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

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

Tuesday, June 5, 2012

Introduction and Overview

Approximately 60 people attended. The agenda included 17 items.

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

Karen Jacobs 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 Orthotics & Prosthetics and Durable Medical Equipment (DME) and Accessories
Tuesday, June 5, 2012, 9:00 am – 5:00 pm
CMS Media Center
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.

O&P

AGENDA ITEM #1
Attachment# 12.070
Request to establish a unique code for a lumbar/truncal orthosis, trade name: Backsmith Selective Stabilization Support.

Primary Speaker: Dr. L. Voigt Smith of Backsmith, Inc.

AGENDA ITEM #2
Attachment# 12.068
Request to establish a code for an energy-storing, custom-engineered, custom fabricated ankle foot orthosis (AFO), utilizing fiber-reinforced polymer composites trade name: Energy Storing AFO.
Primary Speaker: Noel Chladek of Bio-Mechanical Composites, Inc.

AGENDA ITEM #3
Attachment# 12.001
Request to establish a code for an extended life voice prosthesis with magnetic valve closure, trade name: Provox® ActiValve™ Voice Prosthesis. Applicant's suggested language: "Tracheo-esophageal voice prosthesis with magnetic valve closure, inserted by a licensed health care provider, any type".

Primary Speaker: Dr. Donna Graville of Oregon Health & Science University

AGENDA ITEM #4
Attachment# 12.036
Request to establish a HCPCS code to identify injectable tissue bulking agent Hyaluronic acid and dextranomer-linked beads, trade name: Solesta®. Applicant's suggested language: Jxxxx "Hyaluronic acid and dextranomer-linked beads, Solesta, for injection in the anal canal, per mL".

Primary Speaker: Dr. Cary Gentry of Colon and Rectal Specialist

AGENDA ITEM #5
Attachment# 12.067
Request to establish a code for a motorized prosthetic knee, trade name: Power Knee™. Applicant's suggested language: "Addition to lower extremity prosthesis, endoskeletal knee-shin system, motor-powered swing and stance phase with powered knee flexion and extension under full load (battery and charger included)."

No Primary Speaker

AGENDA ITEM #6
Attachment# 12.090
Request new L code for a prosthetic foot that accommodates additional load carriage exceeding 30% of the user's body weight, trade name: Thrive.

Primary Speaker: Steven Reinecke of Freedom Innovations

DME

AGENDA ITEM #7
Attachment# 12.069
Request to establish a code for a mobile arm support, trade name: JAECO WREX (Wilmington Robotic Extension).

Primary Speaker: Mark Conry of JAECO Orthopedic

AGENDA ITEM #8
Attachment# 12.074
Request to establish a code for a portable knee extension device, trade name: Elite Seat®. Applicant's suggested language: "Terminal-extension device: non-custom, supine, portable, patient-controlled ratcheted tension knee device designed to restore terminal extension."

Primary Speaker: Annette Sullivan of Kneebourne Therapeutic

AGENDA ITEM #9
Attachment# 12.089
Request to establish a new code to indentify an off-the-shelf bariatric size lymphedema garment for use with a pneumatic compression pump. Applicant's suggested language: "Segmental Gradient Pressure Pneumatic Appliance, Bariatric, Full-Body, Patient Weight 350 lbs or greater", trade name: Lymphapod.

Primary Speaker: Deborah Gross of Lympha Press USA

AGENDA ITEM #10
Attachment# 12.087
Request to establish a code for an acoustic airway clearance device, trade name: The Frequencer™.

No Primary Speaker

AGENDA ITEM #11
Attachment# 12.085
Request to either establish a new HCPCS code or revise existing A4483 to identify a heat and moisture exchanger (HME) when used with Continuous Positive Airway Pressure (CPAP) machines, trade name: Transcend™ CPAP HME. Applicant's suggested language: Revise of existing code A4483 which currently reads "Moisture exchanger, disposable, for use with invasive mechanical ventilation" to instead read: "Moisture exchanger, disposable, for use with mechanical ventilation. Or to create a new code to read: "Heat and moisture exchanger, disposable, used with positive airway pressure device".

No Primary Speaker

AGENDA ITEM #12
Attachment# 12.082
Request to establish a code for an electrochemical low-dose tissue oxygenation system, trade name: TransCu O_2. Exxxx "Continuous diffusion of oxygen therapy device".

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

AGENDA ITEM #13
Attachment# 12.083
Request to establish a code for a medical therapy device that delivers transcutaneous electrical nerve stimulation (TENS) and low level laser therapy (LLLT) to a patient's limbs, trade name: Neurolumen PN-1000. Applicant's suggested language: "Combination Transcutaneous Electrical Nerve Stimulation and Lower Level Laser (LLLT) Device".

Attachment# 12.084
Request to: 1) to revise the verbiage of code E0731 which currently reads: "FORM FITTING CONDUCTIVE GARMENT FOR DELIVERY OF TENS OR NMES (WITH CONDUCTIVE FIBERS SEPARATED FROM THE PATIENT'S SKIN BY LAYERS OF FABRIC)" to instead read: "FORM FITTING CONDUCTIVE GARMENT FOR DELIVERY OF TENS, NMES, OR COMBINATION TENS/LLLT DEVICE (WITH CONDUCTIVE FIBERS SEPARATED FROM THE PATIENT'S SKIN BY LAYERS OF FABRIC)" to describe assembly wraps used with the Neurolumen PN-1000; and 2) establish a new code to identify gel pads for use with the Neurolumen PN-1000. Applicant's suggest language: Axxxx "Gel pad, for use with combination TENS and LLLT device".

Primary Speaker: Dr. R. Nathan Grantham

AGENDA ITEM #14
Attachment# 12.081
Request to expand the following 3 existing HCPCS code categories: E0277 powered pressure reducing air mattress; E0185 gel or gel-like pressure pad for mattress, standard mattress length and width; and E0184 dry pressure mattress by adding 2 new codes to each of these categories. The proposal is to add a total of 6 new codes that would add distinctions based on width and weight capacity. Trade Names: Power-Pro Elite, Relief Care Pro, Gel Pro and similar bariatric devices.

Primary Speaker: Jim Acker of Blue Chip Medical Products

AGENDA ITEM #15
Attachment# 12.079
Request to reassign the Swing-Away Stump Support and the Angle Adjustable Swing-Away Stump Support from existing code E1020 "RESIDUAL LIMB SUPPORT SYSTEM FOR WHEELCHAIR" alone, to two codes: E1020 (as above) plus existing code E1028 "WHEELCHAIR ACCESSORY, MANUAL SWINGAWAY, RETRACTABLE OR REMOVABLE MOUNTING HARDWARE FOR JOYSTICK, OTHER CONTROL INTERFACE, OR POSITIONING ACCESSORY."

Primary Speaker: Beverly Hogue of Gerber Chair Mates, Inc.

AGENDA ITEM #16
Attachment# 12.072
Request to either establish a unique code to describe a spring assisted forearm crutch "similar to the reimbursement ability of code E0117" OR to revise existing code E0117 to include "spring assisted *forearm*" crutches, trade name: Ergobaum crutches.

No Primary Speaker

AGENDA ITEM #17
Attachment# 12.003
Request to establish a code for a walker with standing assistive apparatus, trade name: EasyRise™ Walker, model 2150/A, 400 lb capacity.

Attachment# 12.004
Request to establish a code for an extra wide universal dualie 6 wheeled walker that assists the user rising from a seated position, trade name: GRAND Line® EasyRise™ Walker (bariatric version), model #2160/1.

Attachment# 12.005
Request to establish a code for a 6 wheeled walker with an attachment holder, trade name: the Grand Line® Extra Wide Universal Dualie 6 Wheeled Walker with Handiholder™ Universal Mount for attachments, model 2151 B/1.

Attachment# 12.017
Request to establish a code for a 400 lb weight capacity tall youth to tall adult 4-wheeled walker with a mount for attachments, trade name: Universal 4-wheeled Double with Button Folding Walker HandiHolder™ mount, model #2146/1.

No Primary Speaker

O&P HCPCS Public Meeting Agenda Item #1
June 5, 2012

Attachment# 12.070

Topic/Issue:

Request to establish a unique code for a lumbar/truncal orthosis, trade name: Backsmith Selective Stabilization Support.

Background/Discussion:

According to the requester, the Backsmith Selective Stabilization Support is a back support that allows mid and low back desired stabilization. It is used for: postural re-education, desired specific and localized thoracic or lumbar stabilization, enhancement of therapeutic extension exercises, remodeling of adaptively shortened para spinal tissue and selective desired stabilization allowing for more functional stability and often centralization of pain with standing or walking activities of daily living. According to the requester, existing code L0625 is the code that comes the closest to describing this device. However, a unique code is being requested because this device is not designed to provide gross or generalized support. It is designed to provide localized control of motion in one or more planes, at desired levels, and localized therapeutic posterior-to-anterior pressure. For a number of patients, selective stabilization is needed, and other devices are not capable of providing this specific type of support and pressure. For those who respond to this new and unique rehab intervention, it is used to reduce and dampen pain allowing other interventions to be less painful and more effective. In many cases, functional restoration of normal movement and motion is the best medicine for mechanical/neurological spine issues, and selective stabilization can be the optimal tool to unleash this potential.

Preliminary Decision:

Existing code L0625 "LUMBAR ORTHOSIS, FLEXIBLE, PROVIDES LUMBAR SUPPORT, POSTERIOR EXTENDS FROM L-1 TO BELOW L-5 VERTEBRA, PRODUCES INTRACAVITARY PRESSURE TO REDUCE LOAD ON THE INTERVERTEBRAL DISCS, INCLUDES STRAPS, CLOSURES, MAY INCLUDE PENDULOUS ABDOMEN DESIGN, SHOULDER STRAPS, STAYS, 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 applicant disagreed with CMS' preliminary decision, stating that since Backsmith Selective Stabilization Support is designed differently, the cost of making and distributing this specialized device is significantly more than what is reimbursed under code L0625. According to the speaker, Backsmith uniquely helps meets unmet patient care needs for many outlier patients with restrictive back-related pain, movement compensations, weakness, and instability. The Selective Stabilization device provides localized and concentrated support to the trunk allowing patients to have improved functional mobility and stability (i.e. with functional walking, standing, squatting and extension exercises), in contrast to other devices coded at L0625, which immobilize and provide generalized support. The applicant requested a unique billing code and more aggressive reimbursement ceiling.

O&P HCPCS Public Meeting Agenda Item #2
June 5, 2012

Attachment# 12.068

Topic/Issue:

Request to establish a code for an energy-storing, custom-engineered, custom fabricated ankle foot orthosis (AFO), utilizing fiber-reinforced polymer composites trade name: Energy Storing AFO.

Background/Discussion:

According to the requester, the Energy Storing AFO is a one-piece brace for the lower leg that fits below the knee and extends out to the end of the toes. The composite structure of the AFO consists of a molded posterior calf band connected to a posterior strut and a molded foot plate. It is molded to a cast model of the patient's limb and is worn inside a shoe. Each structure is engineered in relation to the fiber layers and their orientation to match the specific combination of deficits that each patient presents. This AFO is intended to maintain proper alignment of a diseased or injured lower leg, supplement or replace absent musculature for propulsion and improvement of proprioceptive balance during both standing and walking. The AFO stores and releases the patient's own energy back to the patient during the gait cycle. This characteristic of variable designed resistance strengths is able to be used in the sagittal, transverse and frontal planes. According to the requester, there are no existing codes to describe an energy storing AFO that is custom-engineered and custom-fabricated on a cast model of the patient.

Preliminary Decision:

Existing base code L1960 "AKLE FOOT ORTHOSIS, POSTERIOR SOLID ANKLE, PLASTIC, CUSTOM-FABRICATED", plus existing code L2755 "ADDITION TO LOWER EXTERMITY ORTHOSIS, HIGH STRENGTH, LIGHTWEIGHT MATERIAL, ALL HYBRID LAMINATION/PREPREG COMPOSITE, PER SEGMENT, FOR CUSTOM FABRICATED, ORTHOSIS ONLY" (to identify carbon composite materials), adequately describes the product that is the subject of this request. Existing code L2820 "ADDITION TO LOWER EXTREMITY ORTHOSIS, SOFT INTERFACE FOR MOLDED PLASTIC, BELOW KNEE SECTION" may also be used if the AFO includes a soft interface liner.

Carbon composite materials or similar are considered to be energy storing materials. Code L2275 “ADDITON TO LOWER EXTREMITY, VARUS/VALGUS CORRECTION, PLASTIC MODIFICATION, PADDED/LINED” should not be reported, because this AFO does not provide varus/valgus correction of the ankles.

Medicare Payment:
The payment rules associated with the existing codes apply to this product if covered.
For L1960, L2755 and L2820, Pricing = 38

Summary of Primary Speaker Comments at the Public Meeting:

The applicant commented that the speaker the "Energy Storing AFO" consists of carbon composite material contoured to the patient's model in 4 distinct segments. Each segment is precisely engineered with unidirectional and multidirectional layers interwoven to individualize the specific resistance required in each segment to compensate for a patient's specific deficits and deformities. The base code descriptor for L1960 specifies "solid ankle" and "plastic", and both are completely inconsistent with this orthosis. Other base codes also show no resemblance to this custom design. The applicant reiterated the incoming request to establish a new base L code for an orthosis design that is not only energy storing but is of a nature that the energy storing resistance can be customized to the specific needs of the patient.

O&P HCPCS PUBLIC Meeting Agenda Item #3

June 5, 2012

Attachment# 12.001

Topic/Issue:

Request to establish a code for an extended life voice prosthesis with magnetic valve closure, trade name: Provox® ActiValve™ Voice Prosthesis. Applicant's suggested language: "Tracheo-esophageal voice prosthesis with magnetic valve closure, inserted by a licensed health care provider, any type".

Background/Discussion:

According to the requester, a voice prosthesis is a one-way valve that allows exhaled air to pass from the trachea into the esophagus where a "pseudo" or false voice is produced then closes during swallowing to prevent food and liquids from entering the lungs. The Provox® ActiValve™ is intended to meet the specific needs of those users who suffer a persistent short prosthesis lifetime (less than 4-8 weeks). The applicant proposes a protocol that the Provox device should be considered after a person has experienced 3-5 consecutive short durations of other models of prosthesis (shorter than 4-8 weeks) which were proven to be inefficient due to early leakage of the valve. The Provox® ActiValve™ differs from a "standard" voice prosthesis in that it incorporates two low force magnets (one in the valve flap and one in the outer ring) that increase the pressure needed to open the prosthesis valve flap, reducing the chance of inadvertent opening during swallowing or inhalation. Provox® ActiValve™ is inserted by a health care provider. It is supplied non-sterile with inserter and comes with a "clinician and patient manual", a set of cleaning brushes, a bottle of lubricant, a plug, two device identification cards, and a yellow plastic wallet card. According to the requester, the Provox® ActiValve™ device differs from other trachea-esophageal voice prostheses in that magnetic mechanism prevents inadvertent valve opening and early device leakage. Early device leakage leaves "the potential for pulmonary complications such as infections and aspiration pneumonia and dehydration". In addition, the Provox® ActiValve™ "has been shown to last 500% longer than the average voice prosthesis that is billed under L8509. A new HCPCS code "would allow 3rd party payers to acknowledge this difference in medical policies and reimbursement rates".

Preliminary Decision:

Existing code L8509 "TRACHEO-ESOPHAGEAL VOICE PROSTHESIS, INSERTED BY A LICENSED HEALTH CARE PROVIDER, ANY TYPE" adequately describes voice prostheses inserted by a health care provider. Existing code L8507 "TRACHEO-ESOPHAGEAL VOICE PROSTHESIS, PATIENT INSERTED, ANY TYPE, EACH" adequately describes voice prostheses that are patient self-inserted.

Medicare Payment:

The payment rules associated with the existing codes apply to this product if covered.
For L8509, Pricing = 38
For L8507, Pricing = 38

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with CMS' preliminary decision. According to the speaker ActiValve device has two advantages over the standard indwelling tracheoesophageal prostheses, (TEPs). First, it incorporates two magnets that increase the pressure needed to open the prosthesis valve flap. These magnets decrease inadvertent opening thus decreasing the aspiration of saliva, reflux, and food or liquids. Second, the ActiValve one way valve and valve seat are manufactured from fluoroplastic, which is resistant to the build-up of Candida. According to the speaker, this device is an extremely useful solution for individuals who experience frequent aspiration symptoms and need frequent TEP replacement, and a new "L" code to identify this device and distinguish it from TEPs that do not include a magnetic valve closure.

O&P HCPCS Public Meeting Agenda Item #4
June 5, 2012

Attachment# 12.036

Topic/Issue:

Request to establish a HCPCS code to identify an injectable tissue bulking agent Hyaluronic acid and dextranomer-linked beads, trade name: Solesta®. Applicant's suggested language: Jxxxx "Hyaluronic acid and dextranomer-linked beads, Solesta, for injection in the anal canal, per mL".

Background/Discussion:

According to the requester, Solesta is a biocompatible tissue bulking agent that is composed of non-animal stabilized hyaluronic acid and dextranomer microspheres. It is indicated for the treatment of fecal incontinence in patients 18 years and older who have failed conservative therapy. Solesta works by causing a chemical reaction within the body. The exact mechanism of action has not been identified; but, it is hypothesized that the Solesta injections may narrow the anal canal and expand the submucosal tissue, which in turn, allows better sphincter control. Each Solesta treatment consists of four 1 mL injections into the submucosal layer of the anal canal. The procedure is performed by a physician without anesthesia under direct visualization using an anoscope. Solesta is supplied in a glass syringe containing 1 mL gel. Four pouches, each containing one syringe are packed in a carton together with five needles, patient record labels and a package insert. According to the requester, there are other sodium hyaluronate products that might be considered to be similar to Solesta, however they all have a different clinical indication. Existing codes are inadequate to describe Solesta because the codes for the sodium hyaluronate viscosupplement products all include the brand or product name. The applicant recommends that Solesta "be treated as a drug or biological for Medicare purposes" as other sodium hyaluronate products, and that "an L code is inappropriate". The applicant also commented that existing code L8604 is specifically for a bulking agent used in the urinary tract, and therefore is not appropriate for a bulking agent used in the anal canal.

Preliminary Decision:

Revise code L8604 which currently reads: "INJECTABLE BULKING AGENT, DEXTRANOMER/HYALURONIC ACID COPOLYMER IMPLANT, URINARY TRACT, 1 ML, INCLUDES SHIPPING AND NECESSARY SUPPLIES" to instead read: "INJECTABLE BULKING AGENT, DEXTRANOMER/HYALURONIC ACID COPOLYMER IMPLANT, URINARY TRACT OR ANAL SPHINCTER, 1 ML, INCLUDES SHIPPING AND NECESSARY SUPPLIES".

Medicare Payment:
Based on our preliminary benefit category analysis, we believe that the item would be paid in

accordance with the payment rules that apply to Orthotics, Prosthetics, Prosthetic Devices, and Vision Services if covered.

Summary of Primary Speaker Comments at the Public Meeting:

The speaker stated that Solesta® should be treated and coded like a Drug or Biological. It functions like a drug or biological, physicians purchase, administer and report it like a drug or biological and payers are paying for it as a drug or biological. The speaker commented that if Solesta® is treated as a prosthetic device and assigned an "L" code, Gastroenterologists will not use the product in an office setting, stating "we don't do L codes". Billers are not familiar with L codes. There is a perception that an L code implies a procedure that should be performed in a hospital and "patients don't want to go to the hospital". Solesta® is indicated for the treatment of fecal incontinence in patients 18 years and older who have failed conservative therapy. According to the speaker, Solesta® is a biocompatible, injectable gel that expands the submucosal layer in the proximal anal canal to improve bowel control. It enhances the function of the anal sphincter, but does not replace it. The speaker reiterated that Solesta® is a Drug, Not a Prosthetic Implant, and asked that the HCPCS Workgroup establish a new "J" code.

O&P HCPCS Public Meeting Agenda Item #5
June 5, 2012

Attachment# 12.067

Topic/Issue:

Request to establish a code for a motorized prosthetic knee, trade name: Power Knee™. Applicant's suggested language: "Addition to lower extremity prosthesis, endoskeletal knee-shin system, motor-powered swing and stance phase with powered knee flexion and extension under full load (battery and charger included)."

Background/Discussion:

According to the requester, the Power Knee™ is the first motorized prosthetic knee available for transfemoral amputees weighing up to 275 pounds. It is indicated for use by functional level K3 individuals with a documented comorbidity in their sound limb or spine and by bilateral amputees. The knee houses an electomechanical actuator that actively initiates and controls all aspects of the user's gait. It also provides powered knee flexion and extension under full user load. The motor initiates appropriate movement and function based on data collected through accelerometers, gyroscopes, a torque sensor, and a load sensor. When users walk with the Power Knee, the device samples knee position and loads at the rate of 1,000 times/second to provide appropriate power for the user in all three phases of the extension portion of the gait cycle. At heel strike, the motor permits and encourages active stance flexion, functioning to replace foot/ankle, knee, and hip muscles. This permits a flexion moment that more accurately replicates able-bodied gait while simultaneously providing full support and stability for users. The motor-controlled knee flexion at heel strike also reduces the impact on users, permitting a smoother transition from the sound side to the prosthetic side, facilitating a more symmetrical gait. When users walk down declines and stairs, Power Knee permits leg-over-leg descent. When users stand still, it permits them to stand with the prostehetic knee flexed, as the electromechanical motor actively support the user's weight. Power Knee's motor actively extends the knee from a flexed (seated) position into an extended (standing) one. The motor provides an affirmative, dynamic response that resists gravity, lifting the user up. Upon initial use, a practitioner must program and align the knee. Once programming and alignment are complete, the user needs only to press the power button to use the device. The user must also charge the lithium-polymer batteries that power the device. A 3.5 hour charge is recommended to ensure maximum battery life. On a full charge, battery life is up to 12 hours depending on the user's activities. Each Power Knee comes with two batteries. According to the requester, predecessor devices contain no motor, and current HCPCS codes do not describe a motor-powered knee.

Preliminary Decision:

Establish Lxxxx ADDITON TO LOWER EXTREMITY, PROSTHESIS, ENDOSKELETAL KNEE-SHIN SYSTEM, POWERED AND PROGRAMMABLE FLEXION/EXTENSION ASSIST CONTROL, INCLUDES ANY TYPE MOTOR(S).

The proposed new code, together with existing codes L5856 "ADDITION TO LOWER EXTREMITY PROSTHESIS, ENDOSKELETAL KNEE-SHIN SYSTEM, MICROPROCESSOR CONTROL FEATURE, SWING AND STANCE PHASE, INCLUDES ELECTRONIC SENSOR(S), ANY TYPE; L5828 "ADDITION, ENDOSKELETAL KNEE-SHIN SYSTEM, SINGLE AXIS, FLUID SWING AND STANCE PHASE CONTROL; L5845 "ADDITION, ENDOSKELETAL, KNEE-SHIN SYSTEM, STANCE, STANCE FLEXION FEATURE, ADJUSTABLE; and L5848 "ADDITION TO ENDOSKELETAL KNEE-SHIN SYSTEM, FLUID STANCE EXTENSION, DAMPENING FEATURE, WITH OR WITHOUT ADJUSTABILITY" describe the entire motorized prosthetic knee that is the subject of this request.

Medicare Payment:

The payment rules associated with the existing codes apply to this product if covered.
For L5856, L5828, L5845, and L5848 Pricing = 38

Based on our preliminary benefit category analysis, we believe the new code would be paid in accordance with the payment rules that apply to Orthotics, Prosthetics, Prosthetic Devices, and Vision Services if covered.

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

O&P HCPCS Public Meeting Agenda Item #6
June 5, 2012

Attachment# 12.090

Topic/Issue:

Request for a new "L" code for a prosthetic foot that accommodates additional load carriage exceeding 30% of the user's body weight, trade name: Thrive.

Background/Discussion:

According to requestor, The Thrive is the world's first variable activity and load carriage dynamic prosthetic foot. It is made of carbon fiber and includes two keels. It also has a carbon fiber heel lever and urethane heel bumper. It is available in various sizes (22-30cm), in nine stiffness categories (matched to amputee's activity and weight levels), and is available for amputees weighing up to 365 lbs.

The primary, lower keel provides function for the amputee's activities of daily living. If the amputee is more active or carries a heavy object (up to 30% of the user's body weight), the secondary, upper keel is engaged in addition to the lower keel. The Thrive is indicated for individuals who frequently carry heavy objects, such as automotive mechanics, carpenters, child care providers, construction workers, plumbers, police officers, military personnel, and/or warehouse workers. While there are many models of prosthetic feet available from many manufacturers, none of the existing products provide the unique function of the Thrive to dynamically accommodate increased load.

Preliminary Decision:

Existing code L5981 "ALL LOWER EXTREMITY PROSTHESES, FLEX-WALK SYSTEM OR EQUAL" adequately describes the product that is the subject of this request.

A national program operating need was not identified by Medicare, Medicaid or the Private Insurance Sector to establish a code to identify variability in load bearing. Increased load carriage and vertical shock is a component of existing code L5981 and therefore separate reporting of this feature would be duplicative.

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 applicant disagreed with CMS' preliminary decision, commenting that traditional or standard feet coded at L5981 do not have a dynamic stiffness range to accommodate increased load carriage, and are under rated for overloaded activities. In contrast, the variable stiffness and dual keel design of the Thrive appears to function as a physiological analog that allows for invariant ankle motion between the unloaded and loaded situations. The applicant reiterated the original request for a new "L" code for a novel prosthetic foot component enhancement which enables both the prosthetist and user to safely increase the user's load carriage of up to 30% of the amputee's body weight.

DME HCPCS Public Meeting Agenda Item #7
June 5, 2012

Attachment# 12.069

Topic/Issue:

Request to establish a code for a mobile arm support, trade name: JAECO WREX (Wilmington Robotic Extension).

Background/Discussion:

According to the requester, the WREX mobile arm support allows a person with neuromuscular weakness to freely move his or her arms in all directions including anti-gravity movements. The device uses stored potential energy in elastic bands to elevate the device and the arm. The bands come in different levels of stiffness and the tension can be adjusted. The WREX consists of hollow steel rods, referred to as an exoskeleton, that sit alongside the upper arm and forearm. The rods are arranged in the shape of a parallelogram which allows the elbow elevation to be de-coupled from elbow flexion/extension so that patients can maintain or change their elbow angle independently of how high they raise their elbow. In other words, the joints of the parallelogram allow positioning of the elbow and hand in three-dimensional space. An arm trough is attached to the forearm rod. The user places his or her arm into the trough and it is then secured by velcro straps. The trough is available in three sizes. The WREX can be mounted onto a wheelchair or back brace. According to the requester, existing codes were established to describe the Mobile Arm Support (MAS). The WREX, on the other hand, is a new device and a "functional orthosis" that has additional articulations which are more anatomically aligned providing greater range of motion. In addition the WREX is the only MAS orthotic device that can be attached to a wheelchair for non-ambulatory patients or to a back brace for ambulatory patients with weak upper extremities.

Preliminary Decision:

Either existing base code E2627 "WHEELCHAIR ACCESSORY, SHOULDER ELBOW, MOBILE ARM SUPPORT ATTACHED TO WHEELCHAIR, BALANCED, ADJUSTABLE RANCHO TYPE" or E2628 "WHEELCHAIR ACCESSORY, SHOULDER ELBOW, MOBILE ARM SUPPORT ATTACHED TO WHEELCHAIR, BALANCED, RECLINING", (depending on whether the wheelchair reclines), plus existing code E2631 "WHEELCHAIR ACCESSORY, ADDITION TO MOBILE ARM SUPPORT, ELEVATING PROXIMAL ARM" and/or E2632 "WHEELCHAIR ACCESSORY, ADDITION TO MOBILE ARM SUPPORT, OFFSET OR LATERAL ROCKER ARM WITH ELASTIC BALANCE CONTROL", (depending on the functionality provided), adequately describes the device that is the subject of this application.

A national program operating need was not identified by Medicare, Medicaid or the Private Insurance Sector to code differently based upon the mechanism of connection used by the provider.

Medicare Payment:

The payment rules associated with the existing codes apply to this product if covered.
For E2627, E2628, E2631 and E2632, Pricing = 32

Summary of Primary Speaker Comments at the Public Meeting:

The applicant disagreed with CMS' preliminary decision, stating that the JAECO WREX differs from other arm supports in that it has a shoulder, and it is unique because it uses elastic bands instead of gravity. The applicant stated that the WREX does not have to be mounted to chair or table. It can be attached to a body jacket for ambulatory patients and used as an orthosis. The applicant also claimed that the Orthotic community says that coding the JAECO WREX as a wheelchair attachment precludes use as orthotic.

DME HCPCS Public Meeting Agenda Item #8
June 5, 2012

Attachment# 12.074

Topic/Issue:

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

Background/Discussion:

According to the requester, Elite Seat is a portable, non-custom, patient controlled, ratcheted tension knee device that provides a progressive stretch above and below the knee joint to allow complete relaxation of the hamstring muscle. The Elite Seat is designed to stretch the knee joint to its normal state of HYPER-extension. This rehabilitation device can be used for non-operative and pre/post operative indications. It is specifically used to treat any and all knee injuries that result in a loss of normal or full terminal extension. Elite Seat is portable and can easily be used by a patient in a clinical setting or at home. It is also exclusively "patient controlled" which allows the patient to be in control of their own rehabilitation processes thus eliminating the added expense associated with a nurse or physical therapist. Elite Seat is used 3 to 5 times per day for a period of 10 minutes each session. This device is designed to replace serial casting; Arthroscopy and scar resection; and manual manipulation under anesthesia. It is indicated for patients with joint stiffness and loss of full, terminal extension due to osteoarthritis, total knee arthroplasty, deconditioned knee with a flexion contracture, arthritic knee joint with a flexion contracture, failed post-operative rehabilitation, and arthrofibrosis. The requester claims a significant functional and therapeutic distinction offered by the Elite Seat as compared to other products coded at E1811 STATIC PROGRESSIVE STRETCH KNEE DEVICE, EXTENSION AND/OR FLEXION, WITH OR WITHOUT RANGE OF MOTION ADJUSTMENT, INCLUDES ALL COMPONENTS AND ACCESSORIES". Specifically, code E1811 is unique for products that are designed to stabilize a joint. There is no indication that this code is intended for products that are specifically designed to treat any explicit condition nor does it address devices having a single ultimate objective such as achieving full terminal extension as in the Elite Seat®. Elite Seat® is the only product currently within the E1811 category that has been used in studies to achieve terminal extension, and as such, the Elite Seat should not be included in E1811 with “experimental therapies”.

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.

A national program operating need was not identified by Medicare, Medicaid or the Private Insurance Sector to divide the existing code category on the basis of achieving "terminal extension" of the knee joint.

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:

There was no primary speaker for this item, however the applicant submitted written comments in disagreement with CMS' published preliminary decision. According to the applicant, the EliteSeat® is the only portable knee extension device that is patient controlled in supine position and that enables terminal hyperextension, and as such allows the patient to achieve full terminal extension symmetric to the contralateral knee joint. Based on these operational differences the applicant claims that the Elite Seat confers a significant therapeutic distinction when compared with the use of other products that share code E1811, and therefore, a unique code is warranted for the Elite Seat. In addition, the applicant commented that "capped rental" is not the appropriate Medicare payment mechanism for the Elite Seat because it has a proven attainable prescriptive value (terminal extension) and is only used by the patient until those values have been obtained.

DME HCPCS Public Meeting Agenda Item #9
June 5, 2012

Attachment# 12.089

Topic/Issue:

Request to establish a new code to indentify an off-the-shelf bariatric size lymphedema garment for use with a pneumatic compression pump. Applicant's suggested language: "Segmental Gradient Pressure Pneumatic Appliance, Bariatric, Full-Body, Patient Weight 350 lbs or greater", trade name: Lymphapod.

Background/Discussion:

According to the requestor, Lympapod is a full-body pneumatic compression therapy appliance which includes the garment and hoses. It's a full body pneumatic lymph edema compression system that treats the trunk, torso, legs, genitals, abdomen, hips, buttocks or high upper thighs, designed to fit extremely large/very obese patients from 350-700 lbs who suffer from lymphedema and or venous disorders and/or muscle dysfunction. The physician prescribes treatment pressure, duration and frequency. The system will operate between 20 and 90mmHg, and pressure can be set individually in four separate zones, to address specific needs such as distal fibrosis, discomfort and sensitivity. Generally treatments of 2 hours daily are prescribed, with a one-hour session in the morning and a second one-hour session in the evening. Sometimes one daily session is prescribed. There are no existing code categories to describe a full body, bariatric pneumatic pump garment. Improvements were added to this product to enable usability by bariatric patients. This garment is more complex than the standard garments due to the material used and the way the garment is made.

Preliminary Decision:

Establish Exxxx SEGMENTAL PNEUMATIC APPLIANCE FOR USE WITH PNEUMATIC COMPRESSOR, 2 FULL LEGS AND TRUNK

Medicare Payment:

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

Summary of Primary Speaker Comments at the Public Meeting:

The applicant was happy with a positive preliminary decision to establish a new code, but had concerns over the proposed code text. Specifically, the applicant proposed language that would describe the device as "heavy duty" and for use for "2 full legs and *bilateral* trunk." In addition,

the applicant asked to specify a pneumatic compressor within the appliance code. The applicant would like the code to read "Segmental Pneumatic Appliance for use with Pneumatic Compressor, Heavy Duty, Two Full Legs and Bilateral Trunk." The following reasons were provided for the requested language revision:
1) the addition of "heavy duty" will address the intended use for bariatric patients who weigh 350 pounds or more; 2) the addition of "bilateral" is intended to distinguish the LymphaPod from products coded at E0656, which treat one side of the trunk only. The LymphaPod treats the entire trunk bilaterally; and 3) the language proposed in the preliminary decision is potentially confusing, since it could pertain to products already described by other HCPCS codes (i.e., the combination of the two codes E0667 (leg) and E0656 (trunk).

DME HCPCS Public Meeting Agenda Item #10
June 5, 2012

Attachment# 12.087

Topic/Issue:

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

Background/Discussion:

According to the requester, the Frequencer™ device provides airway clearance by inducing oscillatory sound waves in the chest by means of an electro-acoustical transducer placed externally on the patient's chest. The transducer is connected to a frequency generator which is capable of producing frequencies between 20 and 100Hz. The vibrations in the patient's chest are effective in loosening mucus deposits and promoting bronchial drainage. The Frequencer consists of two parts, a control unit and a transducer. The user places the transducer on the chest. The frequency (adjustable between 20 and 100HZ) and the volume are adjusted in the control unit to create sympathetic resonance that can be felt in the lungs. According to the requester, there are significant differences between devices coded at E0480 "PERCUSSOR, ELECTRIC OR PNEUMATIC, HOME MODEL" and the Frequencer. Specifically: (1) Devices coded at E0480 deliver a frequency pounding or striking action, similar to clapping, to a patient's chest to loosen mucus. The Frequencer uses a different operating principle: higher frequency acoustic waves to excite resonance in the chest. (2) Acoustic wave action makes the Frequencer appropriate patients who are: under 3 years of age; elderly and fragile; agitated; immobilized; obese; and status/post surgery. As such, the applicant claims that there is a significant therapeutic distinction between uses of the Frequencer as compared with the use of other devices also categorized in HCPCS code E0480. (3) The fee associated with the code E0480 is inadequate, "effectively denying the current device to patients covered by Medicare".

Preliminary Decision:

Existing code E0480 "PERCUSSOR, ELECTRIC OR PNEUMATIC, HOME MODEL" 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:

There was no primary speaker for this item.

DME HCPCS Public Meeting Agenda Item #11
June 5, 2012

Attachment# 12.085

Topic/Issue:

Request to either establish a new HCPCS code or revise existing A4483 to identify a heat and moisture exchanger (HME) when used with Continuous Positive Airway Pressure (CPAP) machines, trade name: Transcend™ CPAP HME. Applicant's suggested language: Revise of existing code A4483 which currently reads "Moisture exchanger, disposable, for use with invasive mechanical ventilation" to instead read: "Moisture exchanger, disposable, for use with mechanical ventilation. Or to create a new code to read: "Heat and moisture exchanger, disposable, used with positive airway pressure device".

Background/Discussion:

According to the requester, heat and moisture exchanger (HME) have been an important component of invasive mechanical ventilation systems for many years maintaining moisture levels in the lungs and preserving respiratory tract function. HME technology has been adapted to improve the operational efficiency of CPAP machines in the Transcend™ Sleep Apnea System which provides this simple, but effective waterless humidification system. The Transcend™ Sleep Apnea System uses disposable HME called the Transcend™ CPAP HME. HMEs act as an artificial nose allowing for the majority of heat and moisture lost through exhaled air to be recovered, thereby protecting lung tissue from damage and preserving respiratory tract function. The HME is manually placed into the airway circuitry in mechanical ventilation systems, including the Transcend device. It is activated solely by patient respiration. There are two types: hygroscopic HMEs and hydrophobic HMEs. Hygroscopic HMEs, such as the Transcend CPAP HME, are typically made of foam and attract moisture. Impregnating the foam with calcium chloride, helps the HME retain moisture. Hydrophobic HMEs are typically made from aluminum or a condensation surface made of a hydrophobic resin with a hydrophilic layer, while the membrane is made of ceramic fibers. Either type of HME is configured to provide maximum surface area for contracting airflow in ways that also minimizes resistance to airflow. The Transcend CPAP HME is the only one today that is used for a CPAP machine which is a noninvasive mechanical ventilator. According to the requester, existing HCPCS codes do not describe moisture exchanges for use with non-invasive devices.

Preliminary Decision:

Existing code A9900 "MISCELLANEOUS DME SUPPLY, ACCESSORY, AND/OR SERVICE COMPONENT OF ANOTHER HCPCS CODE" is available for assignment by insurers if they deem appropriate. This device is included in the mask for CPAP, coded at A7030 "FULL FACE MASK USED WITH POSITIVE AIRWAY PRESSURE DEVICE, EACH".

Medicare Payment:

The payment rules associated with the existing code apply to this product if covered.
Pricing = 46

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

DME HCPCS Public Meeting Agenda Item #12
June 5, 2012

Attachment# 12.082

Topic/Issue:

Request to establish a code for an electrochemical low-dose tissue oxygenation system, trade name: TransCu O_2. Exxxx "Continuous diffusion of oxygen therapy device".

Background/Discussion:

According to the requester, the TransCu O_2 is a portable device that delivers a continuous supply of pure oxygen. This non-invasive therapy is used to treat difficult-to-heal wounds and is intended for use with standard moist wound dressings as an adjunctive therapy to feed an oxygen-compromised wound a continuous supply of supplemental low-dose pure oxygen directly to the wound site. TransCu O_2 works by extracting oxygen from room air; concentrating the oxygen to 99.9% through the Proton Exchange Membrane (PEM); and then creating an oxygen rich environment of up to 99% oxygen under the dressing at the wound site. The device can be worn discretely in a pocket, fanny pack or attached to a belt clip like a cell phone. It can provide continuous treatment 24 hours a day, 7 days a week. TransCu O_2 is rented and the disposable accessories are single-use. TransCu O_2 is an advanced wound care technology viewed as the last line of defense in treating difficult-to-heal wounds such as diabetic foot ulcers, venous stasis ulcers, pressure ulcers, infected residual limbs, skin grafts, burns, and frostbite. The system consists of a battery operated microprocessor controlled electrochemical oxygen concentrator device weighing only 9 ounces, a 60-inch oxygen delivery extension set and 12-inch wound site oxygen delivery cannula. The five basic components of the system are the low dose tissue oxygenation system, the battery charger, the protective covering, the oxygen delivery extension set, and the wound oxygen delivery cannula. According to the requester, previously assigned code E0446 "TOPICAL OXYGEN DELIVERY SYSTEM, NOT OTHERWISE SPECIFIED" does not accurately describe the device or the wound care therapy that is provided by the device. There is no existing code category for a medical device that is designed to deliver a low flow of oxygen to continuously diffuse oxygen into a covered moist wound bed at normal atmospheric pressure. The continuous diffusion of oxygen therapy device is different than the topical oxygen therapy extremity chambers both functionally and operationally. TransCu O_2 uses a cannula to continuously deliver oxygen directly to the wound bed under moist wound dressing and has a proton exchange membrane. The treatment mode is continuous oxygen deliver 24/7 and the oxygen flow rate is very low ranging from 3-10 ml/hr. Topical oxygen therapy uses a bag, boot or extremity chamber around the affected area to apply oxygen and uses a tank/stationary concentrator. The treatment mode is 90 minutes for 3 to 5 times/week at a 10LMP pressure at the wound site.

Preliminary Decision:

Existing code E0446 "TOPICAL OXYGEN DELIVERY SYSTEM, NOT OTHERWISE SPECIFIED" adequately describes the product that is the subject of this request. In fact, the TransCu O_2 is the predicate product for which code E0446 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:

The primary speaker disagreed with CMS' preliminary decision, stating that code E0446 does not describe the TransCu O_2 electrochemical low-dose tissue oxygenation system. The speaker stated that they would like to have a new HCPCS code or to modify the code verbiage used in E0446 to "Continuous Diffusion of Oxygen Therapy Device". The speaker claimed it would reflect the distinct technology, function and operations of the TransCu O_2 which sets it apart from topical hyperbaric and oxygen systems. The speaker feels it would address the problems associated with the E0446 coding descriptor or "Topical Oxygen System not otherwise specified". Specifically, the speaker claimed that the text of code E0446 is too broad, and could include other existing or future products. In addition, the word "topical" in the current code text "inappropriately" ties the code to CMS' NCD 20.29 and as such, interferes with Medicare coverage for the TransCu O_2 device. The speaker reiterated the request for a new code describing the TransCu O_2 device as "continuous diffusion of oxygen". The speaker proposed a revision of the language of the existing code as an alternative solution. The speaker also commented that the TransCu O_2 could be distinguished from other devices coded at E0446 based on portability of the TransCu O_2 device. The speaker and the applicant also indicated that the device manufacturer is separately following up with CMS' Coverage and Analysis Group (CAG) pertaining to questions regarding applicability of NCD 20.29.

DME HCPCS Public Meeting Agenda Item #13
June 5, 2012

Attachment# 12.083

Topic/Issue:

Request to establish a code for a medical therapy device that delivers transcutaneous electrical nerve stimulation (TENS) and low level laser therapy (LLLT) to a patient's limbs, trade name: Neurolumen PN-1000. Applicant's suggested language: "Combination Transcutaneous Electrical Nerve Stimulation and Lower Level Laser (LLLT) Device".

Background/Discussion:

According to the requester, the Neurolumen PN-1000 is a medical therapy device that delivers transcutaneous electrical nerve stimulation (TENS) and lower level laser therapy (LLLT) to a patient's limbs. It is indicated for temporary relief of minor muscle and joint pain, arthritis and muscle spasm, relieving stiffness, promoting relaxation of muscle tissue, and to temporarily increase local blood circulation where heat is indicated. It is also indicated for symptomatic relief and management of chronic, intractable pain and adjunctive treatment for post-surgical and post-traumatic acute pain. The device emits therapeutic heat and light using a combination of light-emitting diode (LED) stimulation, low level laser therapy (LLLT), and trancutaneous electrical nerve stimulation (TENS) to promote cellular health and rehabilitation. The light emitting components propagate specific energy for absorption by the mitochondria so that chemiosmosis can occur to promote the production of andenosinetriphosphate (ATP). The augmentation of ATP improves cellular respiration and metabolism allowing more effective expulsion of toxins, metabolites, and bi-products promoting cell regeneration and improved metabolism. Neurolumen PN-1000 consists of a control unit, six 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. Wraps are applied to the feet, ankles, and legs and the gel pads are placed in the cutout in the wrap. The user turns the device on and the unit shuts off automatically when there is no time left on the therapy session timer. The control unit is able to provide up to 30 minutes of therapy on a single charge of the internal lithium-ion battery. Patients may use the device repeatedly for an indefinite period of time. However, the typical duration of therapy lasts for more than a year. According to the requester, there are no existing codes to specifically describe this product.

Preliminary Decision:

Existing code E0730 "TRANSCUTANEOUS ELECTRICAL NERVE STIMULATION (TENS) DEVICE, FOUR OR MORE LEADS, FOR MULTIPLE NERVE STIMULATION" 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

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:

The primary speaker disagreed with CMS' preliminary decision, stating that the Neurolumen PN-1000 (PN-1000) operates significantly differently than TENS device coded at E0730. Specifically, code E0730 limits the application to "Nerve Stimulation" and doesn't accommodate simultaneous photonic therapies, (e.g., wavelengths of light and coherent light properties) that are imperative to the action of the Neurolumen device. The speaker claimed the simultaneous application of LLLT, Infrared, Red and TENS is necessary to provide the dramatic healing properties. Transcutaneous Electrical Nerve Stimulation (TENS) is an ancillary application to the treatment. The speaker requested either a new code or modified code to adequately define the Neurolumen PN-1000, and its unique and innovative technology, stating that without this change, physicians will see the Neurolumen as "just another TENS", and it will not be utilized in practice.

DME HCPCS Public Meeting Agenda Item #13
June 5, 2012

Attachment# 12.084

Topic/Issue:

Request to: 1) to revise the verbiage of code E0731 which currently reads: "FORM FITTING CONDUCTIVE GARMENT FOR DELIVERY OF TENS OR NMES (WITH CONDUCTIVE FIBERS SEPARATED FROM THE PATIENT'S SKIN BY LAYERS OF FABRIC)" to instead read: "FORM FITTING CONDUCTIVE GARMENT FOR DELIVERY OF TENS, NMES, OR COMBINATION TENS/LLLT DEVICE (WITH CONDUCTIVE FIBERS SEPARATED FROM THE PATIENT'S SKIN BY LAYERS OF FABRIC)" to describe assembly wraps used with the Neurolumen PN-1000; and 2) establish a new code to identify gel pads for use with the Neurolumen PN-1000. Applicant's suggest language: Axxxx "Gel pad, for use with combination TENS and LLLT device".

Background/Discussion:

According to the requester, the Neurolumen PN-1000 is a medical therapy device that delivers transcutaneous electrical nerve stimulation (TENS) and lower level laser therapy (LLLT) to a patient's limbs. It is indicated for temporary relief of minor muscle and joint pain, arthritis and muscle spasm, relieving stiffness, promoting relaxation of muscle tissue, and to temporarily increase local blood circulation where heat is indicated. It is also indicated for symptomatic relief and management of chronic, intractable pain and adjunctive treatment for post-surgical and post-traumatic acute pain. The device emits therapeutic heat and light using a combination of light-emitting diode (LED) stimulation, low level laser therapy (LLT), and trancutaneous electrical nerve stimulation (TENS) to promote cellular health and rehabilitation. Neurolumen PN-1000 consists of a control unit, six 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 compound also has an adhesive property that allows the pad to stick to the conductive surface of the wrap circuit board on one side and the patient's skin on the other. Wraps are applied to the feet, ankles, and legs and the gel pads are placed in the cutout in the wrap. The typical duration of therapy lasts for more than a year. Gel pads and wrap assemblies are accessories that require periodic replacement. The replacement rate for the gel pads is one set per 60 treatments. According to the requester, existing codes do not represent these components.

Preliminary Decision:

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 revise existing code E0731 to include the wraps.

Medicare Payment:

The payment rules associated with the existing code apply to this product if covered.
Pricing = 34

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with CMS' preliminary decision, stating that the language of the recommended code A4595 is too restrictive to encompass the design elements of the gel pads used with the Neurolumen PN-1000 device; and code E0731 does not capture the photonic components incorporated into the wraps used with the Neurolumen PN-1000. The speaker reiterated the original request to revise code E0731 and establish a new code for gel pads.

DME HCPCS Public Meeting Agenda Item #14
June 5, 2012

Attachment# 12.081

Topic/Issue:

Request to expand the following 3 existing HCPCS code categories: E0277 powered pressure reducing air mattress; E0185 gel or gel-like pressure pad for mattress, standard mattress length and width; and E0184 dry pressure mattress by adding 2 new codes to each of these categories. The proposal is to add a total of 6 new codes that would add distinctions based on width and weight capacity. Trade Names: Power-Pro Elite, Relief Care Pro, Gel Pro and similar bariatric devices.

Applicant's suggested language:

Exxx1 Powered press-reducing air mattress, heavy duty, extra wide, with a weight capacity greater than 350 pounds, but less than or equal to 750 pounds

Exxx2 Powered pressure-reducing air mattress, extra heavy duty, extra wide, with a weight capacity greater than 750 pounds, but less than or equal to 1000 pounds

Exxx3 Dry pressure mattress, heavy duty, extra wide, with a weight capacity greater than 350 pounds, by less than or equal to 750 pounds

Exxx4 Dry pressure mattress, extra heavy duty, extra wide, with a weight capacity greater than 750 pounds, but less than or equal to 1000 pounds

Exxx5 Gel pressure overlay, heavy duty, extra wide, with a weight capacity greater than 350 pounds, but less than or equal to 750 pounds

Exxx6 Gel pressure overlay, extra heavy duty, extra wide, with a weight capacity greater than 750 pounds, but less than or equal to 1000 pounds

Background/Discussion:

According to the requester, bariatric pressure-reducing mattresses and overlays differ from products currently coded at HCPCS codes E0277, E0184 and E0185 in width, weight capacity, materials, construction and cost to manufacture. The requester comments that other HCPCS code categories for DME have distinguished, products based on weight capacity and pressure reducing mattresses should be similarly distinguished but have been "overlooked". The requester states that "Medicare typically identifies bariatric version of the standard as E1399 "DURABLE MEDICAL EQUIPMENT, MISCELLANEOUS"." Medicare has not issued any such direction regarding bariatric mattresses or overlays.

Preliminary Decision:

Existing code E0277 "POWER PRESSURE-REDUCING AIR MATTRESS" adequately describes the Power-Pro Elite Mattress; Existing code E0184 "DRY PRESSURE MATTRESS" adequately describes the Relief Care Mattress; and existing code E0185 "GEL OR GEL-LIKE PRESSURE PAD FOR MATTRESS, STANDARD MATTRESS LENGTH AND WIDTH" adequately describes the Gel-Pro overlay. Bariatric capacity was contemplated and included in existing codes E0277, E0184, and E0185. A national program operating need was not identified by Medicare, Medicaid or the Private Sector insurers to establish codes to separately identify bariatric mattresses. CMS would, however; be interested in clinical evidence of pressure reduction that confers a difference in clinical outcome for bariatric patients using these pressure-reducing devices.

Medicare Payment:

The payment rules associated with the existing codes apply to this product if covered.
For E0184, Pricing = 32
For E0185, Pricing = 32
For E0277, Pricing = 36

Summary of Primary Speaker Comments at the Public Meeting:

The applicant disagreed with CMS' preliminary decision, claiming that bariatric mattresses were not contemplated when codes E0277, E0184 and E0185 were established. When it comes to pressure sores, bariatric patients are at greater risk due to their size and immobility. Obese patients are prone to profuse sweating. The moisture can cause skin breakdown and rashes that can lead to an ulcer. The applicant stated that bariatric surfaces are functionally and mechanically different than the standard size surfaces, in that they use higher grade materials for durability, require a high output blower system to support added weight and moisture control. The applicant has asked for separate codes and specifications to recognize and differentiate Bariatric support surfaces, similar to codes and specifications for bariatric seating and wheelchairs.

DME HCPCS Public Meeting Agenda Item #15
June 5, 2012

Attachment# 12.079

Topic/Issue:

Request to reassign the Swing-Away Stump Support and the Angle Adjustable Swing-Away Stump Support from existing code E1020 "RESIDUAL LIMB SUPPORT SYSTEM FOR WHEELCHAIR" alone, to two codes: E1020 (as above) plus existing code E1028 "WHEELCHAIR ACCESSORY, MANUAL SWINGAWAY, RETRACTABLE OR REMOVABLE MOUNTING HARDWARE FOR JOYSTICK, OTHER CONTROL INTERFACE, OR POSITIONING ACCESSORY."

Background/Discussion:

According to the requester, the Swing-Away Stump Support and Adjustable Swing-Away Stump Support are attached to the front rigging of wheelchairs to provide the support necessary for proper healing of the residual limb. These supports are designed for individuals who have undergone an upper and/or lower limb amputation. According to the requester, these stump supports were assigned to code E1020 "RESIDUAL LIMB SUPPORT SYSTEM FOR WHEELCHAIR". However, E1020 is applied to every product termed 'Amputee Support'. Several of these supports do not contain separate positioning components. In comparison to other amputee supports, these Swing-Away Stump Supports are more intricate and sophisticated, with well-defined positioning. For this reason, the requester asks that the Swing-Away Stump supports be billable under both codes E1020 and E1028.

Preliminary Decision:

Existing code E1020 "RESIDUAL LIMB SUPPORT SYSTEM FOR WHEELCHAIR" adequately describes the product that is the subject of this request. In fact, this swing away feature was part of the predicate product for which code E1020 was originally established. Therefore use of other codes in addition to E1020 to capture the swing away stump support is not necessary and could be considered duplicative. Code E1028 identifies mounting for joystick or other control interface which clearly does not describe the swing-away stump supports.

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 applicant disagreed with CMS' preliminary decision, stating that it focuses only on the Swing-Away feature of Support Units, and does not address other differences between

"standard" stump support systems and the "Swing-Away" stump support. Specifically, the positioning feature of the "Swing-Away" is adjustable and provides multi-axis support and hardware. The Swing-Away device also incorporates gel pads, as opposed to standard pads. Based on these differences the applicant reiterated the original request to be able to bill two existing codes (E1020 plus E1028) to report the Swing-Away stump support system, and not be limited to code E1020 alone. According to the applicant, the emphasis is on Stump Support Units and how the consist of three distinct parts all being interchangeable with other styles and/or mode types we produce. The applicant claimed, that Support Units have a unique positioning accessory which adjusts to the patients liking and swings away for patient convenience. The applicant would like to reassign the Swing-Away Stump and the Angle Adjustable Swing-Away Stump Support from existing code E1020 to have two codes E1020 and E1028.

DME HCPCS Public Meeting Agenda Item #16
June 5, 2012

Attachment# 12.072

Topic/Issue:

Request to either establish a unique code to describe a spring assisted forearm crutch "similar to the reimbursement ability of code E0117" OR to revise existing code E0117 to include "spring assisted *forearm*" crutches, trade name: Ergobaum crutches.

Background/Discussion:

According to the requester, Ergobaum Is a lightweight crutch made with an aluminum alloy and nylon based parts. The crutch features a multidirectional gripping shoe with ailerons allowing extra stability in all directions (front, back, and side to side), a retractable knee rest that is padded, ergonomic design, adjustable non-slip rubber hand grip with internal shock absorber, shock absorber in the main stem of crutch for fluid motion and to provide return energy, padded and adjustable forearm cup with padded ratcheting strap, light safety reflectors on handle and upper stem of crutch, built in LED lights for maneuvering in the dark, and a safety alert horn built into the handle. It is indicated for long term use cane or rehabilitation purpose (after surgery, etc).as well as mobility assistance for general leg/ankle/foot/foot traumas.

According to the requester, Ergobaum crutches are distinguished from other crutches based on their safety features (lights, reflectors, horn, knee rests); shock absorbing hand grips and legs; and handgrips that reduce wrist tendon subluxation and carpal tunnel syndrome. Code E0111 "does not offer the best fit and reimbursement" for Ergobaum crutches.

Preliminary Decision:

Existing code E0111 "CRUTCH FOREARM, INCLUDES CRUTCHES OF VARIOUS MATERIALS, ADJUSTABLE OR FIXED, EACH, WITH TIP AND HANDGRIPS" adequately describes the forearm crutch that is the subject of this request.

Existing code E0117 "CRUTCH, UNDERARM, ARTICULATING, SPRING ASSISTED, EACH" does not describe Ergobaum crutches because Ergobaum crutches are neither articulating nor underarm 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.

DME HCPCS Public Meeting Agenda Item #17
June 5, 2012

Attachment# 12.003

Topic/Issue:
Request to establish a code for a walker with standing assistive apparatus, trade name: EasyRise™ Walker, model 2150/A, 400 lb capacity.

Background/Discussion:
According to the requester, the EasyRise™ walker is a double folding walker that assists the user rising from a seated position. It has 4 wheels; rear auto braking; telescoping handles; and positionable knee pads that assist the user to stand from a sitting position. The walker is "constructed of the heaviest gauge steel that would allow the telescoping of adjustable parts. It is rated at 400 lb. weight capacity. The weight capacity is only limited by the particular wheels used on the front of the walker". According to the requester, there is not an existing code that describes this product.

Preliminary Decision:

Existing code E0149 "WALKER, HEAVY DUTY, WHEELED, RIGID OR FOLDING, ANY TYPE" adequately describes the product that is the subject of this request.

A national program need was not identified by Medicare, Medicaid or the Private Insurance Sector to establish a new code to separately identify the standing assistive apparatus or a walker with a standing assistive apparatus.

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 #17
June 5, 2012

Attachment# 12.004

Topic/Issue:
Request to establish a code for an extra wide universal dualie 6 wheeled walker that assists the user rising from a seated position, trade name: GRAND Line® EasyRise™ Walker (bariatric version), model #2160/1.

Background/Discussion:
According to the requester, the EasyRise™ Extra Wide Walker is a 600 lb capacity walker with 6 wheels and rear auto braking swivel casters. It includes telescoping handles and positionable knee pads that assist the user to stand from a sitting position. This walker is "constructed of the heaviest gauge steel that would allow the telescoping of the adjustable". According to the requester there is not an existing code that describes this product.

Preliminary Decision:

Existing code E0149 "WALKER, HEAVY DUTY, WHEELED, RIGID OR FOLDING, ANY TYPE" adequately describes the product that is the subject of this request.

A national program operating need was not identified by Medicare, Medicaid or the Private Insurance Sector to establish a code to separately identify standing assistive apparatus or a walker with standing assistive apparatus; or to divide the existing code category on the basis of width, height weight capacity, or materials of manufacture.

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 #17
June 5, 2012

Attachment# 12.005

Topic/Issue:

Request to establish a code for a 6 wheeled walker with an attachment holder, trade name: the Grand Line® Extra Wide Universal Dualie 6 Wheeled Walker with Handiholder™ Universal Mount for attachments, model 2151 B/1.

Background/Discussion:

According to the requester, the Grand Line® Extra Wide Universal 600 lb weight capacity Walker is built to accommodate a variety of attachments, such as a basket holder, basket, bag, tray, IV pole, oxygen tank holder, oxygen concentrator holder or cup holder. Use of these attachments can reduce the need for additional assistance allowing the user to become independently mobile. In addition, use of this walker with the proper attachment can reduce the amount of time spent in a hospital and/or rehab center because a professional is not required to assist with wheeling or carrying equipment. Rear auto-braking swivel casters and 5" front wheels support the heavy attachments and enable better control of the walker while the attachments are in use. The HandiHolder, allows the user the ability to customize the walker to their specifications. Attachments can be changed quickly with a push button action. The current attachments do not alter the use of the walker, they just make mobility and independence a reality. According to the requester, there is no other product on the market that has the ability to accommodate all of these attachments.

Preliminary Decision:

Existing code E0149 "WALKER, HEAVY DUTY, WHEELED, RIGID OR FOLDING, ANY TYPE" adequately describes the product that is the subject of this request.

A national program operating need was not identified by Medicare, Medicaid or the Private Insurance Sector to establish a new code to separately identify a mount for attachments, or a walker that includes a mount for attachments; or to divide the existing code category on the basis of width, height, weight capacity or materials of manufacture.

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 #17
June 5, 2012

Attachment# 12.017

Topic/Issue:

Request to establish a code for a 400 lb weight capacity tall youth to tall adult 4-wheeled walker with a mount for attachments, trade name: Universal 4-wheeled Double with Button Folding Walker HandiHolder™ mount, model #2146/1.

Background/Discussion:

According to the requester, the Universal 4-wheeled walker with HandiHolder™ is a walker with 4 wheels, rear auto braking swivel casters and two 5" wheels in front. This walker includes the HandiHolder™ feature that allows the user to customize the walker to their specifications by adding an array of attachments, such as a basket holder, basket, bag, tray, IV pole, oxygen tank holder, oxygen concentrator holder or cup holder. This reduces the need for others to carry required items that the patient needs. Available attachments do not alter the use of the walker, they just make mobility and independence a reality. According to the requester, there are no similar products on the market, and existing HCPCS codes do not describe this product.

Preliminary Decision:

Existing code E0149 "WALKER, HEAVY DUTY, WHEELED, RIGID OR FOLDING, ANY TYPE" adequately describes the product that is the subject of this request.

A national program operating need was not identified by Medicare, Medicaid or the Private Insurance Sector to establish a new code to separately identify a mount for attachments, or a walker that includes a mount for attachment; or to divide the existing code category on the basis of width, height, weight capacity or materials of manufacture.

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.

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;
- Home Dialysis Supplies and Equipment
- Surgical Dressings
- Therapeutic Shoes and Inserts

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

Fee Schedule Payments

Prior to January 1, 1989, payment for most DMEPOS items and services was made on the basis of the reasonable charge methodology. Reasonable charges are calculated using suppliers' charges and are limited by an inflation adjustment factor. Payment is still made on a reasonable charge basis for 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, supplier price lists, manufacturer suggested retail prices, or wholesale prices plus a markup. The gap-filling methodology is used to estimate the average reasonable charge for the item from the base period.

DMEPOS Payment Categories/HCPCS Pricing Indicators

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

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

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

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

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

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

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

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

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

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

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

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

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

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