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 3, 2014

Introduction and Overview

Approximately 70 people attended. The agenda included 16 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
Orthotics & Prosthetics
Durable Medical Equipment (DME) and Accessories;
Tuesday, June 3, 2014, 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.

O&P

AGENDA ITEM #1
Attachment# 14.076
Request to establish a new level II HCPCS add-on code to identify certified water resistance of an Electrical Terminal Device (ETD).

Primary Speaker: Harold Sears of Motion Control, Inc

AGENDA ITEM #2
Attachment# 14.075
Request to establish a new level II HCPCS code to identify a custom fabricated metacarpal or partial hand external powered prosthesis that includes attachment points for fingers, but does not include fingers or other terminal device.

Applicant's suggested language: Metacarpal or Partial Hand External Powered Prosthesis to Include Self-Suspending Socket, May or May Not Include Flexible Inner Socket/Removable Forearm Section, Electrodes and Cables, External Power Supply (often batteries), Charger (or charging component), Attachment Point for Finger(s), But Does Not Include Fingers or Other Terminal Devices".

Primary Speaker: Mitchell Dobson of Hanger

AGENDA ITEM #3
Attachment# 14.078
Request to revise existing level II HCPCS codes L7260 and L7261 to omit product brand names and to specify the type of control mechanism employed. The subject of this request is the 10S17 Electric Wrist Rotator. Applicant's suggested language: Revise code L7260 which currently reads: "Electronic Wrist Rotator Otto Bock Or Equal" to instead read: L7260 "Electronic Wrist Rotator, Switch Control"; Revise code L7261 which currently reads: "Electronic Wrist Rotator, for Utah Arm", to instead read: "Electronic Wrist Rotator, Myoelectric Control".

No Primary Speaker

AGENDA ITEM #4
Attachment# 14.077
Request to EITHER revise existing level II HCPCS codes L6250, L6300, L6350, L6950 and L6955 to specify "*with or without*" internal locking elbow, and revise existing codes L6960, L6965, L6970 and L6975 to specify mechanical "*or friction*" elbow; OR create nine parallel new codes, substituting the term "friction elbow" for "internal locking elbow" and "mechanical elbow", to identify a multipositional friction prosthetic elbow with forearm, trade name: 12K12 MovolinoArm Friction.

No Primary Speaker

AGENDA ITEM #5
Attachment# 14.079
Second request to establish a new Level II HCPCS base code to identify an "Energy Storing AFO, posterior leaf spring design, custom-fabricated of a composite material to produce a specific loading and return of energy that quantitatively matches the plantar flexor deficits of the patient", trade name: Dynamic Response AFO. Applicant's suggested language: "Energy Storing AFO, Custom Engineered and Fabricated to Match the Patient's Defecit, Utilizing FFA Protocols For Composite Fabrication".

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

AGENDA ITEM #6
Attachment# 14.080
Second request to create a distinction, via coding, between voice prostheses, based on "life expectancy" of the devices, specifically, to establish a new level II HCPCS code to identify an extended life trachea-esophageal 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 Oregan Health & Science University

AGENDA ITEM #7
Attachment# 14.081
Request to establish a new level II HCPCS code to identify a Microprocessor Controlled ankle-Foot system, trade name: Elan. Applicant's suggested language: Endoskeletal ankle foot system, microprocessor controlled feature, independent variable energy storage and hydraulic stance control, independent planter flexion and dorsiflexion dampening with automatic terrain response includes sensors and power source.

Primary Speaker: Alan Kercher of Endolite

AGENDA ITEM #8
Attachment# 14.083
Request to establish a new level II HCPCS code to identify a diaphragmatic/phrenic nerve stimulation device, complete system for initial implantation, trade name: Avery Breathing Pacemaker System. Applicant's suggested language:

LXXXX Diaphragmatic/phrenic nerve stimulation device for management of chronic ventilator insufficiency, includes all internal and external components

Attachment# 14.084
Request to establish a new level II HCPCS code to identify a replacement receiver for the Avery Breathing Pacemaker System, trade name: I-110/I-110A Receiver. Applicant's suggested language:

LXXXX Implantable Monopolar Receiver For Conversion Of Stimulus Energy From External Antenna Into Distinct Pulses For Use With Implantable Diaphragmatic/Phrenic Nerve Stimulation Device, Replacement

Attachment# 14.085
Request to establish a new level II HCPCS code to identify a Transtelephonic Monitoring Transmitter (TTM) for use with The Avery Breathing Pacemaker System. Applicant's suggested language:

LXXXX Transttelephonic Monitoring Transmitter (External) For Use With Implantable Diaphragmatic/Phrenic Nerve Stimulation Device, Replacement

Attachment# 14.086
Request to establish a new level II HCPCS code to identify implantable electrodes for use with the Avery Breathing Pacemaker System, trade names: E377-05 (Monopolar), and E325 (Bipolar) Electrodes. Applicant's suggested language:

LXXXX, Implantable Monopolar Flexible Electrode for Transfer Of Stimulus Pulses To Phrenic Nerve For Use With Implantable diaphragmatic/Phrenic Nerve Stimulation Device, Replacement

Attachment# 14.087
Request to establish a new level II HCPCS code to identify an external, programmable radiofrequency transmitter for use with the Avery Breathing Pacemaker System, trade name: Mark IV Transmitter. Applicant's suggested language:

LXXXX, Programmable Radiofrequency Transmitter (External) For Use With diaphragmatic/Phrenic Nerve Stimulation Device, Replacement

Attachment# 14.088
Request to establish a new level II HCPCS code to identify an externally worn antenna for use with the Avery Breathing Pacemaker System, trade name: 902A/902AL Antenna. Applicant's suggested language:

LXXXX, Antenna (External) for Transcutaneous Transfer Of Stimulus Energy For Use With Diaphragmatic/Phrenic Nerve stimulation Device, Replacement.

No Primary Speaker

AGENDA ITEM #9
Attachment# 14.090
Request to establish a new level II HCPCS code to identify a fracture reduction orthosis, trade name: Bledsoe PHX Fracture Reduction Orthosis. Applicant's suggested language:

LXXXX, Elbow Orthosis, With Fracture-Reduction Hinge(s), With Adjustable Elbow Position Locking Joints(s), Prefabricated Item That Has Been Trimmed, Bent, Molded, Assembled, Or Otherwise Customized To Fit A specific Patient By An Individual With Expertise

Primary Speaker: John Tepper of United Orthopedic Group, MedTech Division

AGENDA ITEM #10
Attachment# 14.089
Request to establish five new HCPCS "L" codes to identify an “Epiretinal Prosthesis System”, known as the Argus II Retinal Prosthesis System. Applicant’s suggested language:
Lxxx1 Implanted Epiretinal Prosthesis System, Includes All Internal And External Components
Lxxx2 Head Mounted Telemetry and Video Data Collection System (Glasses Mounting)
Lxxx3 Video Processing Unit (VPU)
Lxxx4 Video Processing Unit Battery Charger With AC Adapter
Lxxx5 VPU Rechargeable Batteries

Primary Speaker: Brian Mech of Second Sight

DME

AGENDA ITEM #11
Attachment #14.094
Third request to establish a new level II HCPCS code to uniquely identify a fiberoptic targeted phototherapy device, trade name: Levia® or Levia® System, and to revise the language of existing code E0691 to restore the word “panel”. Applicant’s suggested language for proposed new code:

EXXXX Targeted Phototherapy device emitting .85 milliwatts/cm² or greater of UVB fluence, includes fiberoptic attachment that transmits UVB directly to the skin beneath hair.

No Primary Speaker

AGENDA ITEM #12
Attachment# 14.102
Request to establish a new level II HCPCS code to identify Ultraviolet multidirectional light therapy units designed to treat hands and/or feet for multiple dermatologic conditions, trade name: Hand/FootII® Phototherapy Device. Applicant’s suggested language: Ultraviolet Multidirectional Light Therapy System for Hand and/or Feet, Includes Bulbs/Lamps, Timer and Eye Protection.

Primary Speaker: Kenneth Oif of National Biological Corporation

AGENDA ITEM #13
Attachment# 14.096
Request to establish a new level II HCPCS code to identify a Non-Invasive Open Ventilation (NIOV) portable ventilator system, trade name: Breathe Technologies Ventilator; and to discontinue code E1352 “Oxygen Accessory, Flow Regulator Capable of Positive Inspiratory Pressure”.

Primary Speaker: Dr. Neil MacIntyre of Duke University

AGENDA ITEM #14
Attachment# 14.095
Request to establish a new level II HCPCS code to identify a device that changes insulin delivery in response to a patient's condition, trade name: MiniMed® 530G with Enlite. Applicant's suggested language: "Artificial Pancreas System, External, Insulin".

Primary Speaker: Dr. Francine R. Kaufman of Medtronic, Inc.

AGENDA ITEM #15
Attachment# 14.093
Fifth request to establish a new level II HCPCS code to identify a portable knee extension device, trade name: Elite Seat.

Primary Speaker: Michelle Goldner of Kneebourne Therapeutic

AGENDA ITEM #16
Attachment# 14.097
Request to establish a new level II HCPCS code to identify a portable, synchronized, pneumatic compression device, trade names: ActiveCare+S.F.T. and ActiveCare+DTx. Applicant's suggested language: Portable, Synchronized Pneumatic Compression Device.

Primary Speaker: Dr. Michael A. Mont of Sinai Hospital of Baltimore Northwest Hospital

O&P Public Meeting

O&P HCPCS Public Meeting Agenda Item #1
June 3, 2014

Attachment# 14.076
Topic/Issue:

Request to establish a new level II HCPCS add-on code to identify certified water resistance of an Electrical Terminal Device (ETD).

Background/Discussion:

According to the requester, Electric Terminal Devices (ETD) with water resistance certified to withstand immersion to 1.0 meters for ½ hour allow a remarkably wider range of activities than ETD devices that are non-water resistant or less water resistant. However; the same codes and reimbursement apply to water-resistant and non-water-resistant TD's. As such, the expense and effort to provide and certify water resistance goes unacknowledged and unrewarded.

Preliminary Decision:

A national program operating need was not identified by Medicare, Medicaid, or the private insurance sector to establish a code to separately identify a water resistance feature, or to identify "more" or "certified" water resistance. Water resistance is included in the purchase and the pricing for all ETDs, therefore, separate billing for a water resistance feature would be redundant. Existing code L9900 "Orthotic and prosthetic supply, accessory, and/or service component of another HCPCS "L" code", is available for assignment by insurers if deemed appropriate.

Medicare Payment:

If payment were made for this item, we believe it may be included in some other Medicare service or procedure code.

Summary of Primary Speaker Comments at the Public Meeting:

The applicant disagreed with CMS' preliminary decision. According to the speaker, water resistance is an extremely important feature to a prosthetic component. Water resistance literally makes the difference between returning to work or not, and commented that for many individuals. You acknowledged that though water resistance is a feature built into every ETD device, there are several precedents which can be cited for features having separate bulling codes, even if included in every device.

O&P HCPCS Public Meeting Agenda Item #2
June 3, 2014

Attachment# 14.075
Topic/Issue:

Request to establish a new level II HCPCS code to identify a custom fabricated metacarpal or partial hand external powered prosthesis that includes attachment points for fingers, but does not include fingers or other terminal device. Applicant's suggested language: Metacarpal or Partial Hand External Powered Prosthesis to Include Self-Suspending Socket, May or May Not Include Flexible Inner Socket/Removable Forearm Section, Electrodes and Cables, External Power Supply (often batteries), Charger (or charging component), Attachment Point for Finger(s), But Does Not Include Fingers or Other Terminal Devices".

Background/Discussion:

According to the requester, the custom fabricated Metacarpal or Partial Hand external powered prosthesis interfaces with the amputee to allow user control of terminal devices not included with the base codes, similar to other upper extremity prosthetic base codes (i.e., L6920-L6975). The movement of the terminal device(s) would replace some of the missing anatomical features (hand/fingers) allowing different grasping patterns to restore independent functionality in Activities of Daily Living. The requester's interpretation is that existing code L6025 "Transcarpal/Metacarpal or Partial Hand Disarticulation Prosthesis, External Power, Self-Suspended, Inner Socket With Removable Forearm Section, Electrodes and Cables, Two Batteries, Charger, Myoelectric Control of Terminal Device" describes only a complete device, including replacement of all digits of the hand for a wrist/transcarpal disarticulation. As such, L6025 does not describe "non-complete variations" that replace less than all of the fingers and/or deformity for partial hand or transmetacarpal disarticulation. Based on this understanding, the applicant is seeking a new code for a partial hand/metacarpal disarticulation prosthesis and finger attachment plates, that would be billable together with the appropriate number of articulating digits, as coded at L6715. The new base code would also include the self-suspending socket. The requested new code would differ from L6025 in that it would not inherently include the fingers, only the attachment plate to receive the fingers.

Preliminary Decision:

Revise existing code L6025 which currently reads "Transcarpal/metacarpal or partial hand disarticulation prosthesis, external power, self-suspended, inner socket with removable forearm section, electrodes and cables, two batteries, charger, myoelectric control of terminal device" to instead read "Transcarpal/metacarpal or partial hand disarticulation prosthesis, external power, self-suspended, inner socket with removable forearm section, electrodes and cables, two batteries, charger, myoelectric control of terminal device, includes terminal device(s)", to clarify the original intent (and predicate product) that included grasp. Code L6025 is intended, and priced, to include terminal devices up to and including all digits, and as such, separate billing for individual fingers or other terminal devices would be redundant. Code L6025 as originally

stated, and as revised, adequately describes the device that is the subject of this request, including any and all digits/terminal devices.

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 commented that the coding action doesn't entirely address issue in that existing code L6025 does not allow the addition of multiarticulating digits as described by L6715. While the predicate product for which L6025 was created may have included a terminal device(s), the intent could not have included the ability to add L6715 digits specifically, as they were not available at the time L6025 became active.

O&P HCPCS Public Meeting Agenda Item #3
June 3, 2014

Attachment# 14.078
Topic/Issue:

Request to revise existing level II HCPCS codes L7260 and L7261 to omit product brand names and to specify the type of control mechanism employed. The subject of this request is the 10S17 Electric Wrist Rotator. Applicant's suggested language: Revise code L7260 which currently reads: "Electronic Wrist Rotator Otto Bock Or Equal" to instead read: L7260 "Electronic Wrist Rotator, Switch Control"; Revise code L7261 which currently reads: "Electronic Wrist Rotator, for Utah Arm", to instead read: "Electronic Wrist Rotator, Myoelectric Control".

Background/Discussion:

According to the requester, the manufacturer names in the descriptors of existing codes L7260 and L7261 indicate functional differentiation of wrist control, since both designs identified can utilize a variety of controls. Electronic control of the wrist device can be simply indicated by the identification of on-off switching or more technologically advanced functional myoelectric control.

Preliminary Decision:

Discontinue code L7260 "Electronic Wrist Rotator, Otto Bock Or Equal"

Discontinue code L7261 "Electronic Wrist Rotator, For Utah Arm"

Establish LXXXX "Electronic Wrist Rotator, Any Type"

The new code adequately describes the device that is the subject of this request, and other Electronic Wrist Rotators, using any type control mechanism.

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:

There was no primary speaker for this item.

O&P HCPCS Public Meeting Agenda Item #4
June 3, 2014

Attachment# 14.077
Topic/Issue:

Request to EITHER revise existing level II HCPCS codes L6250, L6300, L6350, L6950 and L6955 to specify "*with or without*" internal locking elbow, and revise existing codes L6960, L6965, L6970 and L6975 to specify mechanical "*or friction*" elbow; OR create nine parallel new codes, substituting the term "friction elbow" for "internal locking elbow" and "mechanical elbow", to identify a multipositional friction prosthetic elbow with forearm, trade name: 12K12 MovolinoArm Friction.

Background/Discussion:

According to the requester, the 12K12 MovolinoArm Friction, is a multipositional friction prosthetic elbow indicated for children 3 to 5 years of age. Movolino provides 160 degrees (+/-80 degrees) of humeral rotation and 135 degrees of flexion-extension of the forearm. The parent can position the forearm and hand into the proper elbow position so that activities of gripping and positioning can be accomplished. Movolino uses friction for passive positioning of the elbow with the other hand or another object. This is a less complex method for elbow positioning while preserving the ability to use an external power terminal device. The requester comments that the friction elbow is neither an internal locking elbow nor a mechanical elbow, therefore; new or revised codes are necessary to describe the MovolinoArm Friction.

Preliminary Decision:

The MovolinoArm Friction elbow is captured in Exiting codes: L6250 "Above Elbow, Molded Double Wall Socket, Internal Locking Elbow"; L6300 "Shoulder Disarticulation, Molded Socket, Shoulder Bulkhead, Humeral Section, Internal Locking Elbow, Forearm"; L6950 "Above Elbow, External Power, Molded Inner Socket, Removable Humeral Shell, Internal Locking Elbow, Forearm, Otto Bock Or Equal Switch, Cables, Two Batteries And One Charger, Switch Control Of Terminal Device"; L6955 "Above Elbow, Eternal Power, Molded Inner Socket, Removable Humeral Shell, Internal Locking Elbow, Forearm, Otto Bock Or Equal Electrodes, Cables, Two Batteries And One Charger, Myoelectronic Control Of Terminal Device"; L6960 "Shoulder Disarticulation, External Power, Molded Inner Socket, Removable Shoulder Shell, Shoulder Bulkhead, Humeral Section, Mechanical Elbow, Forearm, Otto Bock Or Equal Switch, Cables, Two Batteries And One Charger, Switch Control Of Terminal Device"; L6965 "Shoulder disarticulation, External Power, Molded Inner Socket, Removable Shoulder Shell, Shoulder Bulkhead, Humeral Section, Mechanical Elbow , Forearm, Otto Bock Or Equal Electrodes, Cables Two Batteries And One Charger, Myoelectronic Control Of Terminal Device"; L6970 "Interscapular-thoracic, External Power, Molded Inner Socket, Removable Shoulder Shell, Shoulder Bulkhead, Humeral Section, Mechanical Elbow, Forearm, Otto Bock Or Equal Switch, Cables, Two Batteries And One Charger, Switch Control Of Terminal Device"; or L6975 "Interscapular-thoracic, External Power, Molded Inner Socket, Removable Shoulder

Shell, Shoulder Bulkhead, Humeral Section, Mechanical Elbow, Forearm Otto Bock Or Equal Electrodes, Cables, Two Batteries And One Charger, Myoelectronic Control Of Terminal Device" depending on product configuration.

A national program operating need was not identified by Medicare, Medicaid, or the private insurance sector to revise these codes or to establish new codes to identify this device. The proposed revision does not improve the code(s).

Medicare Payment:

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

For codes L6250, L6300, L6350, L6950, L6955, L6360, L6365, L6370, and L6975
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 #5
June 3, 2014

Attachment# 14.079
Topic/Issue:

Second request to establish a new Level II HCPCS base code to identify an "Energy Storing AFO, posterior leaf spring design, custom-fabricated of a composite material to produce a specific loading and return of energy that quantitatively matches the plantar flexor deficits of the patient", trade name: Dynamic Response AFO. Applicant's suggested language: "Energy Storing AFO, Custom Engineered and Fabricated to Match the Patient's Defecit, Utilizing FFA Protocols For Composite Fabrication".

Background/Discussion:

According to the requester, the Energy Storing AFO is a custom posterior leaf spring design, fabricated in a composite material, to produce a specific loading and return of energy that matches the deficit of the patient. The AFO is constructed with layers of composite materials. The leaf spring design is proven to be "energy storing". The AFO produces variable amounts of return force. This AFO requires a more entailed evaluation process. A gait assessment and manual muscle testing are performed, to determine the optimal timing for the force to act against the patient and to determine the specific amount of strength deficit of the patient being supplemented by the resistant energy return of the orthosis. This controlled flexible design allows the patient to maintain their proprioceptive balance while stabilizing the ankle and storing and returning energy to replace propulsion. The requester comments that use of this AFO confers higher functional outcomes when compared to use of other "conventional" AFOs; that existing codes do not capture the complex process of engineering, "specialty fabrication" and customizing in the energy storing AFO; and specifically, existing code L1940 "Ankle Foot Orthosis, Plastic Or Other Material, Custom-Fabricated" is a "generic" code that does not distinguish the energy storing AFO. The claim of significant therapeutic distinction is that the "Dynamic Response" Energy Storing AFO compensates for a patient's weak or absent plantar flexion strength and allows the patient to return to a near normal functional gait with minimal increase in energy expenditure. It also creates a stabilizing force in standing that enables the patient to stand for a longer duration. The requester comments that there are no existing codes that describe this custom, leaf spring design AFO; its energy storing or propulsion characteristics; or its efficacy and durability.

Preliminary Decision:

Existing code L1940 "Ankle foot orthosis, plastic or other material, custom-fabricated" adequately describes the AFO that is the subject of this request. The term "plastic other material" includes composite materials. Bio-mechanical composites should not be reported using code L2755 "Addition To Lower Extremity Orthosis, High Strength, Lightweight Material, Hybrid Lamination/Prepreg Composite, Per Segment, For Custom Fabricated Orthosis Only", because this AFO does not provide varus or valgus correction of the ankle.

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 not to establish another HCPCS code. According to the speaker, the "Dynamic Response" Energy Storing AFO compensated for a patient's weak or absent plantar flexion strength. There are two core functions of an ankle foot orthosis. One is to correct or control the skeletal alignment of the ankle and foot so the patient can use them. The second is for the orthosis to act upon the patient, apply force, to assist or replace the action of a weakness or absence of a muscle group. There are no other coded ankle foot orthoses on the market that compensate for the weakness or absence of the plantar flexion of the foot and ankle. The dynamic response confers a significant therapeutic distinction.

O&P HCPCS Public Meeting Agenda Item #6
June 3, 2014

Attachment# 14.080
Topic/Issue:

Second request to create a distinction, via coding, between voice prostheses, based on "life expectancy" of the devices, specifically, to establish a new level II HCPCS code to identify an extended life trachea-esophageal 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, the Provox ActiValve voice prosthesis is indwelling tracheoesophageal voice prosthesis which allows exhaled air to pass freely from the trachea into the esophagus, but closes during swallowing to prevent foods and liquids from the lungs. Like all indwelling voice prostheses it is designed to be placed by a healthcare professional and to remain functional for a period of time. It is designed specifically to last longer than "standard" prostheses. Its inner valve seat and flap configuration are made of blue fluroplastic. The valve flap and valve seat include 2 permanently affixed, low force opposable magnets. The combination of low force magnets with fluroplastic material contribute to the longevity of the device (length of time the patient can wear it), by reducing early leakage and as such, confers a significant therapeutic distinction when compared to use of "standard" voice prostheses. The Provox ActiValve is supplied in one outer diameter shaft; several lengths; and 3 valve strength configurations (each with different opening force). The Provox ActiValve is indicated for persons with conditions that lead to a persistent short device life or inability to use a "standard" voice prosthesis (high pressure during swallowing; prone to yeast build-up on the prosthesis; GERD; esophageal dysmotility; esophageal stricture; dehydration; aspiration pneumonia; and chemical pneumonitis).

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.
Pricing = 38

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with CMS' preliminary decision not to establish another HCPCS code. According to the speaker, ActiValve have" its own 501K" due to significant differences in the ActiValve compared to standard indwelling voice prostheses. This device is intended for patients who experience early device failure with the standard indwelling voice prostheses. The speaker commented that there are significant technical and therapeutic distinctions between the ActiValve and standard indwelling devices, including a different closure mechanism which "prevents aspiration pneumonia"; and the addition of silver oxide which resists fungal colonization. Device failure is reduced and patient wear time is longer. The speaker stated that reimbursement for code L8509 is 10% of provider cost for the ActiValve, and the cost burden of obtaining the device is shifted to patients.

O&P HCPCS Public Meeting Agenda Item #7
June 3, 2014

Attachment# 14.081
Topic/Issue:

Request to establish a new level II HCPCS code to identify a Microprocessor Controlled ankle-Foot system, trade name: Elan. Applicant's suggested language: Endoskeletal ankle foot system, microprocessor controlled feature, independent variable energy storage and hydraulic stance control, independent planter flexion and dorsiflexion dampening with automatic terrain response includes sensors and power source.

Background/Discussion:

According to the requester, the Elan is "an endoskeletal ankle foot system microprocessor controlled feature, self-aligning hydraulic with independent plantar flexion and/or dorsiflexion controls providing variable dampening and automatic response to cadence and terrain, include sensing and power source". A key element of the function of the Elan is to provide more of the stored energy as "assist" in walking fast and ascending incline, and reduce the return of stored energy during descend of incline as "brake". The Elan is suitable for active amputees who participate in outdoor and indoor activities requiring compliance with uneven terrain and who are capable of different cadence. It is programmed to user's requirements and weight/activity using a Bluetooth wireless interface and PC laptop with setup software to provide bespoke programming. Once the Elan is fitted/aligned and adjusted, the integral microprocessor sensing and control system automatically and continuously detects the level of inclination and/or cadence and in response, adjusts the level of plantar flexion/dorsiflexion dampening and thereby the ground compliance and energy return provided by the system. The requester comments that existing codes L5973 and L5968 do not adequately describe all of the primary functions of this device.

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. The feature described by existing code L5968 "Addition to lower limb prosthesis, multiax ial ankle with swing phase active dorsiflexion feature" is included in existing code L5973 and therefore separate billing of code L5968 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 agreed with the CMS' preliminary decision and thanked the workgroup for the clarification of L5968.

O&P HCPCS Public Meeting Agenda Item #8
June 3, 2014

Attachment# 14.083
Topic/Issue:

Request to establish a new level II HCPCS code to identify a diaphragmatic/phrenic nerve stimulation device, complete system for initial implantation, trade name: Avery Breathing Pacemaker System. Applicant's suggested language:

LXXXX Diaphragmatic/phrenic nerve stimulation device for management of chronic ventilator insufficiency, includes all internal and external components

Background/Discussion:

According to the requester, the Avery Breathing Pacemaker System is a diaphragmatic/phrenic nerve stimulator for pediatric and adult patients with chronic ventilator insufficiency due to high spinal cord injuries, central sleep apnea, and other central neurological disorders. The system includes electrodes which are sutured to the phrenic nerves; radio receivers implanted in subcutaneous pockets; external antennas; an external programmable radio transmitter controlling the rate of diaphragmatic pacing; and a transtelephonic monitoring transmitter. The requester comments that a new code is needed in order to accurately describe the system, as payers cannot distinguish between the sophisticated electronics unique to this pacemaker system, and simpler, less expensive devices suitable for other uses.

Preliminary Decision:

A national program operating need was not identified by Medicare, Medicaid, or the private insurance sector to establish a code to identify this system which is included in the procedure.

Medicare Payment:

No separate Medicare payment, we believe it may be included in some other Medicare service or procedure.

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 the recommended preliminary coding decision, stating that there is a compelling national need for a separate code based on the improved health outcomes for individuals using the pacemaker instead of mechanical ventilation. The absence of separate coding for the pacemaker and its unique components dramatically reduces insurance reimbursement. This means that many people who could use the device cannot find hospitals willing to provide the service.

O&P HCPCS Public Meeting Agenda Item #8
June 3, 2014

Attachment# 14.084
Topic/Issue:

Request to establish a new level II HCPCS code to identify a replacement receiver for the Avery Breathing Pacemaker System, trade name: I-110/I-110A Receiver. Applicant's suggested language:

LXXXX Implantable Monopolar Receiver For Conversion Of Stimulus Energy From External Antenna Into Distinct Pulses For Use With Implantable Diaphragmatic/Phrenic Nerve Stimulation Device, Replacement

Background/Discussion:

According to the requester, the Avery Breathing Pacemaker System is a diaphragmatic/phrenic nerve stimulator for pediatric and adult patients with chronic ventilatory insufficiency due to high spinal cord injuries, central sleep apnea, and other central neurological disorders. The system includes electrodes which are sutured to the phrenic nerves; radio receivers implanted in subcutaneous pockets; external antennas; an external programmable radio transmitter controlling the rate of diaphragmatic pacing; and a transtelephonic monitoring transmitter. The implanted receiver translates radio waves into stimulating pulses that are delivered to the phrenic nerve by the electrode. Two receivers are provided on initial issue. The requester comments that the receiver should function well beyond its 5-year warranty, and that replacement of implantable parts is more common for pediatric patients as they age and the physical changes associated with growth necessitate the replacement of the implants. The requester comments that existing code L8682 "Implantable Neurostimulator Radiofrequency Receiver", encompasses a broad array of devices, most of which are less complex and less expensive than components of the Avery system, and the payment rate is below the cost of the Avery device. A new code is necessary in order to ensure accurate claims processing; product data collection; and adequate payment.

Preliminary Decision:

Existing code L8682 "Implantable Neurostimulator Radiofrequency Receiver", adequately describes receiver 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, however; the applicant submitted written comments in disagreement with the recommended preliminary coding decision, stating that there is a compelling national need for a separate code based on the improved health outcomes for individuals using the pacemaker instead of mechanical ventilation. The absence of separate coding for the pacemaker and its unique components dramatically reduces insurance reimbursement. This means that many people who could use the device cannot find hospitals willing to provide the service.

O&P HCPCS Public Meeting Agenda Item #8
June 3, 2014

Attachment# 14.085
Topic/Issue:

Request to establish a new level II HCPCS code to identify a Transtelephonic Monitoring Transmitter (TTM) for use with The Avery Breathing Pacemaker System. Applicant's suggested language:

LXXXX Transttelephonic Monitoring Transmitter (External) For Use With Implantable Diaphragmatic/Phrenic Nerve Stimulation Device, Replacement

Background/Discussion:

According to the requester, the Avery Breathing Pacemaker System is a diaphragmatic/phrenic nerve for pediatric and adult patients with chronic ventilatory insufficiency due to high spinal cord injuries, central sleep apnea, and other central neurological disorders. The system includes electrodes which are sutured to the phrenic nerves; radio receivers implanted in subcutaneous pockets; external antennas; an external programmable radio transmitter controlling the rate of diaphragmatic pacing; and a transtelephonic monitoring transmitter. The external Transtelephonic Monitoring (TTM) data transmitter can provide quantitative data for routine and diagnostic monitoring of the external and implanted diaphragm pacing equipment as well as the patient's physiologic response to stimulation. Using an ordinary telephone, a signal can be sent 24 hours a day from anywhere in the world. The transmitter data is recorded so that analysis can be done during the business day. A report of every TTM signal with analysis comments is sent to the patient's physician to assist in medical diagnosis and treatment decisions. One TTM is provided with the system at initial issue. It is warranted for 1 year. The requester claims that existing code A9279 "Monitoring Feature/Device, Stand-Alone Or Integrated, Any Type, Includes All Accessories, Components And Electronics, Not Otherwise Classfied", covers a wide variety of monitoring devices, rergardless of complexity, or cost, and greater specifically in a new code is needed to help with claims processing.

Preliminary Decision:

A national program operating need was not identified by Medicare, Medicaid, or the private insurance sector to establish a code to identify this device. Existing code A9279 "Monitoring Feature/Device, Stand-Alone Or Integrated, Any Type, Includes All Accessories, Components And Electronics, Not Otherwise Classified", is available for assignment by insurers if they deem appropriate.

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, however; the applicant submitted written comments in disagreement with the recommended preliminary coding decision, stating that there is a compelling national need for a separate code based on the improved health outcomes for individuals using the pacemaker instead of mechanical ventilation. The absence of separate coding for the pacemaker and its unique components dramatically reduces insurance reimbursement. This means that many people who could use the device cannot find hospitals willing to provide the service.

O&P HCPCS Public Meeting Agenda Item #8
June 3, 2014

Attachment# 14.086
Topic/Issue:

Request to establish a new level II HCPCS code to identify implantable electrodes for use with the Avery Breathing Pacemaker System, trade names: E377-05 (Monopolar), and E325 (Bipolar) Electrodes. Applicant's suggested language:

LXXXX, Implantable Monopolar Flexible Electrode for Transfer Of Stimulus Pulses To Phrenic Nerve For Use With Implantable diaphragmatic/Phrenic Nerve Stimulation Device, Replacement

Background/Discussion:

According to the requester, the Avery Breathing Pacemaker System is a diaphragmatic/phrenic nerve stimulator for pediatric and adult patients with chronic ventilatory insufficiency due to high spinal cord injuries, central sleep apnea, and other central neurological disorders. The system includes electrodes which are sutured to the phrenic nerves; radio receivers implanted in subcutaneous pockets; external antennas; an external programmable radio transmitter controlling the rate of diaphragmatic pacing; and a transtelephonic monitoring transmitter. The implanted electrodes deliver stimulating pulses to the phrenic nerve. Two electrodes are included in initial issue of the system. The requester comments that the electrodes can last well beyond their 5-year warranty. Since the consequences of product failure to the patient are life threatening the devices are "over-engineered" and have built-in redundancy. The requester claims that existing code A999 "Miscellaneous DME Supply Or Accessory, Not Otherwise Specified", is not descriptive enough to describe Avery pacemaker electrodes, and code L8680 "Implantable Neurostimulator Electrode, Each", does not adequately describe or reimburse for the Avery pacemaker electrodes.

Preliminary Decision:

A national program operating need was not identified by Medicare, Medicaid, or the private insurance sector to establish a new code to identify this implanted device, which is included in the procedure, and therefore, separate billing would be duplicative. Existing code L8680 "Implantable Neurostimulator Electrode, Each", is available for assignment by insurers if deemed appropriate.

Medicare Payment:

No separate Medicare payment, we believe it may be included in some other Medicare service or procedure.

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 the recommended preliminary coding decision, stating that there is a compelling national need for a separate code based on the improved health outcomes for individuals using the pacemaker instead of mechanical ventilation. The absence of separate coding for the pacemaker and its unique components dramatically reduces insurance reimbursement. This means that many people who could use the device cannot find hospitals willing to provide the service.

O&P HCPCS Public Meeting Agenda Item #8
June 3, 2014

Attachment# 14.087
Topic/Issue:

Request to establish a new level II HCPCS code to identify an external, programmable radiofrequency transmitter for use with the Avery Breathing Pacemaker System, trade name: Mark IV Transmitter. Applicant's suggested language:

LXXXX, Programmable Radiofrequency Transmitter (External) For Use With diaphragmatic/Phrenic Nerve Stimulation Device, Replacement

Background/Discussion:

According to the requester, the Avery Breathing Pacemaker System is a diaphragmatic/phrenic nerve for pediatric and adult patients with chronic ventilatory insufficiency due to high spinal cord injuries, central sleep apnea, and other central neurological disorders. The system includes electrodes which are sutured to the phrenic nerves; radio receivers implanted in subcutaneous pockets; external antennas; an external programmable radio transmitter controlling the rate of diaphragmatic pacing; and a transtelephonic monitoring transmitter. The external transmitter and antenna send energy and stimulus information to the passive receiver implant. The receiver translates radio waves into stimulating pulses that are delivered to the phrenic nerve by the electrode. The diaphragm muscle contracts and produces the inhalation phase of breathing. The transmitter then stops generating signals, which allows the diaphragm to relax, and exhalation occurs. This cycle of signals followed by no signals is repeated automatically by the transmitter, producing a normal breathing pattern. One to two transmitters are provided on initial issue, and warranted for 5-years. The requester comments that code L8680 "Implantable Neurostimulator Electrode, Each", encompasses a broad array of devices most of which are less complex and less expensive than Avery components, and use of L8680 results in inadequate payment and product data collection.

Preliminary Decision:

Existing code L8683 "Radiofrequency Transmitter (external) For Use With Implantable Neurostimulator Radiofrequency Receiver", adequately describes the transmitter 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, however; the applicant submitted written comments in disagreement with the recommended preliminary coding decision, stating that there is a compelling national need for a separate code based on the improved health outcomes for individuals using the pacemaker instead of mechanical ventilation. The absence of separate coding for the pacemaker and its unique components dramatically reduces insurance reimbursement. This means that many people who could use the device cannot find hospitals willing to provide the service.

O&P HCPCS Public Meeting Agenda Item #8
June 3, 2014

Attachment# 14.088
Topic/Issue:

Request to establish a new level II HCPCS code to identify an externally worn antenna for use with the Avery Breathing Pacemaker System, trade name: 902A/902AL Antenna. Applicant's suggested language:

LXXXX, Antenna (External) for Transcutaneous Transfer Of Stimulus Energy For Use With Diaphragmatic/Phrenic Nerve stimulation Device, Replacement.

Background/Discussion:

According to the requester, the Avery Breathing Pacemaker System is a diaphragmatic/phrenic nerve stimulator for pediatric and adult patients with chronic ventilatory insufficiency due to high spinal cord injuries, central sleep apnea, and other central neurological disorders. The system includes electrodes which are sutured to the phrenic nerves; radio receivers implanted in subcutaneous pockets; external antennas; an external programmable radio transmitter controlling the rate of diaphragmatic pacing; and a transtelephonic monitoring transmitter. The antenna consists of flexible wire covered with silicone rubber, and metal connectors that attach to the programmable transmitter. The external transmitter and antennae send energy and stimulus information to the passive receiver implant. Six to ten antenna are provided on initial issue with the implant. They are warranted for 90 days. The requester comments that existing codes A9999 "Miscellaneous DME Supply Or Accessory, Not Otherwise Specified", and L8680 "Implantable Neurostimulator Electrode, Each", do not sufficiently describe these antennae.

Preliminary Decision:

Establish LXXXX "Antenna (External) For Use With Implantable Diaphragmatic/Phrenic Nerve stimulation Device, Replacement, Each.

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:

There was no primary speaker for this item, however; the applicant submitted written comments in disagreement with the recommended preliminary coding decision, stating that there is a compelling national need for a separate code based on the improved health outcomes for individuals using the pacemaker instead of mechanical ventilation. The absence of separate

coding for the pacemaker and its unique components dramatically reduces insurance reimbursement. This means that many people who could use the device cannot find hospitals willing to provide the service.

O&P HCPCS Public Meeting Agenda Item #9
June 3, 2014

Attachment# 14.090
Topic/Issue:

Request to establish a new level II HCPCS code to identify a fracture reduction orthosis, trade name: Bledsoe PHX Fracture Reduction Orthosis. Applicant's suggested language:

LXXXX, Elbow Orthosis, With Fracture-Reduction Hinge(s), With Adjustable Elbow Position Locking Joints(s), Prefabricated Item That Has Been Trimmed, Bent, Molded, Assembled, Or Otherwise Customized To Fit A specific Patient By An Individual With Expertise

Background/Discussion:

According to the requester, The Bledsoe PHX Fracture Reduction Orthosis is intended to treat an injured arm by reducing, aligning, and immobilizing distal third and mid-shaft humeral fractures. The brace extends from the shoulder to the mid-forearm and consists of four main components: Unique fracture-reduction hinge; humeral cuff with shoulder cap; range of motion joint at the elbow; and forearm support. The fracture-reduction hinge component of the humeral cuff is activated by a physician to manipulate the elbow and forearm relative to the humerus for fracture alignment (active fracture reduction). In concert with the humeral cuff, the fracture-reduction hinge applies 3-point pressure to actively reduce the bones in proper alignment for healing, a function unattainable via existing bracing. X-rays are taken to ensure proper positioning and fracture reduction. Complete treatment lasts 8-12 weeks. Absent the hinge, fracture reduction is accomplished only via surgical intervention; or the fracture is simply stabilized via existing bracing options, frequently resulting in deformity. The requester comments that there is no existing code, or methodology incorporated into existing braces, that distinguishes this orthosis by its fracture-reducing function and feature.

Preliminary Decision:

Revise existing code L3760 which currently reads: "Elbow Orthosis, With Adjustable Position Locking Joint(s), Prefabricated, Includes Fitting and Adjustments, Any Type"; to instead read: "Elbow Orthosis With Adjustable Position Locking Joint(s), Prefabricated Item That Has Been Trimmed, Bent, Molded, Assembled, Or Othewise Customized to Fit a Specific Patient by an Individual With Expertise". Revise code L3760 adequately describes the device that is the subject of this application.

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 decision not to establish a new HCPCS code. According to the speaker, the Bledsoe PHX fracture brace is a lower risk, less expensive alternative to surgical intervention. It is not merely a post-operative stabilization brace; it actively reduces fractures. Unlike any other brace, it has a published patent for correcting a bone fracture and varus or valgus deformity. The speaker reiterated the original request for a code, and asked that the language of a potential new code specifically identify the device as a "fracture reduction brace".

O&P HCPCS Public Meeting Agenda Item #10
June 3, 2014

Attachment# 14.089
Topic/Issue:

Request to establish five new HCPCS "L" codes to identify an "Epiretinal Prosthesis System", known as the Argus II Retinal Prosthesis System. Applicant's suggested language:

Lxxx1 Implanted Epiretinal Prosthesis System, Includes All Internal And External Components
Lxxx2 Head Mounted Telemetry and Video Data Collection System (Glasses Mounting)
Lxxx3 Video Processing Unit (VPU)
Lxxx4 Video Processing Unit Battery Charger With AC Adapter
Lxxx5 VPU Rechargeable Batteries

Background/Discussion:

The Argus II Retinal Prosthesis System is a Humanitarian Use Device (HUD) subject to individual approval and continuing review by an Institutional Review Board (IRB). It provides visual information that can range from light detection and localization to motion and form detection. The system consists of implanted and external components. The implant is an epiretinal prosthesis that includes a receiving coil (receives power and information wirelessly from external components); electronics to drive stimulation of electrodes; and an array of 60 electrodes that are surgically implanted in and around the eye by a vitreoretinal surgeon under general anesthesia. The external equipment includes glasses; a video processing unit (VPU), and a cable. The glasses have a mounted miniature camera and a coil. The VPU supplies power and converts video images into stimulation commands. The cable connects the glasses to the VPU. The Argus II Clinical Fitting System and Psychophysical Test System are used in the clinic to test and program the Implant and External Equipment.
The camera captures video images. The images are sent to the VPU and converted into electrical stimulation patterns, which are sent back to the transmitter coil (mounted on the glasses), and transmitted wirelessly via radio-frequency telemetry to the implanted retinal prosthesis. The implant decodes the received instructions and sends signals to the electrode array implanted on the retinal surface. The electrode array emits electrical pulses intended to bypass the damaged photoreceptors and stimulate the retina's remaining "undamaged" cells. The stimulated cells transmit the visual information to the brain via the optic nerve. This process creates the perception of patterns of light. The patient is trained to interpret the light as visual patterns. The system is intended to provide electrical stimulation of the retina to induce visual perception in blind patients; and is indicated for persons with severe to profound Retinitis Pigmentosa (RP), an inherited disease that causes slow but progressive vision loss due to a gradual loss of light-sensitive retinal cells (rods and cones) who: are 25 years of age or older; have bare or no light perception in both eyes and confirmed intact inner layer retina function; have prior history of useful form vision; and who are aphakik or pseudophakik. Clinical considerations: the system is not intended to slow or reverse the progression of disease; it provides "artificial vision; it does not restore normal vision; it is intended to be implanted in a single eye; implants are made

specifically for left eye or right eye; performance may be suboptimal for patients with curvature of retina; a preoperative psychosocial evaluation to determine a patient's level of motivation, expectations and ability to deal with disappointing results is strongly recommended; the patient should have cognitive and physical ability to operate the VPU and glasses; the patient must be able to hear audio alerts; theoretical limit of resolution is 2.1logMAR; up to 5 of the 60 electrodes could be enabled to replace a failed electrode post-implant; and patients should live or temporarily relocate to within proximity to allow full participation in recommended post-op clinical follow-up, fitting, training and visual rehabilitation.
The applicant states that although existing CPT Level III code 0100T describes the implant procedure, it does not cover the implant or patient replacement supplies. And existing HCPCS code C1841 "Retinal Prosthesis, includes all internal and external components" will only be "effective" for 3 years, and is only billable by hospital outpatient departments. As such, new codes are needed for the entire system for use by private insurers; and for reporting external replacement parts; (camera glasses, VPU, batteries).

Preliminary Decision:

Re: Implanted Retinal Prosthesis System, includes all internal components and initial issue of all external components: A national program operating need was not identified by Medicare, Medicaid or the Private Insurance sector to establish a new Level II HCPCS code. Existing CPT Emerging Technology code 0100T "Placement of a subconjunctival retinal prosthesis receiver and pulse generator, and implantation of intra-ocular retinal electrode array, with vitrectomy"; and existing Level II code C1841 "Retinal Prothesis, Includes All Internal and External Components" are available for assignment by insurers if they deem appropriate.

Re: External components for replacement only: A national program operating need was not identified by Medicare, Medicaid or the Private Insurance sector to establish HCPCS code(s). For coding guidance, contact the insurer in whose jurisdiction a claim would be filed.

Medicare Payment:

Payment will be based on the carrier's determination regarding which coverage and payment rules are applicable.

Summary of Primary Speaker Comments at the Public Meeting:

The applicant disagreed with CMS' preliminary coding decision, stating that the subject device is new and unique technology. The applicant also stated that the creation of code C1841 is evidence that CMS recognizes the technology, however; a new code will be needed when code C1418 "expires" to identify replacement components. The applicant stated that the CPT Level III code recognizes the procedure "but does not over the implant itself or replacement parts".

DME Public Meeting

DME HCPCS Public Meeting Agenda Item #11
June 3, 2014

Attachment# 14.094
Topic/Issue:

Third request to establish a new level II HCPCS code to uniquely identify a fiberoptic targeted phototherapy device, trade name: Levia® or Levia® System, and to revise the language of existing code E0691 to restore the word "panel". Applicant's suggested language for proposed new code:

EXXXX Targeted Phototherapy device emitting .85 milliwatts/cm² or greater of UVB fluence, includes fiberoptic attachment that transmits UVB directly to the skin beneath hair.

Background/Discussion:

According to the requester the Levia System is a programmable device that delivers a precise, physician-prescribed treatment regimen of Ultraviolet B light therapy for treatment of skin conditions including psoriasis, vitilgio, atopic dermatitis, seborrheic dermatitis and lichen planopilaris. Each Levia system is individually programmed with specific treatment parameters determined by the prescribing physician. Phototherapy is typically administered every second or third day for a total of three times per week. The Levia System has a distinct quality of NBUV light generated and the ability to control or direct the delivery of the light source which sets it apart from its competitors in already existing HCPCS codes. The Levia system includes a treatment console and connected head piece, similar in style and weight to a hair blow dryer; a scalp psoriasis and lichen planopilaris treatment attachment (brush) with quartz fiberoptic bristles for delivering light directly to the scalp (and other hair bearing areas); and a general skin treatment attachment that delivers a 3 cm² focused beam of UVB light directly onto other affected skin areas, (LiteSpot™). The requester comments that existing codes do not describe the Levia because Levia system; 1) uses a distinct quality of NBUV light and can control and direct light delivery; 2) delivers UVB treatment directly to the scalp; 3) delivers faster treatment times to targeted areas; 4) is the only table top directed UVB phototherapy system for use in the home; and 5) is the only system able to track compliance. In addition, the requester claims a significant therapeutic distinction over fluorescent tubes in effectively treating lichen planopilaris (an uncommon inflammatory scalp disorder).

Preliminary Decision:

Existing code E0691"Ultraviolet light therapy system, includes bulbs/lamps, timer and eye protection; treatment area 2 square feet or less" adequately describes the phototherapy system that is the subject of this request. Code E0691 was revised in 2012 specifically to clarify that the

Levia system is included in this code category. A national program operating need was not identified by Medicare, Medicaid or the Private Insurance sector to reverse this code clarification.

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 #12
June 3, 2014

Attachment# 14.102
Topic/Issue:

Request to establish a new level II HCPCS code to identify Ultraviolet multidirectional light therapy units designed to treat hands and/or feet for multiple dermatologic conditions, trade name: Hand/FootII® Phototherapy Device. Applicant's suggested language: Ultraviolet Multidirectional Light Therapy System for Hand and/or Feet, Includes Bulbs/Lamps, Timer and Eye Protection.

Background/Discussion:

According to the requester, the Hand/Foot II delivers multidirectional ultraviolet light (phototherapy) to a patient's hands and/or feet. Phototherapy is a form of treatment for skin conditions using artificial light wavelengths from the ultraviolet (blue light) part of the light spectrum. The ultraviolet light penetrates the skin in order to kill or slow the growth of abnormal cells. Phototherapy is clinically indicated for patients with psoriasis, other forms of dermatitis, pityriasis lichenoides, cutaneous T cell lymphoma, lichen planus and vitiligo. The most common use for a hand/foot machine is for Palmar-Plantar Psoriasis. Treatments length can vary from 30 seconds to 10 minutes, depending on the specific skin condition (moderate or severe), location on the body; total surface area; and stage of treatment. The requester comments that existing E069X codes for ultraviolet light therapy system are for systems that define a treatment area that does not apply to the Hand/Foot, based on size of treatment area, and/or they describe only single-plane treatment. Therefore a new code is needed to describe the Hand/Foot and other devices like it.

Preliminary Decision:

Existing code E0691 "Ultraviolet light therapy system, includes bulbs/lamps, timer and eye protection; treatment area 2 square feet or less" 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.
Pricing = 32

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with CMS' preliminary decision not to establish a HCPCS code. The speaker commented that existing code E0691 is specifically for units whose treatment area is less than 2 sq. ft. All hand/foot units on the US market by multiple manufacturers have

treatment areas in excess of 2 sq. ft. making this code incorrect. Also, multidirectional ultraviolet light therapy systems are fundamentally different from single planar units in their design and function and there is coding precedent (E0694) to support this. The speaker is recommended a new HCPCS Level II code.

DME HCPCS Public Meeting Agenda Item #13
June 3, 2014

Attachment# 14.096
Topic/Issue:

Request to establish a new level II HCPCS code to identify a Non-Invasive Open Ventilation (NIOV) portable ventilator system, trade name: Breathe Technologies Ventilator; and to discontinue code E1352 "Oxygen Accessory, Flow Regulator Capable of Positive Inspiratory Pressure".

Background/Discussion:

According to the requester, Breathe Technologies' Noninvasive Open Ventilation (NIOV) System is a small, wearable electronically timed controlled volume assist ventilator that augments a patient's spontaneous breathing. It is powered by electricity or an internal battery. The system is designed for use in hospitals, pulmonary rehabilitation programs and in the home to provide therapy for adult patients with respiratory insufficiency. It is designed for patients who are capable of spontaneously breathing a minimum tidal volume of 3.5cc/kg of predicted body weight; for continuous applications such as patient ambulation, physical, occupational or respiratory therapy and other rehabilitation efforts in an in institutional or home care environment. The device is intended for operation by trained personnel, patients or caregiver under the direction of a physician. The NIOV administers physician-prescribed volume to the patient via attached circuit inserted into patient's tracheostomy tube, or via nasal pillow interface. It is connected to a pressurized gas supply, including compressed oxygen or compressed air. The requester objects to assignment to code E1352 for the following reasons: 1) the FDA classified the NIOV as a ventilator, not a flow regulator; 2) the NIOV delivers tidal volume, whereas oxygen regulators do not; and 3) the NIOV was developed to address a significant unmet clinical need to improve endurance and reduce the work breathing for ambulatory patients with respiratory insufficiency.

Preliminary Decision:

Existing code E1352 "Oxygen Accessory, Flow Regulator Capable of Positive Inspiratory Pressure", adequately describes the device that is the subject of this request, when used with pressurized oxygen.

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 commented that while oxygen accessories do not provide pressure, the NIOV device does provide pressure; and since by definition, ventilators generate pressure, the NIOV device is therefore a ventilator. The NIOV is classified by the FDA as a ventilator, and the predicate device for FDA market clearance is also classified as a ventilator. Use of the NIOV improves endurance during ambulation; unloads respiratory muscles and "pushes lungs open". The NIOV therefore confers the clinical benefits of a ventilator and should be coded as such. The speaker reiterated the original request that CMS revise code E1352 and provide appropriate coding, coverage and payment for NIOV device.

DME HCPCS Public Meeting Agenda Item #14
June 3, 2014

Attachment# 14.095
Topic/Issue:

Request to establish a new level II HCPCS code to identify a device that changes insulin delivery in response to a patient's condition, trade name: MiniMed® 530G with Enlite. Applicant's suggested language: "Artificial Pancreas System, External, Insulin".

Background/Discussion:

The requester refers to the MiniMed 530G as an "artificial pancreas system with threshold suspend functionality. The system can automatically take action in response to the patient's glucose levels, without human intervention, (e.g., when a patient is asleep). Specifically, when hypoglycemia is detected and the patient cannot respond, the MiniMed 530G automatically suspends insulin delivery to prevent further lowering of glucose levels. The system is worn externally by the user. It provides subcutaneous insulin infusion therapy to manage diabetes mellitus in persons requiring insulin, age 16 and over. It is available only by prescription. The MiniMed 530G has 5 components: the enlite sensor (1) is inserted below the skin and samples interstitial glucose every 5 minutes. The transmitter (2) receives readings from the sensor and transmits them to the system (3). The system has a continuous glucose monitor which collects and displays the readings and the "artificial pancreas algorithm" analyzes them. The reservoir (4) inserted within the system contains the insulin, which is delivered to the patient subcutaneously through the infusion set (5). In analyzing the glucose levels and trends, the system alerts the user to rates of change and also sounds alarms at levels pre-set by the patient and physician. If the system detects that glucose levels have fallen below the pre-determined threshold, it automatically suspends insulin delivery. Regular insulin infusion automatically resumes after 2 hours. The requester comments that this device differs from conventional insulin pumps in that it includes automatic threshold suspend functionality which is an advancement toward developing complete pancreatic functionality. A unique code is needed to enable payers to implement differential policy and payment for this device.

Preliminary Decision:

Existing code E0784 "External ambulatory infusion pump, insulin" 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 =36

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with CMS' preliminary HCPCS coding decision and suggested that creation of a HCPCS "S" code demonstrate the need for a distinct code for this technology, for use by all insurers; and that existing code E0784 does not recognize new LGS suspend or threshold suspend technology.

DME HCPCS Public Meeting Agenda Item #15
June 3, 2014

Attachment# 14.093
Topic/Issue:

Fifth request to establish a new level II HCPCS code to identify a portable knee extension device, trade name: Elite Seat.

Background/Discussion:

According to the requester, the EliteSeat is a patient-controlled knee extension device designed for non-operative treatments of degenerative knee conditions with a flexion contracture. It is a portable device consisting of a steel frame and PVC-backed nylon fabric. The device is used as a first line of treatment for injuries that result in loss of normal or full terminal extension. It is designed to allow a patient to restore a painful, deconditioned knee to a functional state with significant reduction and/or elimination of pain by regaining terminal extension. It is the only device designed or proven to achieve terminal extension. The EliteSeat is intended to be used as an adjunct to physical therapy and until the patient can attain and maintain the clinical goal of full terminal extension. The requester claims that existing code E1811 "Static Progressive Stretch Knee Device, Extension and/or Flexion, With or Without Range of Motion Adjustment, Includes All Components and Accessories", does not describe the Elite Seat because it is not a "static progressive stretching device" and it does not have range of motion adjustments which lock the joint into a fixed position.

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 Elite Seat.

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 not to establish a new, unique HCPCS code. According to the speaker, the Elite Seat is therapeutically and functionally different than any other product within this code. Elite Seat is a capped rental item because it is

never intended for purchase, and as such; it cannot be described by code E1811. The speaker stated that code E1811 does not describe the function or the “intended pricing” of the Elite Seat.

DME HCPCS Public Meeting Agenda Item #16

June 3, 2014

Attachment# 14.097

Topic/Issue:

Request to establish a new level II HCPCS code to identify a portable, synchronized, pneumatic compression device, trade names: ActiveCare+S.F.T. and ActiveCare+DTx. Applicant's suggested language: Portable, Synchronized Pneumatic Compression Device.

Background/Discussion:

According to the requester, ActiveCare+S.F.T. and ActiveCare+DTx are small, patient portable, battery operated pneumatic compression devices that synchronize compressions based on each patient's individual venous phasic flow pattern. These features produce an optimal hemodynamic profile, while comfortably delivering compression impact to the deep veins with only minor impact on the patient's legs or feet. ActiveCare+DTx also integrates venous obstruction prevention and detection capabilities whereby both operations are carried out simultaneously during therapy. ActiveCare+DTx is able to both detect venous obstructions and alert medical personnel to their presence, substantially reducing the occurrence of serious complications, such as pulmonary embolism. The requester comments that a distinct code is necessary for several reasons: 1) it is the only small, patient portable, battery operated pneumatic compression device that determines each patient's venous phasic flow and synchronizes compression based on the individual's flow pattern; 2) the DTx version integrates venous obstruction prevention and detection feature; and 3) Medicare mistakenly assigned the ActiveCare devices to code E0676, which "unnecessarily limits the indications for use to those related to Deep Vein Thrombosis (DVT)" even though the FDA cleared additional indications for use.

Preliminary Decision:

Existing code E0676 "Intermittent limb compression device (includes all accessories), not otherwise specified" adequately describes the subject of this request. Policy inquiries should be submitted to the insurer.

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 coding decision and reiterated the original request for a unique HCPCS code to identify the ActiveCare+S.F.T. and DTx devices. The speaker commented that these devices have unique functionality in they the optimize the

hemodynamic profile and monitor patient compliance; “prominent clinicians” select these devices; and “well respected certified coders” believe these devices are distinct from devices coded at E0650 through E0676 based on a difference in operation and inclusion of a compliance monitor.

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 for most DMEPOS items and services is now 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.