Centers for Medicare & Medicaid Services (CMS)
Healthcare Common Procedure Coding System (HCPCS)
Public Meeting Summary Report
Durable Medical Equipment (DME)-Day 2
Thursday, May 29, 2008

Introduction and Overview

Approximately 40 people attended. The agenda included 10 items.

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: www.cms.hhs.gov/feeschedulegeninfo.

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

Prior to the Public Meetings, CMS HCPCS workgroup meets to review all HCPCS code applications, and to make 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 website 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)
Thursday, May 29, 2008, 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 #08.56
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 #2
Attachment #08.68
Request to establish a code for a dynamic wheelchair seating frame that allows coordinated movement of the seat, back and footrests, trade name: Kids ROCK™ Active Component.

Primary Speaker: Tom Whelan of Sunrise Medical

AGENDA ITEM #3
Attachment #08.109
Request to establish a code for a manual wheelchair with integrated manual standing component, Trade Name: Superstand.

Attachment #08.110
Request to establish a code for a power standing wheelchair, Trade Name: Powerstand Standing Wheelchair (Models PS-2 and HPS-2).

Primary Speaker: Jennifer Hutter of MedSearch Legal Nurse Consultants

AGENDA ITEM #4
Attachment #08.141
Request to establish a code for a power-assist wheelchair accessory for a manual wheelchair, trade name: Tailwind.

Attachment #08.142
Request to establish a code for a power-assist manual wheelchair, trade name: Tailwind.

Primary Speaker: Peter Thomas of Powers Pyles Sutter & Verville PC

AGEDNA ITEM #5
Attachment #08.42
Request to establish a code for a portable knee hyper-extension device, trade name: Elite Seat.

No Primary Speaker

AGENDA ITEM #6
Attachment #08.64
Request to establish a code for knee/ankle flexionater, trade name: ERMI Knee/Ankle Flexionater.

Attachment #08.66
Request to establish a code for an elbow extensionater, trade name: ERMI Elbow Extensionater.

Attachment #08.67
Request to establish a code for a knee extensionater, trade name: ERMI Knee Extensionater.

Attachment #08.70
Request to establish a code for a knee extensionater, trade name: ERMI Shoulder flexionater.

No Primary Speaker

AGEDNA ITEM #7
Attachment #08.97
Request to establish a code for a dynamic splint, trade name: Elbow Extension Dynasplint® (EED) Type III System.

Attachment #08.98
Request to establish a code for a dynamic splint, trade name: Ankle Dorsiflexion Dynasplint® (ADFD) Type IV System.

Attachment #08.99
Request to establish a code for a dynamic splint, trade name: Knee Extension Dynasplint® (KED) Type III System.

Primary Speaker: George Hepburn of Dynasplint Systems, Inc.

AGENDA ITEM #8
Attachment #08.130
Request to establish 2 codes for heavy duty powered pressure reducing mattresses, trade name: Synergy Air Elite (SAE) Surfaces.

No Primary Speaker

AGENDA ITEM #9
Attachment #08.132
Request to establish a code for a moisture-barrier mattress protector, trade name: Protect-A-Bed.

Attachment #08.133
Request to establish a code for a pressure-relieving organic, latex (memory foam) mattress, trade name: Supple-Pedic and Comfor-Pedic.

Attachment #08.134
Request to establish a code for a memory foam and latex pressure-relieving mattress, trade names: Supple-Pedic and Comfor-Pedic.

Attachment #08.135
Request to establish a code for a memory foam and high-density polyurethane foam pressure-relieving mattress.

No Primary Speaker

AGENDA ITEM #10
Attachment #08.53
Request to establish a code for the personal diabetes manager (PDM), component of the OmniPod® Insulin Management System.

Primary Speaker: Dr. Brent O'Connell of Argenta Advisors

HCPCS Public Meeting Agenda #1
May 29, 2008

Attachment #08.56

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 HCPCS Workgroup changed the descriptor of the E2205 code to include ergonomic and contoured handrims within the same code as standard round-tube handrims. The Natural-Fit is significantly different from other handrims coded at E2205 "MANUAL WHEELCHAIR ACCESSORY, HANDRIM WITHOUT PROJECTIONS (INCLUDES ERGONOMIC OR CONTOURED), ANY TYPE, REPLACEMENT ONLY, EACH" 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 fee structures, and (2) has significant therapeutic distinctions based on published documentation of improved clinical outcomes.

CMS HCPCS Preliminary Decision:
Existing code E2205 MANUAL WHEELCHAIR ACCESSORY, HANDRIM WITHOUT PROJECTIONS, ANY TYPE, REPLACEMENT ONLY, EACH adequately describes a category of items with the same or similar function. Clinical information provided by the applicant does not include evidence that would support a claim of superior clinical outcome when using this device, as compared with other devices

categorized at E2205. No insurer identified a national program operating need to differentiate this item based on a contoured thumb slot and contoured oval and multi-friction surfaces.

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. According to the speaker, Natural-Fit does not belong in existing code E2205. The Natural-Fit has a unique ergonomic design and function that targets a specific, documented subpopulation not addressed by handrims in existing codes; specifically, manual wheelchair users who report CTS-related to pain in the hands and wrists. According to the speaker, this claim of significant therapeutic distinctions is based on published documentation of improved clinical outcomes, and the establishment of a new "E" code is clearly merited.

HCPCS Public Meeting Agenda #2
May 29, 2008

Attachment #08.68

Topic/Issue:
Request to establish a code for a dynamic wheelchair seating frame that allows coordinated movement of the seat, back and footrests, trade name: Kids ROCK™ Active Component. Applicant's suggested language: "Wheelchair accessory, dynamic seating frame that allows coordinated movement of the seat, back and footrests".

Background/Discussion:
According to the requester, the dynamic seating frame is designed to be used in conjunction with a wheelchair and accommodates an individual's movement. The mechanism allows an individual seated in a wheelchair to independently extend at the hips and knees when desired for postural relief or in response to abnormal tone. The kinematics of the system facilitates flexion and extension with minimal displacement at the pelvis during movement, and variable spring resistance returns the individual back to their initial posture. The mechanism consists of dynamic seating frame members and plates, joints and linkages and is designed to be attached to a wheelchair frame. The dynamic seating frame requires the addition of appropriate seat and back cushions, and other postural supports may be added as required based on the medical needs of the end user. The Kids Rock Active Component is prescribed and adjusted by the therapist based on the degree of therapeutic intervention that will most benefit the child. The seating system is fitted to the child's seat depth, back height and lower leg length, the proper seating surface is determined and necessary secondary supports are installed to provide postural alignment while enabling the child to move through a variety of functional positions. The hip angle in the neutral position is adjustable. The patient is able to use the chair for longer periods of time due to increased sitting tolerance afforded by the ability to shift weight when needed. Existing wheelchair accessory or wheelchair seating codes only define seat or back cushions, other fixed positioning components or tilt-in-space seating frames. None of the existing codes define the unique function of the dynamic seating frame.

CMS HCPCS Preliminary Decision:
The reported sales volume for wheelchair seating frame was insufficient to support the request for a revision to the national code set. In accordance with HCPCS coding criteria as published on CMS' HCPCS website, there must be sufficient claims activity or volume, as evidenced by 3 months of marketing activity, so that adding a new code enhances the efficiency of the system and justifies the administrative burden of adding the code. Existing code K0108 "WHEELCHAIR COMPONENT OR ACCESSORY, NOT OTHERWISE SPECIFIED" is available for assignment by payers if they deem appropriate.

Medicare Payment:
The payment rules associated with the existing code apply to this product. Pricing = 46

Summary of Primary Speaker Comments at the Public Meeting:
The primary speaker expressed appreciation for the recognition of the technology. He stated disagreed with the workgroup's preliminary decision. Sales have increased 260 percent over the last 6 months (Nov. 2007-April 2008) compared to the previous 6 months (May 2007-Oct. 2007). The primary target population is pediatric individuals diagnosed with cerebral palsy, that require the use of a wheelchair and who cannot self-propel (dependent). The speaker noted that use of miscellaneous codes can be problematic and reiterated the request for a code based on increased sales, the size of the target population, pediatric application, Medicaid and private insurer claims processing needs, and to ensure access.

HCPCS Public Meeting Agenda #3
May 29, 2008

Attachment #08.109

Topic/Issue:
Request to establish a code for a manual wheelchair with integrated manual standing component, Trade Name: Superstand. Applicant's suggested language: "Wheelchair, Stand-up, manual, folding, custom to individual".

Background/Discussion:
According to the requester, the Superstand Standing Wheelchair is a precision built manual wheelchair crafted to meet an individual patient's needs and specific measurements. The chair is intended for patients who have positioning disorders relating to paralysis, paresis or general weakness. The standing component is an integral part of the base of the chair and as such, is not an add-on feature. The Superstand Wheelchair is 65 pounds, and has a weight capacity of 225 pounds. The chair operates (and looks) like any traditional manual wheelchair except it allows the user to stand with ease and security by performing simple operations. The standing chairs are used throughout the day to relieve the pressure and pain of sitting. The requester offers comments regarding "the medical necessity of standing the wheelchair bound patient" as listed in the "RESNA Position on the Application of Wheelchair Standing Devices." According to the requester, the manual-standing wheelchair base has not been recognized in the current codes. The SADMERC assigned K0009 "OTHER MANUAL WHEELCHAIR/BASE", which is a miscellaneous code.

CMS HCPCS Preliminary Decision:
No insurer identified a national program operating need to establish a code to separately identify this standing feature. Existing code K0009 "OTHER MANUAL WHEELCHAIR/BASE" is available for assignment by payers if they deem appropriate.

Medicare Payment:
The payment rules associated with the existing code apply to this product. Pricing =46

Summary of Primary Speaker Comments at the Public Meeting:
The primary speaker disagreed with the workgroup's preliminary decision stating that the Superstand Standing Wheelchair & Powerstand Standing Wheelchair are completely integrated mechanical devices. The stand-up features cannot be appropriately separated from the wheelchair. According to the speaker repositioning is recognized in existing codes for tilt and recline type wheelchairs when, in reality, STANDING wheelchairs provide many more health benefits; standing is more than convenience. The speaker reiterated the request for a code for integrated standing wheelchairs.

HCPCS Public Meeting Agenda #3
May 29, 2008

Attachment #08.110

Topic/Issue:
Request to establish a code for a power standing wheelchair, Trade Name: Powerstand Standing Wheelchair (Models PS-2 and HPS-2). Applicant's suggested language: "Power Standing Wheelchair, Group 4 Standard, Multiple Power Option, Sling/Solid Seat/Back, Patient Weight Capacity Up To And Including 350 Pounds"

Background/Discussion:
According to the requester, the Powerstand Wheelchair is a precision built power wheelchair that is crafted to meet the individual patient's needs and specific measurements. The chair is intended for patients who have positioning disorders relating to paralysis, paresis or general weakness. The standing component is an integral part of the base of the chair and as such, it is not an add-on feature. The chair operates or drives like any traditional power wheelchair except it allows the user to stand with ease and security by performing simple operations. The Powerstand Wheelchair is 103 pounds without the batteries, and has a weight capacity of 350 pounds. The requester offers comments regarding the medical necessity of standing the wheelchair bound patient as listed in the "RESNA Position on the Application of Wheelchair Standing Devices". According to the requester, the add-on features of the power standing component have been recognized in codes E2300 "POWER WHEELCHAIR ACCESSORY, POWER SEAT ELEVATION SYSTEM" and E2301 "POWER WHEELCHAIR ACCESSORY, POWER STANDING SYSTEM". However, these codes do not represent a complete custom power wheelchair with integrated stand abilities. The SADMERC assigned code K0878 "POWER WHEELCHAIR, NOT OTHERWISE CLASSIFIED", which is a miscellaneous code.

CMS HCPCS Preliminary Decision:
No insurer identified a national program operating need to establish a code to separately identify a powered standing wheelchair. Existing code K0898 "POWER WHEELCHAIR, NOT OTHERWISE CLASSIFIED" is available for assignment by insurers, if they deem appropriate, to identify the power wheelchair component of this device. Existing code E2301 "POWER WHEELCHAIR ACCESSORY, POWER STANDING SYSTEM" is available for assignment by insurers, if they deem appropriate, to identify the standing system.

Medicare Payment:
The payment rules associated with the existing codes apply to this product.
For K0898, Pricing =36
For E2301, Pricing =00

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with the workgroup's preliminary decision stating that the Superstand Standing Wheelchair & Powerstand Standing Wheelchair are completely integrated mechanical devices. The stand-up features cannot be appropriately separated from the wheelchair. According to the speaker repositioning is recognized in existing codes for tilt and recline type wheelchairs when, in reality, STANDING wheelchairs provide many more health benefits; standing is more than convenience. The speaker reiterated the request for a code for integrated standing wheelchairs.

HCPCS Public Meeting Agenda #4
May 29, 2008

Attachment #08.141

Topic/Issue:
Request to establish a code for a power-assist wheelchair accessory for a manual wheelchair, trade name: Tailwind.

Background/Discussion:
According to the requester, the Tailwind Power-assist Wheelchair Accessory permits "transitions" mobility, where transition from manual mobility to power mobility does not require the purchase of a completely separate mobility system. It is indicated for manual wheelchair users who can no longer self-propel or prefer the enhanced function and maneuverability that manual wheelchairs provide. The Tailwind is available as a fully-integrated "all-in-one" power assist, or as an accessory, compatible only to a Tailwind Ultra-Lightweight Wheelchair. This request is for the Tailwind power-assist as an accessory. The Tailwind's integrated software and battery-powered lightweight gearboxes help drive the rear wheels of the wheelchair on a variety of different surfaces and terrains, resulting in augmented wheeling. The Tailwind accessory uses a patented series of sensors and microprocessors that provide motorized assistance in direct correlation to the needs of the user. According to the requester, the Tailwind's two gearboxes, two independent controllers, and a battery mount containing a quick release battery are hardwired together, completing a patented "Closed Loop" electronics package that has no competitor. Existing HCPCS code E0986 "MANUAL WHEELCHAIR ACCESSORY, PUSH ACTIVATED POWER ASSIST, EACH" is inadequate to describe the Tailwind Power-Assist accessory for two reasons: 1) E0986 code does not describe the recently-designed and substantial structural and functional improvements to the Tailwind's Power Assist technology; and 2) E0986 code is to be billed separately for each wheel, rather than once for the integrated Tailwind accessory. Billing E0986 twice would lead to over billing and "possible submission of false claims".

CMS HCPCS Preliminary Decision:
Existing code E0986 "MANUAL WHEELCHAIR ACCESSORY, PUSH ACTIVATED POWER ASSIST, EACH" (1 unit per chair) 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. According to the speaker, the Tailwind power-assist component is a fully integrated system that is not separately housed in each wheel of the wheelchair. The speaker stated that existing code E0986 does not adequately reflect the significant functional and structural differences of the Tailwind power-assist technology.

HCPCS Public Meeting Agenda #4
May 29, 2008

Attachment #08.142

Topic/Issue:
Request to establish a code for a power-assist manual wheelchair, trade name: Tailwind.

Background/Discussion:
According to the requester, the Tailwind Power-assist Wheelchair is an innovative mobility device designed to significantly improve ease of propulsion yet maintain the enhanced maneuverability and functional independence that manual wheelchairs provide. The Tailwind is the only fully integrated, "all-in-one" power-assist wheelchair on the market today. The frame is constructed from high strength aircraft aluminum and is offered in multiple sizes, configurations and colors. It is available with comfortable and extremely lightweight carbon fiber seat and back seating surfaces. A fold-down backrest, quick release wheels and a removable battery make it compact and very easy to transport. The Tailwind's integrated software and battery-powered lightweight gearboxes help drive the rear wheels of the wheelchair on a variety of different surfaces and terrains, resulting in augmented wheeling. As an integrated system, the frame, power source and wheels of the Tailwind are not designed to, and cannot function as, accessories to other manual wheelchairs. The fully-integrated Tailwind weighs approximately 45 pounds. The Tailwind power assist accessory uses a patented series of sensors and microprocessors that provide motorized assistance in direct correlation to the needs of the user. According to the requester, the Tailwind's two gearboxes, two independent controllers, and a battery mount containing a quick release battery are hardwired together, completing a patented "Closed Loop" electronics package that has no competitor. Existing HCPCS codes E0986 "MANUAL WHEELCHAIR ACCESSORY, PUSH ACTIVATED POWER ASSIST, EACH" and K0004 "HIGH STRENGTH, LIGHTWEIGHT WHEELCHAIR" are inadequate to describe the Tailwind for 3 reasons: 1) E0986 code does not describe the recently-designed and substantial structural and functional improvements to the Tailwind's Power Assist technology; 2) E0986 code is to be billed separately for each wheel, rather than once for the integrated Tailwind accessory. Billing E0986 twice would lead to over billing; and 3) K0004, originally assigned to the iGlide manual wheelchair in conjunction with the accessory power assist code does not describe the substantial redesign [from iGlide to Tailwind] as an ultra-lightweight manual wheelchair to which the power-assist technology has been incorporated.

CMS HCPCS Preliminary Decision:
Existing codes K0004 "HIGH STRENGTH, LIGHTWEIGHT WHEELCHAIR" and E0986 "MANUAL WHEELCHAIR ACCESSORY, PUSH ACTIVATED POWER ASSIST, EACH" (1 unit per chair) adequately describes the product that is the subject of this request.

Medicare Payment:
The payment rules associated with the existing codes apply to this product.
For E0986, Pricing =32
For K0004, Pricing = 36

Summary of Primary Speaker Comments at the Public Meeting:
The primary speaker disagreed with the workgroup's preliminary decision. The speaker stated that a new code is necessary for the integrated Tailwind Power-Assist Wheelchair because no present code or combination of codes adequately describes the integrated device. The speaker suggested that the use of the parenthetical "1 unit per chair" causes billing confusion. The speaker also stated that the chair itself is significantly modified to meet K0004 criteria.

HCPCS Public Meeting Agenda #5
May 29, 2008

Attachment #08.42

Topic/Issue:
Request to establish a code for a portable knee hyper-extension device, trade name: Elite Seat. Applicant's suggested language: "Hyper-extension device: Knee specific, portable, patient controlled, continuous passive, HYPER-Extension device with an internal cabling system and ratcheted tension control, specific for supine use."

Background/Discussion:
According to the requester, Elite Seat is a portable knee HYPER-extension device that provides an exclusively patient controlled continuous passive stretch to the knee joint. The Elite Seat is designed to stretch the knee joint to its normal state of HYPER-extension. The device can be used for non-operative and pre/post operative indications. 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 deconditioned knee with flexion contracture. According to the applicant, existing code E1811 "STATIC PROGRESSIVE STRETCH KNEE DEVICE, EXTENSION AND/OR FLEXION, WITH OR WITHOUT RANGE OF MOTION ADJUSTMENT, INCLUDES ALL COMPONENTS AND ACCESSORIES", disregards the need for hyper-extension past zero degrees which is crucial to successful rehabilitation, and "a unique code is important to assure adequate compensation…"

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. Code E1811 does not specify degrees of extension or flexion, therefore it does not exclude this device.

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.

HCPCS Public Meeting Agenda #6
May 29, 2008

Attachment #08.64

Topic/Issue:
Request to establish a code for knee/ankle flexionater, trade name: ERMI Knee/Ankle Flexionater. Applicant's suggested language: "Patient actuated serial stretch knee flexion device, variable load/variable position, patient controlled, hydraulically powered with torque capacity above 125 ft-lbs".

Background/Discussion:
According to the requester, the Knee/ankle flexionater is medical equipment prescribed specifically for patients with a diagnosis of arthrofibrosis or contracture of the knee or ankle. The Knee/ankle flexionater is a self-contained, fully patient controlled, variable load/variable position medical equipment that utilizes a hydraulic pump and quick-release mechanism that allows patients to perform "maximum-stretch-intensity" therapy sessions, alternately stretching and relaxing the scar tissue and adhesions surrounding the affected joints. Torque capacity of the device far exceeds the required levels of 100ft-lbs shown to be delivered to arthrofibrotic patients in out-patient physical therapy. To use the device, the patient sits in the chair, puts his/her foot in the cradle and pulls a lever. Through a combination of therapy and home exercise programs, most patients regain joint range of motion, strength and dexterity, and return to the activities of daily living. 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, the ERMI Knee/ankle flexionater should be uniquely coded and differentiated from other SPS devices currently coded at E1811 "STATIC PROGRESSIVE STRETCH KNEE DEVICE, EXTENSION AND/OR FLEXION, WITH OR WITHOUT RANGE OF MOTION ADJUSTMENT, INCLUDES ALL COMPONENTS AND ACCESSORIES" and E1816 "STATIC PROGRESSIVE STRETCH ANKLE DEVICE, FLEXION AND/OR EXTENSION, WITH OR WITHOUT RANGE OF MOTION OF ADJUSTMENT, INCLUDES ALL COMPONENTS AND ACCESSORIES" because it: 1) has torque potential well above the clinically required levels; 2) is simple for the patient to get into and use leading to high patient compliance and accessibility for older patients with physical limitations and; 3) can be used at home by the patient with the required frequency and duration.

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 the product that is the subject of this request. The amount of torque applied is dependent upon the individual. No insurer (i.e., Medicare, Medicaid, Private Insurance Sector) identified a national program operating need to specify the amount of torque in the code descriptor. Use of code E1810, E1812, E1816 or E1399 is inappropriate.

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.

HCPCS Public Meeting Agenda #6
May 29, 2008

Attachment #08.66

Topic/Issue:
Request to establish a code for an elbow extensionater, trade name: ERMI Elbow Extensionater. Applicant's suggested language: "Patient actuated serial stretch elbow extension device, variable load/variable position, patient controlled, pneumatically powered with capacity of delivering high-intensity torque to the joint".

Background/Discussion:
According to the requester, the Elbow extensionater is a device that facilitates and accelerates recovery from decreased range of motion of the elbow joint for patients diagnosed with arthrofibrosis. The Elbow extensionater is a self-contained, fully patient controlled, variable load/variable position medical equipment 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. Torque capacity of the device far exceeds the required levels to be delivered to arthrofibrotic patients in out-patient physical/occupational therapy. Through a combination of therapy and home exercise programs most patients regain joint range of motion, strength and dexterity, and return to the activities of daily living. To use the ERMI elbow extensionater the patient slides his/her arm into the device and begins therapy by squeezing the bulb to inflate the air bladder and apply a torque about the elbow. According to the requester, this elbow extensionater should be uniquely coded and differentiated from other SPS devices currently coded at E1801 "STATIC PROGRESSIVE STRETCH ELBOW DEVICE, EXTENSION AND/OR FLEXION, WITH OR WITHOUT RANGE OF MOTION ADJUSTMENT, INCLUDES ALL COMPONENTS AND ACCESSORIES" because it: 1) has torque potential well above the clinically required levels; 2) is simple for the patient to get into and use leading to high patient compliance and accessibility for older patients with physical limitations; and 3) can be used at home by the patient with the required frequency and duration.

CMS HCPCS Preliminary Decision:
Existing code E1801 "STATIC PRGRESSIVE STRETCH ELBOW 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. The amount of torque applied is dependent upon the individual. No insurer (i.e., Medicare, Medicaid, Private Insurance Sector) identified a national program operating need to specify the amount of torque in the code descriptor. Use of code L3740 is inappropriate.

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.

HCPCS Public Meeting Agenda #6
May 29, 2008

Attachment #08.67

Topic/Issue:
Request to establish a code for a knee extensionater, trade name: ERMI Knee Extensionater. Applicant's suggested language: "Patient actuated serial stretch knee extension device, variable load/variable position, patient controlled, pneumatically powered with capacity to deliver torque above 125 ft-lbs. to the joint".

Background/Discussion:
According to the requester, the Knee extensionater is a device that facilitates and accelerates recovery from decreased range of motion of the knee joint for patients diagnosed with arthrofibrosis. The knee extensionater is fully a self-contained, patient controlled, variable load/variable position medical equipment 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. Torque capacity of the device far exceeds the required levels of 100 ft-lbs. shown to be delivered to arthrofibrotic patients in out-patient physical therapy. Through a combination of therapy and home exercise programs most patients regain joint range of motion, strength and dexterity, and return to the activities of daily living. To use the knee extensionater the patient sits with the leg elevated and, places his/her heel in the foot cradle and wraps the air bladder around his/her thigh. With the device in place, the patient squeezes the bulb to inflate the air bladder and apply a torque about the knees. According to the requester, this knee extensionater should be uniquely coded and differentiated from other SPS devices currently coded at E1811 "STATIC PROGRESSIVE STRETCH KNEE DEVICE, EXTENSION AND/OR FLEXION, WITH OR WITHOUT RANGE OF MOTION ADJUSTMENT, INCLUDES ALL COMPONENTS AND ACCESSORIES" because it: 1) has torque potential well above the clinically required levels; 2) is simple for the patient to get into and use leading to high patient compliance and accessibility for older patients with physical limitations; and 3) can be used at home by the patient with the required frequency and duration.

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 the product that is the subject of this request. The amount of torque applied is dependent upon the individual. No insurer (i.e., Medicare, Medicaid, Private Insurance Sector) identified a national program operating need to specify the amount of torque in the code descriptor. Use of code L1847 "KNEE ORTHOSIS, DOUBLE UPRIGHT WITH ADJUSTABLE JOINT, WITH INFLATABLE AIR SUPPORT CHAMBER(S), PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT", L2999 "LOWER EXTREMITY ORTHOSES, NOT OTHERWISE SPECIFIED" or E1399 "DURABLE MEDICAL EQUIPMENT, MISCELLANEOUS" is inappropriate.

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.

HCPCS Public Meeting Agenda #6
May 29, 2008

Attachment #08.70

Topic/Issue:
Request to establish a code for a shoulder flexionater, trade name: ERMI Shoulder flexionater. Applicant's suggested language: "Patient actuated serial stretching shoulder device, variable load/variable position, patient controlled, hydraulically powered with capacity of delivering high-intensity torque to the joint".

Background/Discussion:
According to the requester, the shoulder flexionater facilitates and accelerates recovery from decreased range of motion of the shoulder joint for patients diagnosed with arthrofibrosis. The shoulder flexionater is a self-contained, fully patient controlled, variable load/variable position medical equipment that utilizes a hydraulic pump and quick-release mechanism to allow patients to perform "maximum-stretch-intensity" therapy sessions, alternately stretching and relaxing the scar tissue and adhesions surrounding the affected joints. Torque capacity of the device reached beyond the high intensity stretching levels called for in the soft tissue mechanics model. Through a combination of therapy and home exercise programs most patients regain joint range of motion, strength and dexterity, and return to the activities of daily living. To use the shoulder flexionater the patient sits up in the chair, puts his/her arm in the cradle and pulls a lever. The shoulder 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, the ERMI shoulder flexionater should be uniquely coded and differentiated from other SPS devices coded at E1841 "STATIC PROGRESSIVE STRETCH SHOULDER DEVICE, WITH OR WITHOUT RANGE OF MOTION ADJUSTMENT, INCLUDES ALL COMPONENTS AND ACCESSORIES" because it: 1) has torque potential well above the clinically required levels; 2) is simple for the patient to get into and use leading to high patient compliance and accessibility for older patients with physical limitations; and 3) can be used at home by the patient with the required frequency and duration.

CMS HCPCS Preliminary Decision:
Existing code E1841 "STATIC PROGRESSIVE STRETCH SHOULDER DEVICE, WITH OR WITHOUT RANGE OF MOTION ADJUSTMENT, INCLUDES ALL COMPONENTS AND ACCESSORIES" adequately describes the product that is the subject of this request. The amount of torque applied is dependent upon the individual. No insurer (i.e., Medicare, Medicaid, Private Insurance Sector) identified a national program operating need to specify the amount of torque in the code descriptor. Use of L1840 "KNEE ORTHOSIS, DEROTATION, MEDIAL-LATERAL, ANTERIOR CRUCIATE LIGAMENT, CUSTOM FABRICATED" or E1399 "DURABLE MEDICAL EQUIPMENT, MISCELLANEOUS" is inappropriate.

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.

HCPCS Public Meeting Agenda #7
May 29, 2008

Attachment #08.97

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 stainless steel, length and tension adjustable, includes custom fitted 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 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, "the costs in achieving the advanced technologies combined within the EED Type III System are inadequately covered by the reimbursement without a coding change."

CMS HCPCS Preliminary Decision:
Existing code E1800 "DYNAMIC ADJUSTABLE ELBOW EXTENSION/FLEXION DEVICE, INCLUDES SOFT INTERFACE MATERIAL" adequately describes a category of products which performs the same function. No insurer (i.e., Medicare,

Medicaid, Private Insurance Sector) identified a national program operating need to distinguish this product from other products currently coded at E1800.

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 decision. The speaker stated this code is so general as to not allow for differentiation between two or more different products or services that significantly affect the outcome of treatment with dynamic splint. Also, the code description does not account for the devices being custom fitted. On average, it takes between 45 minutes to an hour to custom fit each of the devices to a patient. According to the speaker, the reimbursement associated with this code is so low that the reimbursement fails to provide enough money to cover expenses associated with providing the products and services required by the beneficiary. The speaker discussed the advances in the technology and the evolution of associated costs since the code was originally established, such as a difference in welding method, upgrading of screws, spacers against screws, new "pull-button technology" and multiple "customization" options.

HCPCS Public Meeting Agenda #7
May 29, 2008

Attachment #08.98

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 stainless steel, length and tension adjustable, includes custom fitted 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 patient's 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, the ADFD Type IV is vastly different than other devices currently coded at E1815 "DYNAMIC ADJUSTABLE ANKLE EXTENSION/FLEXION DEVICE, INCLUDES SOFT INTERFACE MATERIAL", including the ADFD Type III system. The ADFD Type IV system provides a clinical advantage based on advanced design and technology in 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, "the costs in achieving the advanced technologies combined within the ADFD Type IV are 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 a category of products which performs the same function. No insurer (i.e., Medicare, Medicaid, Private Insurance Sector) identified a national program operating need to distinguish this product from other products currently coded at E1815.

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 decision. The speaker stated this code is so general as to not allow for differentiation between two or more different products or services that significantly affect the outcome of treatment with dynamic splint. Also, the code description does not account for the devices being custom fitted. On average, it takes between 45 minutes to an hour to custom fit each of the devices to a patient. According to the speaker, the reimbursement associated with this code is so low that the reimbursement fails to provide enough money to cover expenses associated with providing the products and services required by the beneficiary. The speaker discussed the advances in the technology and the evolution of associated costs since the code was originally established, such as a difference in welding method, upgrading of screws, spacers against screws, new "pull-button technology" and multiple "customization" options.

HCPCS Public Meeting Agenda #7
May 29, 2008

Attachment #08.99

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 stainless steel, length and tension adjustable, includes custom fitted 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, none of the dynamic splinting devices currently coded at E1810 "DYNAMIC ADJUSTABLE KNEE EXTENSION/FLEXION DEVICE, INCLUDES SOFT INTERFACE MATERIAL", 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 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, "the costs in achieving the advanced technologies combined within the KED Type III system are inadequately covered by reimbursement without a coding change."

CMS HCPCS Preliminary Decision:
Existing code E1810 "DYNAMIC ADJUSTABLE KNEE EXTENSION/FLEXION DEVICE, INCLUDES SOFT INTERFACE MATERIAL" adequately describes a category of products which performs the same function. No insurer (i.e., Medicare, Medicaid, Private Insurance Sector) identified a national program operating need to distinguish this product from other products currently coded at E1810.

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 decision. The speaker stated this code is so general as to not allow for differentiation between two or more different products or services that significantly affect the outcome of treatment with dynamic splint. Also, the code description does not account for the devices being custom fitted. On average, it takes between 45 minutes to an hour to custom fit each of the devices to a patient. According to the speaker, the reimbursement associated with this code is so low that the reimbursement fails to provide enough money to cover expenses associated with providing the products and services required by the beneficiary. The speaker discussed the advances in the technology and the evolution of associated costs since the code was originally established, such as a difference in welding method, upgrading of screws, spacers against screws, new "pull-button technology" and multiple "customization" options.

HCPCS Public Meeting Agenda #8
May 29, 2008

Attachment #08.130

Topic/Issue:
Request to establish 2 codes for heavy duty powered pressure reducing mattresses, trade name: Synergy Air Elite (SAE) Surfaces.
Applicant's suggested language:
Exxx1: "Heavy duty, powered pressure-reducing air mattress, with weight capacity greater than 300 pounds; width range (39" – 47")"
Exxx2: "Heavy duty, powered pressure-reducing air mattress, with weight capacity greater than 300 pounds; extra wide, width greater than 47""

Background/Discussion:
According to the requester, the Synergy Air Elite Bariatric Low Air Loss Therapy is an alternating pressure and low air loss mattress replacement system. The system is comprised of a pressure regulated blower unit (csi-079) and a mattress replacement (csi-072) with 18 alternating air cells, which rest on a 2" foam base. The surface width is designed to fit on bariatric hospital bed frames. All the cells are ventilated to provide true low air loss therapy. Synergy is designed so that every third cushion deflates in a cyclical manner. The advantage to the patient is that the patient is supported by two thirds more surface area at any given time. This is especially important to address the needs of the bariatric patient. The vented air cushions provide low air loss therapy through the waterproof, vapor permeable cover to address the microclimate of the skin reducing heat and moisture. SAE is used for the bariatric patient (greater than 300 pounds) that requires the management, prevention or treatment of Stage II, III and IV pressure ulcer(s). According to the requester, code E1399 "DURABLE MEDICAL EQUIPMENT, MISCELLANEOUS" does not capture the features of bariatric, heavy-duty pressure reducing air mattresses; and it prevents electronic claims processing.

CMS HCPCS Preliminary Decision:
Existing code E0277 "POWERED PRESSURE-REDUCING AIR MATTRESS" adequately describes the product that is the subject of this request. E0277 includes powered pressure reducing mattresses of any size, dimension or weight capacity.

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.

HCPCS Public Meeting Agenda #9
May 29, 2008

Attachment #08.132

Topic/Issue:
Request to establish a code for a moisture-barrier mattress protector, trade name: Protect-A-Bed.

Background/Discussion:
According to the requester, the moisture barrier mattress protector is a polyurethane barrier film that is waterproof and breathable. It is effective in preventing bacteria and breeding of dust mites (a major cause of asthma, eczema and rhinitis). The moisture barrier also protects and keeps the mattress from getting wet and stained. It moderates temperature and enhances sleeping comfort. The moisture-barrier is intended for all patients who are incontinent. According to the requester, existing codes do not adequately describe the moisture barrier because existing hospital moisture-barriers do not meet the same standards. Specifically, this product can be washed at high temperatures to keep the material "sterilized" without delaminating the polyurethane coating, whereas other products cannot.

CMS HCPCS Preliminary Decision:
No insurer identified a national program operating need to establish a code to separately identify mattress protectors. The moisture barrier is included in the overlay or mattress codes. Existing code A9900 "MISCELLANEOUS DME SUPPLY, ACCESSORY, AND/OR SERVICE COMPONENT OF ANOTHER HCPCS CODE" is available for assignment by payers, if they deem appropriate, in accordance with their programs and policies.

Medicare Payment:
The payment rules associated with the existing code apply to this product. Pricing = 46

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

HCPCS Public Meeting Agenda #9
May 29, 2008

Attachment #08.133

Topic/Issue:
Request to establish a code for a pressure-relieving organic, latex (memory foam) mattress, trade name: Supple-Pedic and Comfor-Pedic.

Background/Discussion:
According to the requester, the Memory Foam mattress is a 2 piece pressure-relieving mattress, made of a 3" Talalay-Latex topper with a 6" latex-base. This is an organic mattress without fire-retardant chemicals. It is used by patients who are allergic to fire-retardant chemicals; patients who need help with sleep-disorders; burn-patients; bed-ridden patients; and patients recovering from orthopedic surgery. Memory foam molds, contours and conforms to the shape of your body as you lay-down on the material. According to the requester, memory foam mattresses do not wear out easily compared to traditional mattresses because they are made of a heavier and denser material. Memory foam reduces and eliminates pressure points because it conforms to the shape of your body. There is less tossing and turning while you're sleeping with a memory foam mattress because your body's natural sleeping position determines the shape of a memory foam mattress. There are also fewer problems with morning soreness. According to the requester, existing codes do not adequately describe this product because existing hospital beds do not meet the same standards.

CMS HCPCS Preliminary Decision:
No insurer (i.e., Medicare, Medicaid, Private Insurance Sector) identified a national program operating need to consider a code to identify this product that has not yet been marketed.

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 #9
May 29, 2008

Attachment #08.134

Topic/Issue:
Request to establish a code for a memory foam and latex pressure-relieving mattress, trade names: Supple-Pedic and Comfor-Pedic.

Background/Discussion:
According to the requester, the Memory Foam mattress is a 2 piece pressure-relieving mattress made of 3" memory foam with a 6" latex-base, made without fire-retardant chemicals. It is used by patients who are allergic to fire-retardant chemicals; patients who need help with sleep-disorders; burn-patients; bed-ridden patients; and patients recovering from orthopedic surgery. Memory foam molds, contours and conforms to the shape of your body as you lay-down on the material. According to the requester, memory foam mattresses do not wear out easily compared to traditional mattresses because they are made of a heavier and denser material. Memory foam reduces and eliminates pressure points because it conforms to the shape of your body. There is less tossing and turning while you're sleeping with a memory foam mattress because your body's natural sleeping position determines the shape of a memory foam mattress. There are also fewer problems with morning soreness. According to the requester, existing codes do not adequately describe this product because existing hospital beds do not meet the same standards.

CMS HCPCS Preliminary Decision:
No insurer (i.e., Medicare, Medicaid, Private Insurance Sector) identified a national program operating need to consider a code to identify this product that has not yet been marketed.

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 #9
May 29, 2008

Attachment #08.135

Topic/Issue:
Request to establish a code for a memory foam and high-density polyurethane foam pressure-relieving mattress.

Background/Discussion:
According to the requester, the Memory Foam mattress is a 2-piece pressure-relieving mattress made of 3" memory foam with a 6" high-density polyurethane foam-base, made without fire-retardant chemicals. It is used by patients who are allergic to fire-retardant chemicals; patients who need help with sleep-disorders; burn-patients; bed-ridden patients; and patients recovering from orthopedic surgery. Memory foam molds, contours and conforms to the shape of your body as you lay-down on the material. According to the requester, memory foam mattresses do not wear out easily compared traditional mattresses, because they are made of a heavier and denser material. Memory foam reduces and eliminates pressure points because it conforms to the shape of your body. There is less tossing and turning while you're sleeping with a memory foam mattress because your body's natural sleeping position determines the shape of a memory foam mattress. There are also fewer problems with morning soreness. According to the requester, existing codes do not adequately describe this product because existing hospital beds do not meet the same standards.

CMS HCPCS Preliminary Decision:
No insurer (i.e., Medicare, Medicaid, Private Insurance Sector) identified a national program operating need to consider a code to identify this product that has not yet been marketed.

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 #10
May 29, 2008

Attachment #08.53

Topic/Issue:
Request to establish a code for the personal diabetes manager (PDM), component of the OmniPod® Insulin Management System. Applicant's suggested language: "External ambulatory insulin delivery and monitoring system, controller for programming, regulating and monitoring insulin infusions with integrated home blood glucose meter"

Background/Discussion:
According to the requester, the PDM is a wireless, menu-driven, hand-held device, similar in look and size to a personal digital assistant. The patient uses the PDM to regulate the infusion of insulin, program the OmniPod with personalized insulin delivery instructions or individualized bolus suggestions and to check blood glucose levels using common blood glucose test strips. The PDM facilitates disease management by seamlessly 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 and OmniPod contain integrated circuitry which enables wireless communications between the two devices at a range of up to two feet omni-directionally. The PDM is specifically matched to the particular OmniPod in use via a wireless protocol established during the OmniPod activation process, but the two devices only communicate with each other during programming of insulin delivery instructions and OmniPod status checks. This design enables secure, unique, and discreet communications between the OmniPod and the PDM, while allowing the patient to manage their diabetes with complete discretion and store the PDM separately when it is not needed. Once insulin delivery is started, the patient uses the PDM to adjust basal rate, program bolus doses, view history records, and check blood glucose as needed. According to the requester, existing code E0607 "HOME BLOOD GLUCOSE MONITOR" does not accurately describe the functionality of the PDM. The blood glucose monitoring function is a secondary feature of the PDM. Its primary function is to provide a user interface used to control and monitor insulin delivery by the OmniPod component of the system.

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. No insurer (i.e., Medicare, Medicaid, Private Insurance Sector) identified a national program operating need to separately code the controller/programming function of the Omnipod.

Medicare Payment:
For E0607, the payment rules associated with the existing code apply to this product.
Pricing = 32
For A9274, the payment rules associated with the existing code apply to this product.
Pricing = 00
For the PDM, based on guidance contained in an informal benefit category determination, 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. The Personal Diabetes Management (PDM) component of the OmniPod Insulin Management System is a diabetes treatment device that does not deliver, but rather regulates the flow of insulin. According to the speaker, there has been confusion from the payer community on how to code for the OmniPod System as it does not fit the definition of either an insulin pump (E0784) or a blood glucose monitor (E0607). The speaker reiterated the request for a code and suggested language different from the original proposal.

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. An additional payment is made for those beneficiaries who require portable oxygen. The beneficiary takes over ownership of the equipment after the 36th monthly payment is made, after which payment for 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 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.