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

Durable Medical Equipment (DME) and Accessories; Orthotics & Prosthetics

Tuesday, June 4, 2013

Introduction and Overview

Approximately 70 people attended. The agenda included 21 items.

Cindy Hake, Chair, of the CMS' HCPCS Coding Workgroup, provided an overview of the HCPCS public meeting procedures as it relates to the overall HCPCS coding process.

Joel Kaiser the Director of the Division of Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Policy, presented an overview of the methods used for setting the payment amount for DME, prosthetics, orthotics and supplies and when the different payment categories are used. The overview was also provided as a written document to the agenda and is attached to this summary. For additional information, the DME payment rules are located at Section 1834 (a) of the Social Security Act. The Medicare fee schedule for DME, Prosthetics, Orthotics and Supplies, and background information, can be accessed and downloaded free of charge at: http:www.cms.gov/DMEPOSFeeSched/.

Prior to the Public Meetings, over the course of several months, the CMS HCPCS Coding Workgroup convene, discuss, and establish preliminary coding recommendations, on all HCPCS code applications. CMS also assigns preliminary recommendations regarding the applicable Medicare payment category and methodology that will be used to set a payment amount for the items on the agenda. The preliminary coding and payment recommendations are posted on the CMS HCPCS web site at http://www.cms.gov/MedHCPCSGenInfo/08_HCPCSPublicMeetings.asp#TopOfPage, as part of the HCPCS public meeting agendas.

Information provided at the CMS HCPCS Public Meetings is considered by the CMS HCPCS Coding Workgroup at a subsequent workgroup meeting. The Workgroup reconvenes after the public meetings and reconsiders its preliminary coding recommendation in light of any new information provided, and formulates its final coding decisions. CMS maintains the permanent HCPCS Level II codes, and reserves final decision making authority concerning requests for permanent HCPCS codes. Final decisions regarding Medicare payment are made by CMS and must comply with the Statute and Regulations. Payment determinations for non-Medicare

insurers, (e.g., state Medicaid Agencies or Private Insurers) are made by the individual state or insurer.

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

The latest information on the process for developing agendas and speaker lists for the public meetings, as well as Guidelines for Proceedings at CMS' Public Meetings can be found on the CMS HCPCS web site specifically at: http://www.cms.gov/MedHCPCSGenInfo/08_HCPCSPublicMeetings.asp#TopOfPage. In addition, the standard application format for requesting a modification to the HCPCS Level II Code Set, along with instructions for completing the application, and background information regarding the HCPCS Level II coding process is available at: http://www.cms.gov/MedHCPCSGenInfo/01_Overview.asp#TopOfPage . The application form is updated annually and posted on the CMS HCPCS web site sometime in the summer. A decision tree, outlining CMS' decision-making criteria is also available at: http://www.cms.gov/MedHCPCSGenInfo/Downloads/decisiontree/pdf .

Centers for Medicare & Medicaid Services (CMS) Healthcare Common Procedure Coding System (HCPCS) Public Meeting Agenda for
Durable Medical Equipment (DME) and Accessories;
Orthotics & Prosthetics
Tuesday, June 4, 2013, 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.

DME

AGENDA ITEM #1
Attachment# 13.086
Request to establish a new Level II HCPCS code with different language than code E0446, which was established in 2010 to identify a portable device that delivers oxygen to a wound bed. Trade Name: TransCu O2®.

No Primary Speaker

AGENDA ITEM #2
Attachment# 13.008
Request to establish a new Level II HCPCS code to identify a sensor augmented external insulin pump (pump only); and to revise the language of existing code E0784. Trade Name: REAL-Time Revel.

Primary Speaker: Dr. Bruce Bode of Atlanta Diabetes Associates

AGENDA ITEM #3
Attachment# 13.084
Request to create "mid-level" codes to identify ventilators that meet the needs of patients who require more than bi-level ventilator support, but who do not yet require a life-support ventilator. The applicant suggests EITHER expanding the language of existing volume control ventilator codes E0461 and E0450 to include volume targeted ventilators with pressure support mode; OR establishing 2 new Level II HCPCS codes to identify volume targeted ventilators with pressure support mode for use with invasive or non-invasive interface. Trade Name: Philips Respironics BiPAP A40 Auto-titrated Ventilatory Support System.

Primary Speaker: Dr. James Lamberti of National Association for Medical Direction of Respiratory Care

AGENDA ITEM #4
Attachment# 13.071
Request to **EITHER**: establish three new Level II HCPCS codes to describe a powered obstructive sleep apnea (OSA) treatment device and components that deliver continuous *negative* pressure in the oral cavity. **OR**: modify existing codes E0601 "Continuous Airway Pressure (CPAP) Device" and accessory codes A7037, A7044 (for tubing and oral interfaces, respectively), to omit references to "positive" pressures. Trade Name: Winx™ Sleep Therapy System.

Primary Speaker: Matt Vaska of ApniCure

AGENDA ITEM #5
Attachment# 13.089
Request to establish a new Level II HCPCS code to identify a lightweight, portable, enclosed negative pressure ventilating chamber, Trade Name: Porta-Lung.

No Primary Speaker

AGENDA ITEM #6
Attachment# 13.060
Request to establish a single new Level II HCPCS code for a portable cervical traction device that applies "pneumatic radial traction", Trade Name: Posture Pump® Cervical Disk Hydrator® (Model 1000).

No Primary Speaker

AGENDA ITEM #7
Attachment# 13.085
Request to establish 2 new Level II HCPCS codes to identify heavy duty tilt seating systems: one code for weight capacity 251 to 450 pounds, and another code for weight capacity 451 to 600 pounds, Trade Name Boss HD Equalizer.

Primary Speaker: Jim Ernst of Burke / Leisure-Lift, Inc.

AGENDA ITEM #8
Attachment# 13.082
Request to establish a new Level II HCPCS code to identify a single-patient use transcutaneous electric nerve stimulator, Trade Name: InterX ® 900, Single Patient System, neurostimulation device.

Primary Speaker: Paul Magee of Neuro Resource Group

AGENDA ITEM #9
Attachment# 13.088
Request to establish a new Level II HCPCS code to identify a device that delivers a combination treatment modality including Transcutaneous Electrical Nerve Stimulation (TENS), Light Emitting Diodes (LED) and Low Level Laser Therapy (LLLT), Trade Name: Neruolumen PN-1000.

No Primary Speaker

AGENDA ITEM #10
Attachment# 13.083
Request to establish a series of 4 new Level II HCPCS codes to identify the components of a home phototherapy treatment system, Trade Name: Levia® UVB Select™ Personal Targeted Phototherapy® system, AND to revise existing code E0691 to restore the word "panel".

Primary Speaker: Dr. Ethan Lerner of Lerner Medical Devices, Inc.

AGENDA ITEM #11
Attachment# 13.090
Request to reassign the Hope Crutch to existing Level II HCPCS code E0110 “Crutches, Forearm, Includes Crutches of Various Materials, Adjustable or Fixed, Pair, Complete with Tips and Handgrips”; instead of code E0114 “Crutches Underarm, Other than Wood, Adjustable or Fixed, Pair, With Pads, Tips and Handgrips”.

No Primary Speaker

O&P

AGENDA ITEM #12
Attachment# 13.087
Request to revise the language of existing HCPCS code L8687. Trade Name: Precision Spectra™ Spinal Cord Stimulation (SCS).

Primary Speaker: Matt Gunderman of Boston Scientific Corporation

AGENDA ITEM #13
Attachment# 13.059
Request to establish a new Level II HCPCS code for a single-use "continence control device" intended to prevent the release of stool from an end colostomy while allowing flatus from the stoma to be deodorized and released. Trade Name: Vitala®.

Primary Speaker: Joseph Rolley of ConvaTec, Inc.

AGENDA ITEM #14
Attachment# 13.017
Request to establish a new Level II HCPCS code to identify a Trabecular Micro-Bypass stent, Trade Name: iStent®.

Primary Speaker: Dr. Steven Vold of Vold Vision

AGENDA ITEM #15
Attachment# 13.076
Fourth request to establish a new Level II HCPCS "L" code to uniquely identify a prosthetic cable control and locking system. Trade Name: Sure-Lok™.

No Primary Speaker

AGENDA ITEM #16
Attachment# 13.077
Request to establish a new Level II HCPCS "L" code to identify a bionic ankle-foot prosthetic device, Trade Name: BiOM® iWalk

Primary Speaker: Dr. Hugh Herr of iWalk, Inc.

AGENDA ITEM #17
Attachment# 13.079
Request to EITHER establish a new Level II HCPCS code OR revise existing code L2114 to identify a Tibial Ankle Foot Orthosis (TAFO), Trade Name *PFS Med* TAFO, which is not designed for full weight bearing ambulation, but does allow assisted crutch or walker ambulation due to its lightness and anatomical support.

Primary Speaker: Robin Irish of PFS Med, Inc.

AGENDA ITEM #18
Attachment# 13.073
Request to **EITHER** establish a new Level II HCPCS code to identify a carbon fiber composite ankle foot orthosis, **OR** revise existing code L1932. Trade Name: Noodle®AFO

No Primary Speaker

AGENDA ITEM #19
Attachment# 13.074
Request to establish a new Level II HCPCS code to describe a hip flexion/plantar flexion assist hip-knee-ankle-foot-orthosis (HKAFO), Trade Name: Kickstart Kinetic Orthosis.

Primary Speaker: Brian Glaister of Cadence Biomedical

AGENDA ITEM #20
Attachment# 13.026
Request to establish a new Level II HCPCS code to identify the Bledsoe PHX elbow orthosis.

Primary Speaker: Dr. John Vanderhoof of St. Luke's Medical Center

AGENDA ITEM #21
Attachment# 13.091
Request to establish a new Level II HCPCS base code to identify an AFO design that replaces or supplements the missing posterior calf group function, active plantar flexion. Trade Name: Dynamic Response AFO, or "DR-AFO".

Primary Speaker: Noel Chladek of Bio-Mechanical Composites, Inc.

DME Public Meeting

DME HCPCS Public Meeting Agenda Item #1
June 4, 2013

Attachment# 13.086
Topic/Issue:

Request to establish a new Level II HCPCS code with different language than code E0446, which was established in 2010 to identify a portable device that delivers oxygen to a wound bed. Trade Name: TransCu O2®. Applicant's suggested language: "Continuous diffusion of oxygen therapy device".

Background/Discussion:

According to the requester, the TransCu $O^{2®}$ is a lightweight portable device that delivers a continuous supply of pure oxygen. It is comprised of 5 components: 1) the main component which houses internal componentry (proton exchange membrane, oxygen flow sensor, pressure transducer, microprocessor, rechargeable battery, alarm) and operating functions and displays; 2) battery charger; 3) 60 inch cannula; 4) 60 inch cannula extension set; and 5) a "fanny pack". The cannula is placed in the middle of the wound, the cannula and wound are covered with a moisture absorbent dressing, a thin film dressing covers the moisture absorbent dressing creating an oxygen rich environment. The device is used in conjunction with moist wound dressings to treat patients with difficult-to-heal wounds. It incorporates enhanced fuel cell chemistry, utilizing a Proton Exchange membrane (PEM) to electrochemically generate the low-flow of pure oxygen. The portable Continuous Diffusion of Oxygen (CDO) therapy device is different than topical oxygen therapy extremity chambers in that: 1) it delivers oxygen directly to the wound bed under moist wound dressings "vs. topical oxygen therapy"; 2) the source of oxygen is a Proton Exchange Membrane (as opposed to a tank or stationary concentrator; 3) it delivers oxygen continuously (as opposed to 90-minute treatments 3 to 5 times per week); and 4) the oxygen flow rate is very low 3 to 10 ml/hr. (as opposed to 10 LMP pressure). The applicant claims that the "TransCu O® delivers significantly improved medical outcomes in patients with difficult to heal wounds". According to the applicant, code E0446, which was established to identify the TransCu O^{2}® device, does not reflect the portable technology that is designed to deliver a low-flow of oxygen to continuously diffuse the oxygen into a covered moist wound bed at normal atmospheric pressure.

Preliminary Decision:

Existing code E0446 "Topical Oxygen Delivery System, Not Otherwise Specified, Includes All Supplies and Accessories", adequately describes the device that is the subject of this request, which is, in fact, the predicate device for which this code was originally established in 2011.

Medicare Payment:

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

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

DME HCPCS Public Meeting Agenda Item #2
June 4, 2013

Attachment# 13.008
Topic/Issue:

Request to establish a new Level II HCPCS code to identify a sensor augmented external insulin pump (pump only); and to revise the language of existing code E0784 which currently reads "External Ambulatory Infusion Pump, Insulin", to instead read "External Ambulatory Infusion Pump, Insulin, Simple", in order to differentiate, via coding, sensor augmented insulin pumps, and exclude them from code E0784. Trade Name: REAL-Time Revel.

Background/Discussion:

According to the requester, the sensor augmented insulin pump system includes 5 components: the pump, which includes the insulin delivery mechanism and the integrated continuous glucose monitor; transmitter; sensor; infusion set and insulin reservoir. Sensor augmented pumps deliver insulin and also have an integrated continuous glucose monitor (CGM) which monitors the patient's glucose for low and high levels. The pump automatically alerts the patient via alarms so the patient can adjust the insulin delivery. The requester claims a significant therapeutic distinction between sensor augmented insulin pumps and "simple" pumps (that only deliver insulin). Specifically, "integration of insulin infusion with CGM into a single pump results in improved clinical outcomes related to better glycemic control" The requester states that this sensor-augmented insulin pump with an integrated CGM is not only different from "simple" insulin pumps, but also different from "free-standing" CGM devices that are separate from the pump and do not communicate with the pump, in that the integrated device does not require patient self-monitoring and interpretation of glucose levels. According to the requester, integration of the CGM represents a clinical advancement that is not captured in existing code E0784, and numerous 3rd party payers have a need to ditstinguish between "simple" pumps and sensor augmented pumps based on different coverage criteria and payment levels.

Preliminary Decision:

Existing code E0784 "External Ambulatory Infusion Pump, Insulin" adequately describes the product that is the subject of this request

Medicare Payment:

The payment rules associated with the existing code apply to this product if covered.
Pricing =36

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with CMS' preliminary decision and made the following comments in support of the original request to separately identify, via HCPCS coding, sensor-augmented pumps, and to distinguish them from self-described "simple pumps" (without integrated sensors):

1) Sensor augmented pumps (SAPs) are categorized by the FDA as class III devices and as such, should not be coded together with "simple pumps" (which are class II devices).
2) "CMS should administrate what the FDA approves".
3) Inclusion of SAPs in code E0784 is a violation of the Social Security Act.
4) Several payers have a program operating need for differential coding.
5) SAPs confer significantly improved clinical outcomes when compared with "simple pumps" re: A1c control, morbidity and mortality.
6) It is inappropriate to include class II and class III devices together in a competitive Bidding Category.

DME HCPCS Public Meeting Agenda Item #3
June 4, 2013

Attachment# 13.084
Topic/Issue:

Request to create "mid-level" codes to identify ventilators that meet the needs of patients who require more than bi-level ventilator support, but who do not yet require a life-support ventilator. The applicant suggests EITHER expanding the language of existing volume control ventilator codes E0461 and E0450 to include volume targeted ventilators with pressure support mode; OR establishing 2 new Level II HCPCS codes to identify volume targeted ventilators with pressure support mode for use with invasive or non-invasive interface. Trade Name: Philips Respironics BiPAP A40 Auto-titrated Ventilatory Support System. Applicant's suggested language:

EITHER

Revise the language of existing code E0461 which currently reads: "Volume Control Ventilator, Without Pressure Support Mode, May Include Pressure Control Mode, Used With Non-Invasive Interface (E.G. Mask)"; to instead read: "Volume Controlled *or Volume Targeted* Ventilator, *With or* Without Pressure Support Mode, May Include Pressure Control Mode, Used With Non-Invasive Interface (e.g. Mask)"; and

Revise the language of existing code E0450 which currently reads: "Volume Control Ventilator, Without Pressure Support Mode, May Include Pressure Control Mode, Used With Invasive Interface (E.G., Tracheostomy Tube)"; to instead read: "Volume Controlled *or Volume Targeted* Ventilator, *With or* Without Pressure Support Mode, May Include Pressure Control Mode, Used With Invasive Interface (e.g., Tracheostomy Tube)".

OR establish new codes

Exxx1 Volume Targeted Ventilator, With Pressure Support Mode, (Moderate Assist Device) Used With Non-Invasive Interface (e.g., mask); and

Exxx1 Volume Targeted Ventilator, With Pressure Support Mode, (Moderate Assist Device) Used With Invasive Interface (e.g., Tracheostomy Tube

Background/Discussion:

According to the requester, the BiPAP A40 is a microprocessor controlled blower and valve based ventilatory system that allows for precise control of the rate of change in pressure support provided to individuals with respiratory disease. It can simultaneously deliver targeted tidal volume through pressure support while providing automatic adjustments to the expiratory positive airway pressure and automatic adjustments to the backup rate based on the patient's

spontaneous respiratory rate. This dynamic pressure adjustment with a targeted delivery of volume allows for treatment with the lowest possible pressure levels necessary to maintain airway patency. The system includes a base ventilator unit, detachable battery module, battery, secure digital (SD) card, AC power adapter, power cord, power cord retainer, carrying case, flexible tubing and breathing circuit filters and interface. An integrated heated humidifier can be purchased separately. Individuals with progressive chronic respiratory disease predictably move along a continuum of increasing ventilator support progressing beyond what "traditional bi-level devices" (coded at E0471 and E0472) can deliver (nocturnal therapy), to requiring treatment with a life support ventilator (coded at E0463 and E0464). This request is to establish codes to identify "mid-level ventilators", including the systems that are the subject of this request that can meet the needs of individuals in this transition, in particular, patients that require more than nocturnal support and up to 16-18 hours of ventilator support per day.

Preliminary Decision:

Existing code E0471 "Respiratory Assist Device, Bi-Level Pressure Capability , With Back-Up Rate Feature, Used With Noninvasive Interface, e.g., Nasal or Facial Mask (Intermittent Assist Device With Continuous Positive Airway Pressure Device)" or E0472 "Respiratory Assist Device, Bi-Level Pressure Capability , With Back-Up Rate Feature, Used With Invasive Interface, e.g., Tracheostomy Tube (Intermittent Assist Device With Continuous Positive Airway Pressure Device)"; (based on whether the interface is non-invasive or invasive); adequately describes the device that is the subject of this request.

Medicare Payment:

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

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker stated the applicant disagreed with CMS' preliminary recommendation, stating that volume targeted ventilators provide new technology for home ventilation. The representative also stated that the FDA classifies the new technology as MNT (a continuous ventilator, minimal ventilator support), which meets the needs of patients who do not require life-support ventilator but require more than nocturnal bi-level ventilator support. Therefore, the existing codes E0471 and E4072 do not adequately describe the BiPAP A40.

DME HCPCS Public Meeting Agenda Item #4
June 4, 2013

Attachment# 13.071
Topic/Issue:

Request to **EITHER**: establish three new Level II HCPCS codes to describe a powered obstructive sleep apnea (OSA) treatment device and components that deliver continuous *negative* pressure in the oral cavity. Trade Name: Winx™ Sleep Therapy System. Applicants suggested language:

EX1 "Continuous Negative Oral Pressure Device to Treat Obstructive Sleep Apnea, Electrically-Powered, Each";

AX1 "Oral Interface Used With Negative Oral Pressure Device to Treat Obstructive Sleep Apnea, Each";

AX2 "Tubing Used With Negative Oral Pressure Device to Treat Obstructive Sleep Apnea, Each"

OR: modify existing codes E0601 "Continuous Airway Pressure (CPAP) Device" and accessory codes A7037, A7044 (for tubing and oral interfaces, respectively), to omit references to "positive" pressures.

Background/Discussion:

According to the requester, the Winx Sleep Therapy System is a medical device that delivers Oral Pressure Therapy (OPT), (a proprietary term), and is indicated for use to treat obstructive sleep apnea (OSA) for patients aged 18 years or older. The system includes a console (consisting of a vacuum pump, removable power cord, and reservoir for the collection of excess saliva); an oral interface, (a soft mouthpiece fabricated in multiple sizes that incorporates a lip seal and connector for tubing); and thin, flexible tubing, which connects the oral interface to the mouthpiece. The negative pressure generated by the console and conveyed via tubing through the mouthpiece into the oral cavity creates a pressure gradient that draws the soft palate into contact with the tongue to open the airway and permit improved airflow during sleep. The negative pressure in the oral cavity is isolated from the nasal-pharyngeal airway by the seal that occurs between the soft palate and the tongue. The patient inserts the mouthpiece and presses a button on the console, which automatically sets and maintains therapeutic vacuum levels. The pump applies continuous negative pressure to the oral interface using feedback control. According to the requester, unlike existing continuous positive airway pressure (CPAP) devices that deliver positive pressure in the airway, the Winx system generates continuous negative pressure in the oral cavity, and existing codes that describe positive airway pressure devices do not describe devices that deliver negative oral pressures.

Preliminary Decision:

Establish Axxxx "Oral interface Used With Respiratory Suction Pump, Each" to identify the oral interface.

Existing code A7002 "Tubing, Used with Suction Pump, Each" adequately describes the tubing.

Existing code E0600 "Respiratory Suction Pump, Home Model, Portable or Stationary, Electric" adequately describes the suction pump.

Medicare Payment:

Based on our preliminary benefit category analysis, we believe that AXXXX would be paid in accordance with the payment rules that apply to inexpensive and other routinely purchased items if covered.

The payment rules associated with the existing codes apply to this product if covered.
For A7002, Pricing = 32
For E0600, Pricing = 36

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker thanked CMS for coding the oral interface, and requested additional coding changes to facilitate payment. Specifically, the speaker reiterated the original request for 3 new codes with different language to separately identify the 3 components of the system, consistent with the FDA approval as a 3-piece system. And alternatively, if new codes are not established consistent with this request; the speaker asked that CMS assign the Winx and accessories to the existing codes for CPAP devices and accessories (E0601, A7037 and A7044-for the device, tubing and oral interface, respectively).

DME HCPCS Public Meeting Agenda Item #5
June 4, 2013

Attachment# 13.089
Topic/Issue:

Request to establish a new Level II HCPCS code to identify a lightweight, portable, enclosed negative pressure ventilating chamber, Trade Name: Porta-Lung.

Background/Discussion:

According to the requester, the Porta-Lung is a sealed pressure chamber in which the patient's body below the neck is enclosed within a pressurized cylinder. The atmospheric pressure within the chamber is displaced, allowing ambient air to flow into the patient's lungs. The device is indicated for patients with weakness or paralysis of respiratory muscles, chronic hypoventilation syndrome, Muscular Dystrophy, spinal and post-polio muscular atrophy, and non-obstructive sleep apnea. It consists of a fiberglass body chamber, clear polycarbonate plastic door and stainless steel latching system, stainless steel headrest, aluminum spiral collar, and mattress and pillows. According to the requester, the assignment of HCPCS code E0460 "Negative Pressure Ventilator, Portable or Stationary" to this device in 1989 was incorrect. Specifically, code E0460 describes the pump (drive) attached to the chamber, but not the chamber itself.

Preliminary Decision:

Existing code E0460 "Negative Pressure Ventilator, Portable or Stationary", adequately describes the device that is the subject of this request. In fact, this device is the predicate product for which code E0460 was originally established.

Medicare Payment:

The payment rules associated with the existing code apply to this product if covered.
Pricing = 31

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

DME HCPCS Public Meeting Agenda Item #6
June 4, 2013

Attachment# 13.060

Topic/Issue:

Request to establish a single new Level II HCPCS code for a portable cervical traction device that applies "pneumatic radial traction", trade name: Posture Pump® Cervical Disk Hydrator® (Model 1000). Applicants suggested language: EXXXX "Pneumatic radial traction equipment, cervical, free-standing stand/frame, providing traction on the cervical anatomy in the supine position".

Background/Discussion:

According to the requester, the Posture Pump® consists of: a frame made of acrylonitrile butadiene styrene (ABS) thermoplastic material; an expandable elliptical air cell made of heat-sealable urethane with a neoprene cover; a "pneumatic hand pump" (bulb) with a push-button release valve and 30 inches of tubing, made of rubber/plastic; and a dual-action neoprene head restraint designed for persons with temporomandibular joint (TMJ) syndrome (does not aggravate TMJ), which includes an adjustable forehead strap and removable chin strap (which is not necessary for the effective use of the device). None of the components are disposable. The portable, 3 lb. system requires no assembly, weights, cables or ropes. The Posture Pump is used by patients with chronic neck pain due to a musculoskeletal or neurological impairment. To use the device, the patient lies in a supine position, slides and centers the device under the back of his/her neck, fastens the forehead restraint, and slowly inflates the air cell using the hand pump. The joints are tractioned in 3 directions: vertically, horizontally, and these forces expand against the occiput and against the upper thoracic region. The combination of these simultaneously applied forces produce "radial traction", also known as "Expanding Ellipsoidal Decompression (EED®)". It is a process in which joints of the cervical spine are tractioned and simultaneously aligned into the cervical spine's proper configuration vertically and in both horizontal directions, instead of one or two directions, which – according to the requester - distinguishes this device from other cervical traction devices coded at E0849 and E0855. The requester also claims that the Posture Pump provides a greater degree of disc height change than other forms of traction, and that "use of the Posture Pump® may be associated with improved outcomes as compared to patients using linear traction". The requester states that the Posture Pump was assigned to code E0849 in 2010; reassigned to E0855 in 2012 (on the basis that it "incorporates the mandible into the traction force"); reassigned to code A9270 in August 2012 on the basis that it "does not appear to provide 30 lbs. of continuous adjustable pull" and "does not distort the natural curve of the spine"; and in December 2012 was reassigned to E1399. The applicant seeks a new Level II HCPCS code on the basis of the PDAC's assignment of the product to E1399.

Preliminary Decision:

Existing code E0856 "Cervical Traction Device, Cervical Collar With Inflatable Air Bladder", adequately describes the product that is the subject of this request.

Medicare Payment:

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

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

DME HCPCS Public Meeting Agenda Item #7
June 4, 2013

Attachment# 13.085
Topic/Issue:

Request to establish 2 new Level II HCPCS codes to identify heavy duty tilt seating systems: one code for weight capacity 251 to 450 pounds, and another code for weight capacity 451 to 600 pounds, Trade name Boss HD Equalizer. Applicant's suggested language:

Exxx1 "Wheelchair Accessory, Power Seating System, Tilt Only, Patient Weight Capacity 251 to 450 pounds"

Exxx2 "Wheelchair Accessory, Power Seating System, Tilt Only, Patient Weight Capacity 451 to 600 pounds"

Background/Discussion:

According to the requester, this bariatric tilt seating system includes a solid seat platform and a solid back; any frame width and depth; detachable or flip-up fixed height or adjustable height armrests; fixed or flip-up footplates; a motor and related electronics with variable speed programmability; a switch control which is independent of the power wheelchair drive control interface; and hardware to attach the seating system to the wheelchair base. It has the ability to tilt up to 50 degrees from horizontal; a back height up to 24.5 inches; an adjustable back and the ability to support beneficiary weight up to 600 pounds. This particular device is available to fit three models of this manufacturer's wheelchairs (4.5, 6/6NS and 6.75). Existing codes for tilt-in-space seating systems (E1002, E1006, E1007 and E1008) are for products that can only accommodate up to 250 lb patient weight capacity. These seating systems are not built to handle a heavier individual. They do not have 2 actuators, heavier gauge steel, or other accommodations made to handle patients over 250 lbs, such as heavy duty bearings, bigger wire sizes, stronger reinforced backrests, more durable arm supports, longer and stronger lap restraints, oversized footrests with special mounting, and multiple depth and width adjustments. In addition, existing codes are identified by the 250 lb. weight limit in the current Wheelchair Accessory LCD.

Preliminary Decision:

Existing code E1002 "Wheelchair Accessory, Power Seating System, Tilt Only" adequately describes the devices that are the subject of this application. Use by bariatric persons was contemplated when this code was established.

Medicare Payment:

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

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker stated that code E1002 does not contemplate systems that support a patient weight of 451 lbs or greater. In addition, the Boss HD Equalizer has specialized tilt sensors and more actuators that were not in existence when code E1002 was not established. Also, Medicare policy does not identify maximum weight and does not state "HD" and therefore, existing code category E1002 does not adequately describe the Boss HD Equalizer.

DME HCPCS Public Meeting Agenda Item #8

June 4, 2013

Attachment# 13.082

Topic/Issue:

Request to establish a new Level II HCPCS code to identify a single-patient use transcutaneous electric nerve stimulator, Trade Name: InterX ® 900, Single Patient System, neurostimulation device. Applicant's suggested language: EXXXX Transcutaneous Electric Neurostimulator Device for Nerve Stimulation".

Background/Discussion:

According to the requester, the InterX 900 is a single-patient therapy system that provides non-invasive, interactive neurostimulation to the cutaneous nerves, activating the body's natural pain relieving mechanisms. It is used for the sumptomatic relief and management of chronic pain, and also as an adjunctive treatment in the management of post-surgical and post-traumatic pain. The system consists of a power driver and a conductive garment with leads and electrodes. The power driver delivers 15 - 480 pulses per second. The amplitude ranges from 35 - 60mA, and current density ranges of 170 - 220mA per square inch. Treatment is delivered up to 20 minutes, one to three times per day, depending on the condition being treated. Based on the patient's condition, optimal treatment points are identified which relate to major nerve branches, trigger points and localized areas of sympathetic skin response. The conductive garment is placed on the targeted area of the skin and connected to the power driver. Although the InterX 900 device is "Regulated as a Transcutaneous Electrical Nerve Stimulator for Pain Relief", it functions differently than the TENS device. The design and interactive waveform of the InterX 900 provides a "customized therapy that is not possible with a classic TENS". The InterX mechanism of action uses high density, high amplitude current that is not restricted by muscle contraction versus a lower amplitude, lower density current used by TENS which disperses through tissue and is intensely restricted by muscle contraction. Tens has 4 leads/arrays with 4 electrodes. The InterX claims to have 4 leads with 18 electrodes. The requester is seeking a distinction from TENS, via HCPCS coding, "which will allow both government and private insurers to more precisely and efficiently report and administer claims and coverage for this unique neurostimulation device".

Preliminary Decision:

Existing codes E0730 "Transcutaneous Electrical Nerve Stimulation (TENS) Device, Four or More Leads, For Multiple Nerve Stimulation" and E0731 "Form Fitting Conductive Garment for Delivery of TENS or NMES (With Conductive Fibers Separated from the Patient's Skin by Layers of Fabric)"; together, adequately describe the device that is the subject of this request.

Medicare Payment:

The payment rules associated with the existing codes apply to this product if covered.
For E0730, Pricing = 32
For E0731, Pricing = 34

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with CMS' preliminary recommendation stating that the InterX®900 has a different waveform and amplitude which confers physiological and clinical benefits when compared to the use of traditional stimulation therapies. The InterX®900 requires no conductive gel, the electrodes can be smaller and more closely spaced, while using nine pairs verses two or four as used in TENS.

DME HCPCS Public Meeting Agenda Item #9
June 4, 2013

Attachment# 13.088
Topic/Issue:

Request to establish a new Level II HCPCS code to identify a device that delivers a combination treatment modality including Transcutaneous Electrical Nerve Stimulation (TENS), Light Emitting Diodes (LED) and Low Level Laser Therapy (LLLT), Trade Name: Neruolumen PN-1000.

Background/Discussion:

According to the requester, the Neurolumen PN-1000 delivers TENS, LED and LLLT, and is indicated for (LED) temporary relief of minor muscle and joint pain, arthritis, muscle spasm, relieving stiffness, promoting relaxation of muscle tissue, and to temporarily increase local blood circulation where heat is indicated; and also for (TENS) symptomatic relief and management of chronic, intractable pain and adjunctive treatment for post-surgical and post-traumatic acute pain. The device consists of a control unit, 6 e-photonic wraps, a charger for recharging the internal battery, and 8 electro-gel pads with an adhesive conductive gel compound that is contained on the surface of the electrode pad. The gel allows the pad to "stick" to the conductive surface of the "e-photonic wrap" circuit board on one side, and to the patient's skin on the other. The control unit could normally be rented, and has a life of more than 5 years. The gel pads, wrap assemblies, and battery are accessories to the device and would need periodic replacement. The wrap assemblies are replaced, based on condition, once every 6 months. The typical treatment duration is for more than one year. The Neurolumen augments its photonic energy delivery mechanism with an articulated electrical stimulation. This TENS stimulates vascular circulation which improves tissue perfusion, providing a mechanism to transport toxins and other metabolite waste from the tissues surrounding the affected cells. The result is a more lasting treatment protocol than LLLT or LED alone. This combined energy is "e-photonic". Existing codes do not represent the components or function of this device, hence the request for a new "E" code to identify the combination modality of TENS, LED and LLT; to more adequately define this treatment alternative; and to enable access to it.

Preliminary Decision:

Existing code Existing code E0730 "Transcutaneous Electrical Nerve Stimulation (TENS) Device, for or More Leads, for Multiple Nerve Stimulation" adequately describes the TENS component of this device; existing code A4595 "Electrical Stimulator Supplies, 2 Lead, Per Month, (e.g., TENS, NMES)" adequately describes the gel pads, three units may be billed if 6 leads are used. A national program operating need was not identified by Medicare, Medicaid or the private insurance sector to identify LED or LLLT therapy.

Medicare Payment:

The payment rules associated with the existing codes apply to this product if covered.
For E0730, Pricing = 32
For A4595, Pricing = 34

Based on guidance contained in Chapter 1, Part 4, Section 270.6 of the Medicare National Coverage Determinations manual, we believe there would be no Medicare payment for the infrared components of this device.

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

DME HCPCS Public Meeting Agenda Item #10
June 4, 2013

Attachment# 13.083
Topic/Issue:

Request to establish a series of 4 new Level II HCPCS codes to identify the components of a home phototherapy treatment system, Trade Name: Levia® UVB Select™ Personal Targeted Phototherapy® system, AND to revise existing code E0691 to restore the word "panel". Applicant's suggested language:

EXXXX Ultraviolet B, Targeted Light Therapy, Table Top Treatment System, Includes Lamp, Optical Filters, Programming Console, Eye Protection and Beam Delivery Attachments to Treat Multiple Small Area ($3cm^2$) increments of skin and scalp psoriasis.

AXXXX Treatment Programming Module (Programmed USB Flash Memory Drive)

AXXXX Replacement, Lamp, Targeted Therapy

AXXXX Replacement, Calibration Light Meter

Revise existing code E0691 which currently reads: "Ultraviolet Light Therapy System, Includes Bulbs/Lamps, Timer and Eye Protection; Treatment Area 2 Square Feet or Less"; to instead read: "Ultraviolet Light Therapy System PANEL, Includes Bulbs/Lamps, Timer and Eye Protection; Treatment Area 2 Square Feet or Less".

Background/Discussion:

According to the requester, the personal targeted phototherapy system is a programmable device that delivers a precisely calibrated narrow band UVB light therapy directly to the affected area of the scalp or other body area. It is indicted for conditions including psoriasis, vitiligo, atopic dermatitis, and seborrheic dermatitis. The system includes a treatment console and connected hand piece similar in style and weight to a hair dryer; a scalp psoriasis treatment attachment with quartz fiber-optic bristles (LiteBrush) for delivering light through the hair directly to the affected area of the scalp; and a general skin treatment attachment (LiteSpot) that delivers a 3 cm2 focused beam of UVB light directly to other affected skin areas. The requester states that this personal targeted phototherapy system has "significant scientific and technological distinctions" when compared to other similar devices that are currently marketed, and as such, a new HCPCS code is warranted. Specifically, existing HCPCS codes E0691, E0692, E0693 and E0694 do not adequately describe directed light therapy designed to treat only the affected areas of the body; and existing code A4633 describes "conventional fluorescent tubes; not the high-pressure, metal halide short arc lamps necessary for directed phototherapy. In addition, there are no HCPCS codes that describe programming or reprogramming a computerized UVB home therapy system.

Preliminary Decision:

Existing code E0691 "Ultraviolet Light Therapy System, Incudes Bulbs, Lamps, Timer and Eye Protection; Treatment Area 2 Square Feet or Less", adequately describes the device that is the subject of this request. In fact, code E0691 was revised in 2012 specifically to include this device. Existing code A4633 "Replacement Bulb/Lamp for Ultraviolet Light Therapy System, Each", identifies a replacement bulb/lamp. Calibration is included in normal maintenance and is not separately billable. A national program operating need was not identified by Medicare, Medicaid or the private insurance sector to establish a code to identify the programming module; to establish differential coding based on light source; or to split treatment area of "2 square feet or less" (as in code E0691), into smaller treatment area increments.

Medicare Payment:

The payment rules associated with the existing codes apply to this product if covered.
For E0691, Pricing = 32
For A4633, Pricing = 32

Based on our preliminary benefit category analysis, we believe that there would be no Medicare payment for the programming module.

Routine regulation/maintenance of equipment is not covered so there would be no separate Medicare payment for the calibration light meter.

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with CMS' preliminary recommendation on the basis that "a respected certified coder" disagrees. Specifically: 1) the Levia system performs a significantly different function that other items coded at E0961; 2) Levia operates differently than other items coded at E0691 (better quality light and ability to control or direct delivery of light); 3) CPT codes specify "targeted phototherapy", and HCPCS Level II codes should, too; and 4) the Levia system should be identified by a miscellaneous code because "it does not meet volume and marketing criteria".

DME HCPCS Public Meeting Agenda Item #11
June 4, 2013

Attachment# 13.090
Topic/Issue:

Request to reassign the Hope Crutch to existing Level II HCPCS code E0110 "Crutches, Forearm, Includes Crutches of Various Materials, Adjustable or Fixed, Pair, Complete with Tips and Handgrips"; instead of code E0114 "Crutches Underarm, Other than Wood, Adjustable or Fixed, Pair, With Pads, Tips and Handgrips".

Background/Discussion:

According to the requester, the Hope crutch is an aluminum crutch with a telescoping extension for height adjustment. It is available in 3 sizes: Adult (for patients 5'2" to 6'0"); Tall Adult (for patients 6'0" to 6'8"); and Extra Tall (for patients 6'6" to 7'2"). The requester claims that the extra tall size is not available in conventional, axillary crutches. The Hope crutch includes an ergonomic handle and uses a 2-inch diameter rubber tip, which the requester claims is wider than the tip used on other crutches. Its design includes a 6-inch "stabilizer" extending upward behind the shoulder, allowing a second point of contact (in addition to the hand grip). This stabilizer takes the stress off the wrist, elbow, rotator cuff and spine. It also allows the body to move like a pendulum, letting the spine hang straight and keeping the body more upright, as compared to using axillary crutches, where users lean and hunch forward while gripping the handles tightly. The 6-inch stabilizer provides the ability to keep the crutch from slipping out from under the arm, as happens with an axillary crutch. According to the requester, squeezing the axillary crutch between the arm and the body causes nerve damage, heart and blood circulation problems and underarm irritation. The Hope crutch offers easier use and added stability when compared with axillary crutches. Some people who are unable to use axillary crutches are able to use the Hope crutch instead of using a wheelchair. This speeds recovery and prevents muscle atrophy, bedsores and bladder infections, and also reduces injuries to caregivers' backs. According to the requester, the Hope crutch is an improvement on the two points of contact of the forearm crutch, in that the stabilizer behind the shoulder (as the 2nd point of contact) gives extra support and stability, similar in principle to the cuff of the forearm crutch providing extra stability by holding the user's arm. The axillary crutch, on the other hand, does not have a useful second point of contact with the body. The requester, therefore, is seeking to have the Hope crutch assigned to the same code category as the forearm crutch (E0110).

Preliminary Decision:

Existing code E0114 "Crutches, Underarm, Other Than Wood, Adjustable or Fixed, With Pad, Tip, Handgrip, With or Without Shock Absorber, Each ", adequately describes the crutch that is the subject of this application. Code E0110 "Crutches, Forearm, Includes Crutches of Various Materials, Adjustable or Fixed, Pair, Complete with Tips and Handgrips" is not a code for crutches with 2 points of contact. It is a code that specifically identifies forearm crutches.

Medicare Payment:

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

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

O&P Public Meeting

O&P HCPCS Public Meeting Agenda Item #12
June 4, 2013

Attachment# 13.087
Topic/Issue:

Request to revise the language of existing HCPCS code L8687 which currently reads: "Implantable Neurostimulator Pulse Generator, Dual Array, Rechargeable, Includes Extension"; to instead read: "Implantable Neurostimulator Pulse Generator, Multiple Arrays (Two or More), Rechargeable, Includes Extension". Trade Name: Precision Spectra™ Spinal Cord Stimulation (SCS).

Background/Discussion:

According to the requester, the Precision Spectra SCS system includes: a rechargeable Implantable Pulse Generator (IPG) with 4 ports (4 locations to which an electrode array can be attached); an IPG Port Plug; an external Trial Stimulator; a patient trial belt; a patient trial kit; a remote computer programmer (that allows the patient to control the therapy); a remote control kit; an NM-6210 USB Power Supply; a remote control holster; and lead electrode arrays or cables. The system is implanted by a physician in an operating room, usually in a hospital or ambulatory surgery center. It generates and delivers electrical impulses to spinal nerves to treat pain. The electrical impulses originate in the pulse generator and are transmitted via electrode arrays. The electrical impulses induce parasthesia, (a tingling sensation) over a region on the spinal cord that masks pain signals. This system is indicated as an aid in the management of chronic intractable pain of the trunk and/or lower limbs, including unilateral or bilateral pain associated with failed back surgery syndrome, and intractable low back pain and leg pain. Existing code L8687 describes a dual array system. Revision of code L8687 to include pulse generators to which 2 or more electrode arrays can be attached will more accurately describe the neurostimulators in use which accommodate more than a single array.

Preliminary Decision:

Establish L86XX "Implantable Neurostimulator, Pulse Generator, Any Type" for use to report Implantable Neurostimulators on Medicare claims.

Medicare Payment:

The fee schedule amounts for the new code for all types of pulse generators will be based on the established Medicare fee schedule amounts for all types of pulse generators under the previous single code E0756 Implantable Neurostimulator Pulse Generator (discontinued 12/31/2005).

Once the new code becomes effective, the following codes would no longer be valid for

Medicare purposes: L8685 "Implantable Neurostimulator Pulse Generator, Single Array, Rechargeable, Includes Extension; L8686 "Implantable Neurostimulator Pulse Generator, Single array, Non-Rechargeable, Includes Extension"; L8687 "Implantable Neurostimulator Pulse Generator, Dual Array, Rechargeable, Includes Extension"; and L8688 "Implantable Neurostimulator Pulse Generator, Dual Array, Non-Rechargeable, Includes Extension".

This decision for Medicare is based on the fact that the need to explode the one code for pulse generator systems, E0756, into four codes for the purpose of tracking utilization for different types of pulse generator systems never materialized. Since Medicare data indicates that beneficiaries have only been receiving one type of pulse generator system since 2006, the Medicare program never had a need to maintain codes for different types of pulse generator systems in order to track utilization and is reverting back to use of a single code since different types of systems are not used by Medicare beneficiaries.

Summary of Primary Speaker Comments at the Public Meeting:

Written comments were submitted, disagreeing with CMS' preliminary recommendation. The commenter reiterated the original request to modify the language of L8687 to specify "multiple Arrays (two or more)"; and requested that the same language modification also be made to existing code L8688.

O&P HCPCS Public Meeting Agenda Item #13
June 4, 2013

Attachment# 13.059
Topic/Issue:

Request to establish a new Level II HCPCS code for a single-use "continence control device" intended to prevent the release of stool from an end colostomy while allowing flatus from the stoma to be deodorized and released. Trade Name: Vitala®. Applicant's suggested language: "Continence Control Device for Colostomy".

Background/Discussion:

According to the requester, the Vitala® continence control device (CCD) is a pouch less ostomy management device for individuals with an end colostomy. It consists of an outer ring; a self-inflating Air Seal subassembly which contains a soft foam insert that expands upon application and rests against the stoma to prevent the release of stool; a filter subassembly which allows flatus to be deodorized and released; an expandable container to collect stool which might be released upon removal, when the Air Seal is released; a cap which provides a flatus vent path out of the device and structural support for the filter and expandable container; and a coupling which holds the device to the skin barrier. The Vitala® enables users to experience up to 12 hours of continence. One or more devices may be worn for up to a total of 12 hours maximum wear time in a 24 hour period. It is worn until the user feels a sensation of fullness, and at that point the user removes the Vitala CCD and applies an ostomy pouch for full evacuation. The Vitala® CCD is not to be used by patients with a history of chronic liquid stool, as it may result in leakage. It is not intended for use by individuals with an end colostomy with a stoma protrusion greater than 0.8 in. (2 cm). It is not to be used until 6 weeks post-surgery, when the abdomen and periostomal area have fully healed, when all structures and drains have been removed. It is not to be used while experiencing G.I. symptoms such as cramping, bloating, bleeding, liquid stool, or other changes in stomal output. It is not intended for use by individuals with an ileostomy, urostomy or any other ostomy that is not an end colostomy. When the device is worn, it is intended to be used only with 1 ¾ inch or 2 ¼ inch Natura® two-piece skin barriers.

According to the requester, "traditional" ostomy management options function by allowing feces to be excreted "at will" from the stoma and stored in a pouch that hangs on the abdomen. Some people with colostomies opt to irrigate as a part of their management routine. Irrigating the large intestine may extend the time period between bowel movements, thus freeing individuals from wearing a full-size collection pouch between irrigations.

The Vitala CCD is currently covered under Medicare Part B and has been assigned to HCPCS code A5055 "Stoma Cap" by the PDAC. According to the requester, however; the Vitala® is neither a stoma cap nor a stoma plug, as coded at A5081: "Continent device: Plug for Continent Stoma". Stoma caps are low-tech devices designed to absorb only small amounts of mucous drained from a stoma, and are only indicated for use on an irrigated colostomy. They do not seal the stoma, and come off if a significant amount of stool is excreted; and they do not provide

continence wile worn. In addition, reimbursement policies for stoma caps do not allow for access to both a regular pouch in addition to the stoma cap. This is an issue for Vitala®users who rotate use of the Vitala and a regular pouch every 12 hours. Stoma plugs are "designed primarily for continent *urinary* stomas" and are not used on incontinent colostomy stomas. They are also "low tech" and priced accordingly. Other key differences between the Vitala® CCD and stoma caps and plugs and colostomy pouches are that the Vitala: seals the stoma and retains stool within the body; provides "continence" while worn, which the applicant defines as a prosthetic functionality and "the ability to retain feces until a proper time for discharge"; permits retention of stool between evacuations naturally within the body; provides control over noise due to flatus; and provides users with temporary freedom from wearing a pouch without irrigation. The clinical benefits of these differences include: a non-surgical, non-invasive method to achieve up to 12 hours of continence; restoration of a person's ability to voluntarily control their bowel function and timing of excretion; and significantly higher self-reported Health-related Quality of Life scores (as per interim results of an on-going European study comparing Vitala® users to persons who wear pouches). There are no other noninvasive devices on the market in the US that provide continence control with an end colostomy, and no other devices that provide a seal to an incontinent colostomy stoma and continence control while worn. No other ostomy device provides the prosthetic functionality of the Vitala® CCD, and there are no codes within the HCPCS code set that adequately describe the Vitala® device.

Preliminary Decision:

Existing code A5055 "Stoma Cap", adequately describes the product that is the subject of this request.

Medicare Payment:

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

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with CMS' preliminary recommendation, stating that the Vitala® Continence Control Device represents a new level of functionality in Ostomy care. Specifically, the Vitala® provides continence to individuals with an end colostomy. The Vitala® reduces odors and noise and has been tested up to 12 hours of wear time. The applicant states because of the clinical use of the technology, existing code A5055 does not adequately describe the Vitala®. The applicant reiterated the original request to establish a new, unique code to identify the Vitala®.

O&P HCPCS Public Meeting Agenda Item #14
June 4, 2013

Attachment# 13.017
Topic/Issue:

Request to establish a new Level II HCPCS code to identify a Trabecular Micro-Bypass stent, Trade Name: iStent®. Applicant's suggested language: LXXXX "Ocular Implant, ab interno trabecular meshwork stent".

Background/Discussion:

According to the requester, the iStent is an L-shaped titanium stent measuring 1 mm (L) by 0.3mm (H) with a snorkel length of 0.25 mm and a nominal snorkel bore diameter of 120 µm. It is implanted into the trabecular meshwork through a small incision made to accommodate the placement of an intraocular lens in cataract surgery. The device creates a patent and permanent opening in the trabecular meshwork directly into Schlemm's Canal (a circular canal located in the angle of the front part of the eye behind the trabecular meshwork into which aqueous humor drains in a normal eye), restoring the flow of aqueous humor through the primary natural, physiologic outflow pathway. The stent is pre-loaded onto the end of a disposable insertion instrument. It is designed to treat Open-Angle Glaucoma (OAG). According to the requester, the iStent is the first "prosthetic" device that stents open the trabecular meshwork to re-establish natural flow of aqueous humor from the anterior chamber of the eye into Schlemm's Canal. It differs from aqueous shunts currently coded at L8612 in terms of mechanism of action, material, size, design, anatomical location, surgical technique, targeted patient population and complications and thus, a new code is warranted to distinguish the iStent device. Specifically, L8612 describes devices that surgically bypass the eye's natural drainage pathways. In addition, aqueous shunt surgery using devices currently coded at L8612 requires a highly invasive procedure requiring an external (ab externo) micro incision of the conjunctiva and sclera, and consequently these types of shunts and this procedure is indicated for glaucoma patients for whom medical and conventional surgical treatments have failed. The iStent, on the other hand, is implanted internally (ab interno) through the same small incision created to place an intraocular lens in cataract surgery. The requester claims that the clinical outcomes of the two procedures are "strikingly dissimilar". Complication rates with the ab externo approach are high and include serious adverse events. However, the safety profile of Micro-invasive Glaucoma Surgery (MIGS) devices, like the iStent is much stronger, and to date, no device-related serious adverse events have been reported.

Preliminary Decision:

Existing code C1783 "Ocular Implant, Aqueous Drainage Assist Device", adequately describes the product that is the subject of this request.

Medicare Payment:

This code is recognized under OPPS and ASC.

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with CMS' preliminary recommendation, stating that the iStent is first of its kind technology and is not an aqueous shunt but a micro stent; and the technology represents a paradigm shift, not an incremental change. Therefore, the iStent® is not adequately described by existing code C1783. The speaker also stated that new CPT code (0191T) was created for the procedure that uses the iStent, which is a different procedure.

O&P HCPCS Public Meeting Agenda Item #15
June 4, 2013

Attachment# 13.076
Topic/Issue:

Fourth request to establish a new Level II HCPCS "L" code to uniquely identify a prosthetic cable control and locking system. Trade Name: Sure-Lok™. Applicant's suggested language: "Addition to Upper Limb Prostheses, Manual lock for Cable-Controlled System".

Background/Discussion:

According to the requester, the Sure-Lok is the world's first manually controlled locking cable control system developed for use in upper limb prosthetics. It includes a unidirectional cable locking and control technology incorporating a manually actuated, self-energizing cam mechanism. It mounts to the surface of a new or existing prosthesis. A "standard" or "heavy duty" control cable is attached to the control harness and terminal device in a cable-driven prostheses and controls the opening and closing of that specific terminal device only. The Sure-Lok functions differently, as it allows the user to lock the terminal device in an infinite number of positions. In addition, the Sure-Lok offers the following benefits that the requester believes constitute a therapeutic distinction between it and other locking control systems: reduced average harness pressure; reduced risk of repetitive stress and cumulative trauma injuries; decreased overall energy expenditure; increased TD pinch force; improvement on existing prosthetic technology; ability for individuals with shorter limbs using VO systems to maintain desired TD prehension or grip for longer periods and also to maintain all levels of cable tension for longer periods; reduced contralateral or sound-side hand involvement; and the Sure-Lok is "reasonable and necessary" to improve the function of individuals with upper limb amputations. According to the requester, there is no existing HCPCS code that describes a locking cable control system. "Codes that come close only in part to the design of a locking control system would include L6655, L6660, L6675 & L6676. However, the reasons these codes are not applicable are due to the Sure-Lok™ Cable Lock & Control System's COST, FUNCTION and THERAPEUTIC DISTINCTIONS".

Preliminary Decision:

This cable control and locking functionality is included in one of the following 3 base codes: L6675 "Upper extremity addition, harness, (e. g. Figure of eight type), single cable design"; L6676 "Upper extremity addition, harness, (e. g. Figure of eight type), dual cable design"; or L6677 "Upper extremity addition, harness, triple control, simultaneous operation of terminal device and elbow"; depending on level of amputation. Therefore code L9900 "Orthotic and prosthetic supply, accessory, and/or service component of another HCPCS "l" code" captures this feature and is available for assignment by insurers.

Medicare Payment:

The payment rules associated with the existing codes L6675 L6676 or L6677 apply to this product if covered. Pricing = 38

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

O&P HCPCS Public Meeting Agenda Item #16
June 4, 2013

Attachment# 13.077
Topic/Issue:

Request to establish a new Level II HCPCS "L" code to identify a bionic ankle-foot prosthetic device, Trade Name: BiOM® iWalk. Applicant's suggested language: LXXXX "Endoskeletal Ankle Foot System, Microprocessor Controlled Swing/Stance and Dorsi/Plantar Flexion, Motorized Stance Powered Propulsion and Ankle Stiffness Modulation, Personalized Biomimetic Tuning, Quantitative Biomimetic Outcome Validation".

Background/Discussion:

According to the requester, the BiOM system consists of hardware: (artificial muscle-tendon assembly; artificial Achilles tendon; artificial skeleton; artificial foot; artificial sensors; computation and drive electronics (sensors, 3 microprocessors, and drive electronics); lithium-polymer battery (6 cells) and charger; personal bionic tuning device (used by clinicians with android-based tablet)); and software: biomimetic control firmware and personal bionic tuning application using Bluetooth technology. It provides stiffness modulation after heel strike, which decelerates the body and thereby reduces impact loads. The system is adjusted with personal bionic tuning, where ankle stiffness and powered levels are personalized for each patient, enabling them to walk within normal biologic ranges. This device is intended for use by K3 patients within the Medicare population. According to the requester the BiOM functions differently than other ankle foot prostheses in that it is motor powered (e.g., as opposed to microprocessor or spring technology); 2) it is the first device that provides stiffness modulation; and 3) it is the first prosthetic system that can be electronically tuned and personalized to achieve a biomechanically accurate ankle-foot response using personal bionic tuning. The BiOM also provides a significant therapeutic distinction when compared with other Ankle-foot prostheses in that it 1) improves gait stability by modulating ankle stiffness; 2) decreases walking metabolism and increased preferred walking speed through ankle powered propulsion; 3) reduces gait asymmetries by emulating normal ankle-foot biomechanics; and 4) mitigates stress-related challenges through late-stance powered propulsion and early stance stiffness modulation. This device provides late-stance powered propulsion increasing energy return by 100% and mechanical power delivery by 800%, compared to all other commercially available ankle-foot prosthetic devices. The current HCPCS code set does not describe a prosthetic ankle foot system with late-stance powered propulsion, stiffness modulation and personal bionic tuning.

Preliminary Decision:

Existing code L5973 "Endoskeletal Ankle Foot System, Microprocessor Controlled Feature, Dorsiflexion and/or Plantar Flexion Control, Includes Power Source", adequately describes the device that is the subject of this request.

Medicare Payment:

The payment rules associated with the existing code apply to this product if covered.
Pricing = 38

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with the preliminary HCPCS coding recommendation, stating that existing code L5973 does not describe the BiOM iWalk. Specifically, the device that is the subject of this application provides net positive power, which is not captured in code L5973.

O&P HCPCS Public Meeting Agenda Item #17
June 4, 2013

Attachment# 13.079
Topic/Issue:

Request to EITHER establish a new Level II HCPCS code OR revise existing code L2114 to identify a Tibial Ankle Foot Orthosis (TAFO), Trade Name *PFS Med* TAFO, which is not designed for full weight bearing ambulation, but does allow assisted crutch or walker ambulation due to its lightness and anatomical support.

Background/Discussion:

According to the requester, the *PFS Med* TAFO is a semi-rigid, yet malleable ankle foot orthosis that provides support while it restricts or eliminates motion in the injured ankle/heel complex and/or tibia/fibula area. It is indicated for a wide range of trauma or complex lower extremity injuries. The Orthotist or fitter conforms the TAFO to fit the patient. The requester states that there are no other similar *malleable* orthotics with an exaggerated heel pocket, seven sizes, longer calf length (2/3 to ¾), fleece lining, and riveted and padded straps. The requester states that existing code L4398 "Foot Drop Splint, Recumbent Positioning Device, Prefabricated, Includes Fitting and Adjustment" does not describe the *PFS Med* TAFO, which is primarily used on ambulatory patients who use crutches or walkers to provide anatomical support and positioning. Also, existing codes L2114 "Ankle Foot Orthosis, Fracture Orthosis, Tibial Fracture Orthosis, Semi-Rigid, Prefabricated, Includes Fitting and Adjustment" and L1930 "Ankle Foot Orthosis, Plastic or Other Material, Prefabricated, Includes Fitting and Adjustment" do not describe the "mobility tolerance versus ambulation without modalities ability" of the *PFS Med* TAFO. This device is unique due to the material, the malleability, exaggerated heel space, and how the straps are attached, and therefore a new or revised code is warranted.

Preliminary Decision:

Existing code L4398 "Foot Drop Splint, Recumbent Positioning Device, Prefabricated, Includes Fitting and Adjustment", adequately describes the product that is the subject of this request.

Medicare Payment:

The payment rules associated with the existing code apply to this product if covered.
Pricing = 38

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with CMS' preliminary recommendation, stating that the product was modified to include a rubberized foot after the original code application was submitted to CMS, and with this modification, the device now meets the criteria for inclusion in code L2114.

O&P HCPCS Public Meeting Agenda Item #18
June 4, 2013

Attachment# 13.073
Topic/Issue:

Request to **EITHER** establish a new Level II HCPCS code to identify a carbon fiber composite ankle foot orthosis, Trade Name: Noodle® AFO. Applicant's suggested language: LXXXX "AFO, Rigid Posterior Section, Total Carbon Fiber or Equal Material, Dynamic, Prefabricated, Includes Fitting and Adjustment"; **OR** revise existing code L1932 which currently reads: AFO, Rigid Anterior Tibial Section, Total Carbon Fiber or Equal Material, Prefabricated, Includes Fitting and Adjustment", to instead read: "AFO, Rigid anterior *or Posterior* Section, Total Carbon Fiber or Equal Material, Prefabricated, Includes Fitting and Adjustment.

Background/Discussion:

According to the requester, the Noodle carbon fiber composite ankle foot orthosis is a lightweight, durable AFO intended for users with varying degrees of foot drop who would benefit from a dynamic energy-storing AFO to improve gait. The footplate and flexible strut of this device facilitate a more natural gate than more rigid carbon fiber AFOs. The AFO provides gait assistance by controlling plantar flexion and reducing energy consumption with dynamic dorsiflexion and improved loading response. The Noodle AFO incorporates a posterior shell design with energy storing carbon fiber composite dynamic lateral strut and footplate. The proximal location of the posterior shell along with the anterior shell applies a posteriorly directed force to extend the knee posteriorly during mid and terminal stance phases of gait. By using the mechanical advantage of leverage, the Noodle maximizes the mechanical effect of a posteriorly directed force to extend the knee posteriorly with the proximal anterior shell. The requester claims the Noodle can be provided as either an off-the-shelf or a custom device.

Preliminary Decision:

Existing code L1930 "Ankle Foot Orthosis, Plastic or Other Material, Prefabricated, Includes Fitting and Adjustment", contemplates the use of carbon fiber, and adequately describes the device that is the subject of this request.

Medicare Payment:

The payment rules associated with the existing code apply to this product if covered.
Pricing = 38

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

O&P HCPCS Public Meeting Agenda Item #19
June 4, 2013

Attachment# 13.074
Topic/Issue:

Request to establish a new Level II HCPCS code to describe a hip flexion/plantar flexion assist hip-knee-ankle-foot-orthosis (HKAFO), Trade Name: Kickstart Kinetic Orthosis.

Background/Discussion:

According to the requester, the Kickstart device is comprised of a pelvic band/belt, hip joint, single lateral upright with thigh and calf cuffs, heavy duty knee joint, ankle joint, custom molded foot plate with stirrup and the components are anodized to resist corrosion. It has the base structure of an HKAFO, however its main functional component and the distinguishing feature of this device is an adjustable tension system that assists hip flexion, knee extension and ankle plantar flexion. This component consists of two large pulleys, two small pulleys, two cables, a spring and the tension adjustment mechanism, which allows the tension on the spring to be adjusted to the optimal functional tension for use and then released when not in use. The Kickstart guides the lower limb through the swing phase of gait by powering plantar flexion from terminal stance to toe off, then powering hip flexion for the remainder of swing. It also assists with knee extension due to the smaller diameter of the pulley at the knee. The kinetic component provides the power and the base structure provides the stability both in swing and stance. The Kickstart is primarily used to help reduce gait deviations acquired when persons cannot move their leg through swing phase in a normal motion. People with neurological conditions that affect the strength, balance and coordination of the muscles around the hip and in the lower limb (some examples include CVA, incomplete spinal cord injury, MS, TBI and MD), could benefit from the use of this device. According to the requester, no other device combines energy storage to assist hip flexion with the support of an HKAFO, and therefore existing codes do not adequately describe this device.

Preliminary Decision:

Existing base code L2000 "Knee Ankle Foot Orthosis, Single Upright, Free Knee, Free Ankle, Solid Stirrup, Thigh and Calf Bands/Cuffs (single Bar AK Orthosis), Custom-Fabricated" (which includes the dynamic component); plus addition codes L2200 "Addition to Lower Extremity, Limited ankle Motion, Each Joint"; L2250 "Addition to Lower Extremity, Foot Plate, Molded to Patient Model, Stirrup Attachment"; L2780 "Addition to Lower Extremity Orthosis, Non-Corrosive Finish, Per Bar"; and L2630 "Addition to Lower Extremity, Pelvic Control, Band and Belt, Unilateral", OR code L2000 plus addition codes L2640 "Addition to Lower Extremity, Pelvic Control, Band and Belt, Bilateral"; and L2385 "Addition to Lower Extremity, Straight Knee Joint,Heavy Duty, Each Joint" OR code L2000 plus addition code L2600 "Addition to Lower Extremity, Pelvic Control, Hip Joint, Clevis Type, or Thrust Bearing, Free, Each";

depending on the joints, level of amputation; and whether unilateral or bilateral; adequately describe the device that is the subject of this request.

Medicare Payment:

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

For codes L2000, L2200, L2250, L2385, L2600, L2630, L2640 and L2780
Pricing = 38

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with CMS' preliminary recommendation, stating that none of the codes we offered describe the kinetic assist (spring and ratchet mechanism). In addition, the level of amputation does not apply (kick start for full leg). The applicant states he did meet with the Pricing, Data Analysis and Coding (PDAC) Contractor and was referred to CMS for a new code. There is no existing code for dynamic assist further up the leg. The speaker requested either a new code to describe the dynamic assist function, or a new code for the entire device, (language proposed).

O&P HCPCS Public Meeting Agenda Item #20
June 4, 2013

Attachment# 13.026
Topic/Issue:

Request to establish a new Level II HCPCS code to identify the Bledsoe PHX elbow orthosis. Applicant's suggested language: "Elbow Orthosis, with Fracture Reduction (Varus/Valgus Positioning) Hinge, with Adjustable Elbow Position Locking Joint(s), Prefabricated, Includes Fitting and Adjustment".

Background/Discussion:

According to the applicant, the Bledsoe PHX Elbow Orthosis extends from the mid-upper arm (humerus) to the mid-forearm (radius/ulna). The brace consists of 4 main components: a unique fracture reduction hinge (varus/valgus positioning hinge); a humeral cuff; a range of motion joint at the elbow; and a forearm support. The brace secures to the patient's humerus and forearm and uses a fracture reduction hinge secured to the humeral cuff to manipulate the elbow and forearm relative to the humerus to align bones. The fracture reduction hinge, in conjunction with the humeral cuff applies 3-point pressure to move and reduce the bones above and below the fracture site in proper alignment for healing. The humeral cuff and range of motion joint immobilize the joints above and below the fracture site for stabilization. The forearm support controls the wrist and aids in immobilizing the elbow. The humeral cuff compresses using the Sarmiento principle to align and immobilize the fracture for healing. The brace also functions to reduce the degree of varus deformity common in mid-shaft fractures treated with traditional braces. According to the requester, currently marketed fracture braces, and those with existing HCPCS codes, do not include the unique fracture reduction hinges feature of the PHX Elbow Orthosis which actively reduces the fracture. Existing codes apply to braces indicated for post-operative care of fixated fracture or to provide protection for stable fracture and/or soft tissue injuries. The PHX elbow orthosis, on the other hand, is intended to treat an injured arm by reducing, aligning and immobilizing the distal third humeral fractures without surgical intervention and as such, it is an alternative to Open Reduction and Internal Fixation (ORIF) surgery for some patients with distal humeral fractures.

Preliminary Decision:

Existing code L3760, Elbow Orthosis, With Adjustable Position Locking Joint(s), Prefabricated, Includes Fitting and Adjustments, Any Type", 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 = 38

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with CMS' preliminary recommendation. The primary speaker stated that orthoses coded at L7760 are intended for post-operative stabilization only, and do not have the additional feature of the varus/valgns hinge, which is unique to the device that is the subject of this application. This device is the only brace that actively reduces humeral fractures, and it is not adequately described by existing codes.

O&P HCPCS Public Meeting Agenda Item #21
June 4, 2013

Attachment# 13.091
Topic/Issue:

Request to establish a new Level II HCPCS base code to identify an AFO design that replaces or supplements the missing posterior calf group function, active plantar flexion. Trade Name: Dynamic Response AFO, or "DR-AFO".

Background/Discussion:

According to the requestor, the Dynamic Response AFO is a lightweight, low-profile base orthotic composite structure composed of multiple layers of carbon fiber or fiberglass. It has 4 distinct segments: a calf cuff and strapping enclosure; a flat posterior leaf spring that contours to the shape of the leg, extending from the calf cuff down the posterior leg, under the heel and to the metatarsal heads; a molded foot plate under the plantar surface, the layers of which are interwoven into the layers of the posterior spring; and a toe plate (another flat leaf spring) extending from the hind foot to the ends of the toes, interwoven with the foot plate and posterior spring. The calf cuff and foot plate provide positioning control to maintain the lower leg's orientation to the mechanical structures. The leaf springs are mechanical structures that provide a controlled, pre-determined amount of resistance as they bend, to match the patient's absent or weakened lower leg musculature. The material size and number of layers of the section is gauged to meet each patient's unique combination, and as such, is "re-engineered" 1) to alter the design's composition, changing the gradient resistance force to match the patient's strength deficits; and 2) to alter the contour of the design, controlling the timing of when the gradient resistance force acts against the patient in their gait cycle. Historically, AFO designs are based on the principals of guiding ankle motion or a rigid (solid) stop to a motion of the ankle. This design, however; applies a variable resistance force over a variable range of movement, and allows the resistance force to replace an absence of strength without limiting normal range of motion, allowing the orthosis to control a deviation in the gait cycle without limiting return to a normal, biomechanical gait pattern. It also creates variable resistance in relation to the amount of force the patient puts into the structure, providing a stabilizing force during standing still, from the weight of the patient. Then the resistance force increases as the patient begins forward motion into the structure, in conjunction with their weight. The absence of a rigid or solid stop to the patient's motion allows for a larger step; and the increasing resistance force maintains stability. This provides the additional functions of allowing variable cadence speed and maintaining proprioceptive balance. The requester claims a therapeutic distinction when this AFO design is used, compared with other AFOs, in that it provides a controlled resistance force. There is no other AFO design on the market that produces a force to replace plantar flexion (weak or absent plantar flexors). Use of this device requires a more comprehensive level of evaluation to determine the patient's specific combination of strength and positional deformity deficits, and to determine the amount of positional correction that is available. "Existing codes do not encompass this advanced, custom re-engineered design, or the complex evaluation and

fabrication process to make it available." This device is used with active military only, and is not available to the civilian market.

Preliminary Decision:

Existing code L1940 “Ankle Foot Orthosis, Plastic or Other Material, Custom-Fabricated”, adequately describes the device that is the subject of this request.

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

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with CMS' preliminary recommendation, stating that the difference between the subject product, (the Dynamic AFO) and L1940 is resistance pushing back to replace lost muscle strength. The speaker commented that the Dynamic AFO is a custom-made flex foot, and the difference is going back to the normal function. The speaker suggests that the Medicare fee associated with existing code L5980 is more appropriate for the subject device.

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, has an expected life of at least 3 years 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;
- Surgical Dressings
- Therapeutic Shoes and Inserts

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 IOLs inserted in a physician's office. 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 or, supplier price lists. 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. Payment for E0935 is based on a daily rental fee schedule basis since coverage of this device is limited to 21 days.

- **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, were purchased 75 percent of the time or more from July 1986 through June 1987,or which are accessories used in conjunction with a nebulizer, aspirator, continuous airway pressure device, or respiratory assist device. The beneficiary has the option to acquire the item on a purchase or monthly rental basis. Total payments for the item cannot exceed the purchase fee schedule amount for the item.

- **Pricing = 33 Oxygen and Oxygen Equipment**
  Monthly fee schedule payments are made for furnishing oxygen and oxygen equipment. This monthly payment includes payment for all stationary oxygen equipment, supplies, and accessories and delivery of oxygen contents (stationary and portable). A monthly add-on to this payment is made for portable oxygen equipment only for those beneficiaries who require portable oxygen. The monthly payments for oxygen equipment cap after the 36th monthly payment is made, after which payment for the ongoing delivery of contents continues for 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. The beneficiary takes over ownership of the item after the 13th rental payment is made. The rental fee for capped rental items, other than power wheelchairs, for each of the first 3 months of rental is equal to 10 percent of the purchase fee for the item. The rental fee for months 4 through 13 is equal to 7.5 percent of the purchase fee for the item. The rental fee for power wheelchairs for each of the first 3 months of rental is equal to 15 percent of the purchase fee for the item. The rental fee for power wheelchairs for months 4 through 13 is equal to 6 percent of the purchase fee for the item. Complex rehabilitative power wheelchairs can also 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 and judgment of a reasonable payment amount, which, at a minimum, includes a review of the costs of labor and material used in constructing the equipment.

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

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