also stated that the Medicare fee associated with the existing code is so low that the reimbursement fails to cover expenses associated with providing the products and services. The speaker claimed that a national program operating need for unique codes exists based on a claim that "insurers are unable/unwilling to reimburse properly for the Dynasplint System based upon the current coding and corresponding Medicare fee schedule."

HCPCS Public Meeting Agenda Item #10
May 28, 2009

Attachment: #09.062

Topic/Issue:
Request to establish a code for a dynamic splint, trade name: Knee Extension Dynasplint® (KED) Type III System. Applicant's suggested language: "Dynamic knee extension device, bilateral length and tension adjustable struts, includes soft interface material"

Background/Discussion:
According to the requester, the Knee Extension Dynasplint (KED) system is a dynamic splint designed to restore range of motion (ROM) in a contracted knee. It is indicated for orthopedically or neurologically caused extension deficit in knee ROM. The KED Type III is commonly worn at night, while the wearer is asleep. According to the requester, existing HCPCS code E1810 "DYNAMIC ADJUSTABLE KNEE EXTENSION/FLEXION DEVICE, INCLUDES SOFT INTERFACE MATERIAL" does not describe this product because it does not describe the bilateral stainless steel struts, and limb length accommodations during the fitting and dynamic tension adjustment. In addition, none of the dynamic splinting devices currently coded at E1810 including the KED Type III system, are designed with all the facets included in the KED Type III system. The KED Type III provides a clinical advantage based on advanced design and technology in at least one of 4 key areas that provide a "significantly superior level of care". Specifically: (1) The KED Type II uses welded stainless steel bilateral struts with pull-button technology for length and rotational stability and a circular tension control readout window that enables a patient to easily stay within recommended tension guidelines. This promotes constant, even force in line with the plane of motion of the knee joint, avoiding torsion, shearing and deterioration of the connective tissue. Other devices employ a unilateral strut and tensioning system that can shift out of position during wear and risk causing further damage to connective tissue and can be detrimental to rehabilitation. (2) The KED Type III uses two industrial strength compression springs, (one in each strut). These quality springs generate greater range of force and maintain better consistency of stretch when compared with coil springs used in other devices, which are weaker and degenerate over time. (3) The KED Type III uses telescoping, length adjustable struts that permit the maximum lever arm available to apply stretch. Devices without length adjustable struts do not enable individualized maximization of stretch and thereby reduce clinical outcomes, by comparison. (4) The KED Type III soft interface is custom-fit to provide even stretch, displace pressure and protect skin integrity. This increases safety, efficacy, comfort and compliance. Use of devices that do not include custom-fitting or "high-level" custom-fitting could result in adverse effects such as sores, and do not ensure precise application of stretch. And finally, "there exists a national program operating need to establish this new code due to the fact that reimbursement rates tied to existing codes are insufficient to reimburse for the Knee

Extension Dynasplint Type III System." The advanced technologies and extensive custom fitting of the system are not inadequately covered by the reimbursement without a coding change.

CMS HCPCS Preliminary Decision:
Existing code E1810 "DYNAMIC ADJUSTABLE KNEE 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. Pricing = 36

Summary of Primary Speaker Comments at the Public Meeting:
The primary speaker disagreed with the workgroup's preliminary coding decision and also commented that Medicare reimbursement is insufficient. According to the speaker, the existing codes are general and do not describe the specific device features/components (e.g., adjustable length, custom fitting) of the Dynasplint systems that are the subject of this request. Therefore, the existing codes do not allow for differentiation of dynamic splint devices that lead to a significantly different treatment outcome (ref. Article in Journal of Sports Rehabilitation not yet published). The speaker also stated that the Medicare fee associated with the existing code is so low that the reimbursement fails to cover expenses associated with providing the products and services. The speaker claimed that a national program operating need for unique codes exists based on a claim that "insurers are unable/unwilling to reimburse properly for the Dynasplint System based upon the current coding and corresponding Medicare fee schedule."

HCPCS Public Meeting Agenda Item #11
May 28, 2009

Attachment: #09.081

Topic/Issue:
Request to establish a code for a patient-operated, hand-held, battery-powered device, trade name: Personal Therapy Manager (myPTM). Applicant's suggested language "Personal Therapy Manager (external) for use with implantable programmable infusion pump."

Background/Discussion:
According to the requester, the Personal Therapy Manager (PTM) is a patient-operated, hand-held, battery-powered device utilized with a Medtronic SynchroMed II programmable Infusion System. It is prescribed for people with difficult-to-treat chronic pain, including those suffering from daily pain associated with cancer or cancer treatment. The PTM enables patients to direct the SynchroMed II pump to deliver physician-prescribed supplemental doses of medication to the intrathecal space (fluid-filled area in the spinal column through which pain signals travel). The PTM is prescribed by physicians and is intended for use by patients in their home and, if applicable, their places of work. It is intended for patients with implantable programmable infusion pumps who have chronic intractable pain. While the PTM empowers a patient to respond to symptoms at onset of pain, the physician maintains control over the critical dosing parameters of the infusion protocol including the maximum number of boluses per day and the "lockout interval" which ensures that enough time has elapsed between the patient-activated doses. Patients cannot increase any dosage of medication. Not every pump patient receives a PTM, and the initial PTM is often provided separately from the rest of the pump system, at different episodes of care, in different settings, and by different providers depending on the physician's clinical judgment. The applicant is seeking coding/guidance for hospitals that provide the initial PTM at a clinic visit months after pump implantation and for physicians that supply the PTM in the office, unconnected with the hospital's provision of the implantable pump system. Hospitals cannot use E0783 again or use C1772 for HOPPS, since these codes are for the entire pump system. Hospital as well as physicians also apparently 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 this product 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. Pricing = 32

Summary of Primary Speaker Comments at the Public Meeting:
The primary speaker disagreed with the workgroup's preliminary decision that the external, hand-held PTM for use with implantable programmable infusion pumps is included in the existing code (E0783) for the implantable, programmable pump and all components. The speaker stated that existing code E0783 was established before the hand-held PTM technology was developed, and since the hand-held PTM device is "not integral to" (physically separated from) the pump and not all patients receive one, or receive one at the same time the pump is issued, the PTM ought to be considered a separate device and identified as such via a separate HCPCS code. The speaker claimed that the PTM, by itself, meets the definition of Durable Medical Equipment (DME) and that it is covered under CMS' National Coverage Decision (NCD) 280.14. The speaker also claimed that the PTM performs a different function [e.g., compared with programmable pumps without hand-held PTM devices] and confers a significant therapeutic distinction in that it enables patients with breakthrough pain to deliver supplemental doses of pain medication.

HCPCS Public Meeting Agenda Item #12
May 28, 2009

Attachment: #09.055

Topic/Issue:
Request to establish a new code for a percutaneous electrode array (PEA), trade name: Deepwave(R) Percutaneous Electrode Array (PEA). Applicant's suggested language: Axxxx "Percutaneous electrode array, per set"

Background/Discussion:
According to the requester, PEA electrodes are sterile, single-use disposable percutaneous electrodes comprised of over 1000 micro-needles of 316L surgical stainless steel that are 0.74 millimeters in length and set within a 2.5-inch diameter patch. The electrode array is placed against the skin and is pressed firmly in order to advance the needles through the skin. PEA facilitates the delivery of therapeutic energy through the skin into deep tissue by providing percutaneous access for electrical pain-blocking signals. The Deepwave PEA is used with electrical stimulation pain devices and is indicated for the symptomatic relief of chronic, intractable pain, post surgical and post-traumatic acute pain, post-traumatic pain, and post-operative pain. A pair of electrodes is connected to the stimulation device via a lead wire cable. According to the requester, existing code A4595 does not describe this product because electrodes coded under A4595 describe a transcutaneous, re-useable, non-sterile electrode that does not penetrate the skin surface and does not provide percutaneous delivery. Percutaneous electrodes are sterile, single-use, and comprised of a large micro-needle array that breaks the skin. Manufacturing costs are significantly higher than a standard hydrogel electrode. The significant difference between transcutaneous surface electrodes and percutaneous electrodes warrants consideration of a separately identifiable code for the percutaneous electrode array.

CMS HCPCS Preliminary Decision:
Existing code A4595 "ELECTRICAL STIMULATOR SUPPLIES, 2 LEAD, PER MONTH, (E.G. TENS, NMES)" adequately describes the product that is the subject of this request.

Medicare Payment:
The payment rules associated with the existing code apply to this product. Pricing = 34

Summary of Primary Speaker Comments at the Public Meeting:
The primary speaker disagreed with the workgroup's preliminary decision. According to the speaker the Percutaneous Electrode Array (PEA) differs from other electrodes under existing code A4595 in that the PEA electrode arrays: 1) are not re-useable; 2) are substantially more expensive than conventional electrodes; 3) are not routinely supplied in a clinic or facility; and 4) they are "percutaneous" (pushed-in by a health-care

professional, and “puncture the skin”. For these reasons, the speaker believes that a specific, proprietary supply code is warranted.

HCPCS Public Meeting Agenda Item #13
May 28, 2009

Attachment: #09.065

Topic/Issue:
Request to establish a code for an ultraviolet light panel containing 6' 6-lamp UVB-Narrowband, trade name: Panosol II.

Background/Discussion:
According to the requester, an ultraviolet light panel includes 6' 6-lamp UVB Narrowband and a highly polished reflective material with sockets, ballasts, and an electronic timer. Panosol II is used to treat a number of diseases including: Psoriasis, Eczema, Photodermatoses, Parapsoriasis, etc. Panasol treats diseased areas on the body while the patient stands approximately 6 to 8 inches from the screen surface. The timer is set to the dosage recommended by the health care professional and the reflector allows for maximum uniform distribution of ultraviolet radiation over the areas being treated. This product differs from similar products because it features a controlled prescription timer which enables the doctor to prescribe a home unit with a controlled number of uses. According to the requester, existing codes do not distinguish the type, number or cost of lamps used or differences in the safety and effectiveness of the technology. Existing code E0693 "ULTRAVIOLET LIGHT THERAPY SYSTEM PANEL, INCLUDES BULBS/LAMPS, TIMER AND EYE PROTECTION, 6 FOOT PANEL" was established for products that met old standards, namely, a 4-lamp UVB-Broadband system.

CMS HCPCS Preliminary Decision:
Existing code E0693 "ULTRAVIOLET LIGHT THERAPY SYSTEM PANEL, INCLUDES BULBS/LAMPS, TIMER AND EYE PROTECTION, 6 FOOT PANEL" adequately describes the product that is the subject of your request. Code E0693 is not limited to use by broadband products.

Medicare Payment:
The payment rules associated with the existing code apply to this product. Pricing = 32

Summary of Primary Speaker Comments at the Public Meeting:
There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item #14
May 28, 2009

Attachment: #09.049

Topic/Issue:
Request to establish a new code for portable liquid oxygen systems, trade name: HomeLox Portable Liquid Oxygen System. Applicant's suggested language "Portable liquid oxygen system, rental; home liquefier used to fill portable liquid oxygen devices; includes portable container, supply reservoir, contents gauge, cannula or mask, and tubing." As an alternative, the applicant suggests modifying the language of existing code K0738 which currently reads: "Portable gaseous oxygen system, rental; home compressor used to fill portable oxygen cylinders; includes portable containers, regulator, flowmeter, humidifier, cannula or mask, and tubing" to add liquid transfill generators.

Background/Discussion:
According to the requester, the HomeLox Portable Liquid Oxygen System (HomeLox) is a liquid oxygen transfill system for home use that generates and stores 93% +/- 3% liquid oxygen. The HomeLox automatically replenishes liquid oxygen stored in the base unit. It collects room air and converts it into prescription grade liquid oxygen by lowering the temperature of the oxygen to -279 degrees Fahrenheit (-173 degrees Celsius). The device then stores the liquid oxygen until the patient requires access to additional oxygen for portable use. The HomeLox is composed of an oxygen generator (also sometimes referred to as a compressor or concentrator) and a low temperature refrigeration system. The GoLox-93, a component of Home Lox, is an insulated portable liquid oxygen container that the oxygen user can fill whenever necessary, allowing access to portable oxygen therapy. Together the Home Lox and GoLox can be classified as an oxygen generating portable equipment (OGPE) system. The proposed new code or revised HCPCS code plus code E0434 - "Portable liquid oxygen system, rental"; together would adequately describe the HomeLox Portable Liquid Oxygen System, which includes the GoLox tank as a component. Code K0738, as it currently reads, by itself, describes portable gaseous oxygen generating systems for use with cylinders. This code does not make reference to liquid oxygen generating systems and does not reference use of portable liquid systems.

CMS HCPCS Preliminary Decision:
Establish Exxxx PORTABLE LIQUID OXYGEN SYSTEM, RENTAL; HOME LIQUEFIER USED TO FILL PORTABLE LIQUID OXYGEN CONTAINERS, INCLUDES PORTABLE CONTAINERS, REGULATOR, FLOWMETER, HUMIDIFIER, CANNULA OR MASK AND TUBING, WITH OR WITHOUT SUPPLY RESERVOIR AND CONTENTS GAUGE

Medicare Payment:
Based on guidance contained in an informal benefit category determination, we believe that the item would be paid in accordance with the payment rules that apply to oxygen and oxygen equipment.

Summary of Primary Speaker Comments at the Public Meeting:
The primary speaker agreed with the workgroup's preliminary decision and stated that the proposed new code would "appropriately facilitate the rental of such equipment…"

HCPCS Public Meeting Agenda Item #15
May 28, 2009

Attachment: #09.068

Topic/Issue:
Request to establish a code for home oxygen liquefier and portables, trade names: VIAspire Personal Oxygen System: Model 300D VIAspire Liquefier; and Models 300P, 600P, 1200P VIAspire Oxygen Portables. Applicant's suggested language: "Portable liquid oxygen system, rental"

Background/Discussion:
The VIAspire Liquefier converts gaseous oxygen from any concentrator to liquid. It is capable of creating up to 5 L/day from a concentrator, generator or a wall/tank source. The liquefier also stores two liters, so liquid oxygen is always available. Typically the unit runs for four hours per day, liquefying enough oxygen for two fills, or 12 -16 hours ambulatory use, and the portables fill in minutes. This technology is intended as an accessory to an oxygen concentrator and liquid oxygen storage system, for use as an aid or adjunct to delivering supplemental oxygen therapy in the home. The portables provide all day usage for the patient with no need to run tubing through the house. The two smaller portables provide the SmartDose technology feature that helps to maintain higher patient saturation levels during ambulation, supporting greater patient activity. According to the requester, the VIAspire Liquid Portable's design is similar to the standard cryogenic designs in today's portables with a significant difference in a clinically validated superior dosing algorithm. Other conserving devices on the market today do not follow any standard for the volume of oxygen delivered per breath (the dose), therefore patients may receive (substantially) less oxygen per breath than the physician expects or prescribes. This gap is further compounded when the patient attempts to ambulate, which increases their breath rate and oxygen requirements. VIAspire's Smartdose technology can deliver higher saturation levels along with longer ambulation time, leading to better patient outcomes. The Inspired Technologies, Inc. algorithm is responsive to the patient's activity level by monitoring their respiratory rate and supplements the dose as the patient's activity requires. According to the requester, no existing codes define making liquid oxygen in the home, or incorporating smart dose technology in portable units to adjust oxygen dose during elevated breath rates to promote higher saturation during exercise. This product also differs from other products coded at K0738 because the products are gaseous systems, not liquid.

CMS HCPCS Preliminary Decision:
Establish Exxxx PORTABLE LIQUID OXYGEN SYSTEM, RENTAL; HOME LIQUEFIER USED TO FILL PORTABLE LIQUID OXYGEN CONTAINERS, INCLUDES PORTABLE CONTAINERS, REGULATOR, FLOWMETER, HUMIDIFIER, CANNULA OR MASK AND TUBING, WITH OR WITHOUT SUPPLY RESERVOIR AND CONTENTS GAUGE

Medicare Payment:

Based on guidance contained in an informal benefit category determination, we believe that the item would be paid in accordance with the payment rules that apply to oxygen and oxygen equipment.

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

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 and fiscal intermediaries (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).

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 monthly payments for the ongoing delivery of contents continue for 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 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. 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 splints, casts, and other devices used to reduce a fracture or dislocation, dialysis supplies and equipment, and intraocular lenses (IOLs) inserted in physician's offices.