

**Centers for Medicare & Medicaid Services (CMS) Healthcare Common Procedure Coding System (HCPCS) Public Meeting Agenda for
Orthotics & Prosthetics
Durable Medical Equipment (DME) and Accessories;
Wednesday, May 27, 2015, 9:00 am – 5:00 pm
CMS Auditorium
7500 Security Boulevard
Baltimore (Woodlawn), Maryland 21244-1850**

8:15 a.m. Arrival and sign-in

9:00 a.m. Welcome
Background and purpose of meeting
Meeting Format and Ground Rules

For each agenda item, a written overview of the request and CMS’s preliminary coding decision is provided. An overview of Medicare pricing/payment, methodology is also attached to this agenda. Preliminary decisions are not final or binding upon any payer, and are subject to change. Meeting participants will hear presentations about the agenda item from the registered primary speaker and other speakers (if any). Presentations will be followed by an opportunity for questions regarding that particular agenda item. The public meetings provide an opportunity for the general public to provide additional input related to requests to modify the HCPCS code set. Final decisions are not made at the public meetings. Applicants will be notified of final decisions in November.

The agenda includes a summary of each HCPCS code application on the agenda. The information provided in each summary reflects claims made by the applicant and should not be construed as a statement of fact or an endorsement by the federal government.

DME

AGENDA ITEM #1

Attachment# 15.109

Request to establish two unique Level II HCPCS codes, one each to identify a Power Center Mount Elevating Foot Platform with Articulation, and a Power Center Mount Foot Platform Extension.

Applicant's suggested language:

EXXX1 - Center-mount Power Elevating Foot Platform with Articulation

EXXX2 - Power Center Mount Foot Platform Extension Feature

Attachment# 15.110

Request to establish a unique Level II HCPCS code to identify Single Spine Backrest System, trade name: standard Mono Backrest System. Applicant's suggested language: EXXXX - Wheelchair Accessory, Mono Backrest

Attachment# 15.111

Request to establish a unique Level II HCPCS code a dynamic backrest frame component for adult wheelchairs, Trade name: Sunrise Dynamic Back. Applicant's suggested language: EXXXX - Wheelchair Accessory, Dynamic Backrest

AGENDA ITEM #2

Attachment# 15.104

Request to establish a unique Level II HCPCS code to identify TRU-Balance[®] 2 (TB2[®]) Center Mount Power Articulating Foot Platform, and TRU-Balance[®] 3 (TB3[®]) Center Mount Power Articulating Foot Platform. Applicant's suggested language: Wheelchair accessory, Center Mount Power Elevating Foot Platform, with Articulation.

AGENDA ITEM #3

Attachment# 15.105

Request to establish a unique Level II HCPCS code to identify a Power Center Mount Foot Platform with Articulation, Trade Name: Motion Concepts LNX

AGENDA ITEM #4

Attachment# 15.108

Request to establish a unique Level II HCPCS code to identify a Center Mount Power Elevating Foot Platform with Articulation or Power Elevating Center Mount Leg rests - 170°

AGENDA ITEM #5

Attachment# 15.106

Request to establish two new Level II HCPCS codes: one to identify a portable oxygen delivery system, Trade Name: TransCu O2[®]; and another to identify a wound dressing intended for use with the TransCu O2 device, Trade Name: OxySpur[™].

Applicant's suggested language:

EXXXX - Portable Continuous Diffusion of Oxygen Therapy Device

AXXXX - Portable Continuous Diffusion of Oxygen Dressings and Cannula

O&P

AGENDA ITEM #6

Attachment# 15.115

Third request to establish a new Level II HCPCS code to identify a custom Dynamic Response Orthotic Pylon (Strut) “energy storing AFO”.

AGENDA ITEM #7

Attachment# 15.003

Fourth request to establish unique Level II HCPCS “addition” code to separately identify a manual prosthetic cable control and locking system for upper extremity prostheses, Trade Name: Sure-Lok™. Applicant’s suggested language: LXXXX-Addition to upper extremity, locking mechanism for primary control cable with manual lock/unlock of terminal device or other, surface or subsurface mount

AGENDA ITEM #8

Attachment# 15.061

Repeat request to establish a unique Level II HCPCS code to identify injectable implants Prolaryn™ Plus and Prolaryn™ Gel (formerly Radiesse Voice and Radiesse Voice Gel). Applicant's suggested language: L86XX - Injectable bulking agent, calcium hydroxylapatite or sodium carboxymethylcellulose, vocal fold, 1cc, includes shipping and necessary supplies.

AGENDA ITEM #9

Attachment# 15.114

Third request to create a distinction, via HCPCS coding, between trachea-esophageal voice prostheses that have a magnetic valve closure (Trade Name: Provox® ActiValve™ Voice Prostheses) and those that do not.

Applicant’s suggested language:

Establish new code: Tracheo-esophageal voice prosthesis, *active valve closure type*, inserted by a licensed health care provider; and

Revise existing code L8509 which currently reads: “Tracheo-esophageal voice prosthesis, inserted by a licensed health care provide, *any type*”; to instead read: “Tracheo-esophageal voice prosthesis, *standard type*, inserted by a licensed health care provider”.

AGENDA ITEM #10

Attachment# 15.117

Request to modify existing Level II HCPCS code L8621 “Zinc air battery for use with cochlear implant device, replacement (each)” to include use with auditory osseointegrated (AOI) devices. Applicant's suggested revised language for L8621: Zinc air battery for use with cochlear device implant and auditory osseointegrated device sound processors replacement (each).

AGENDA ITEM #11

Attachment# 15.116

Repeat request to establish 4 unique Level II HCPCS codes to identify Argus II Retinal Prosthesis System (Argus II) external patient-worn components.

Applicant's suggested language:

XXXX1 - Head mounted telemetry and video data collection system (glasses mounting)

XXXX1 - Video processing unit (VPU) for use with retinal prosthesis vision system

XXXX3 - VPU battery charger with AC adapter for use with retinal prosthesis vision system

XXXX4 - VPU rechargeable batteries for use with retinal prosthesis vision system

DME HCPCS Public Meeting Agenda Item #1
May 27, 2015

Attachment# 15.109

Topic/Issue:

Request to establish two unique Level II HCPCS codes, one each to identify a Power Center Mount Elevating Foot Platform with Articulation, and a Power Center Mount Foot Platform Extension.

Applicant's suggested language:

EXXX1 - Center-mount Power Elevating Foot Platform with Articulation

EXXX2 - Power Center Mount Foot Platform Extension Feature

Background/Discussion:

Sunrise Medical, LLC submitted a request to establish two new HCPCS codes, one each to identify a power center mount elevating foot platform with articulation, and a power center mount foot platform extension. According to the requester, the center mount power elevating foot platform with articulation attaches to the center of the seat. It provides power-operated elevation of both legs via one center mounted mechanism that contains all components needed for elevation of the lower extremities, and articulates to accommodate changes in the knee joint as the leg elevates. The power function allows the individual in the wheelchair to independently elevate their lower extremities to increase circulation, reduce edema when used in conjunction with tilt, recline or a combination, and facilitate a change in their position. Persons who benefit by this feature include full-time wheelchair users. It is also useful for persons who need a shorter wheelchair base in order to navigate small or tight areas their home environment. The device includes the attaching hardware, the elevating and articulating section which replaces any standard front rigging, standard pads, actuator and any components/electronics required for the stated functions. It also includes a single foot platform/footrest.

The additional foot platform extension allows the person in the wheelchair to independently extend the foot platform/footrest. The extension moves the footrest to the floor for standing pivot transfers. The requester comments that this feature is independent of the elevation feature and requires a separate actuator to operate. It includes the extension element, additional actuator and electronic specific to the stated function. When used with other power seating options, this system requires an expandable controller, and wiring harness. These items are not included in the purchase of the extension feature. In addition, if drive-thru required, the system would also require a an electronic connection accessory between the wheelchair controller and two or more power seating motors, including all related electronics and hardware, as coded at E2311.

The requester claims the following differences between center-mount technologies and “traditional” elevating leg rests: position of lower extremities; position of feet; accommodation

of home environment that is small or difficult to maneuver. The requester also claims that the addition of the powered extension feature enables independent or minimally assisted standing pivot transfers. And, that new unique codes are warranted, based on these differences.

Preliminary Decision:

Establish EXXXX: Power Wheelchair Accessory, Center Mount Power Elevating Leg rest/Platform, Complete System, Any Type.

A national program operating need was not identified by Medicare, Medicaid or the Private Insurance sector to establish a code to identify a foot platform extension feature.

Medicare Payment:

Based on Medicare programs instructions in section 60.3.1 of Chapter 23 of the Medicare Claims Processing Manual, the fee schedule amounts for code E1010 would apply to this new code.

For the extension feature, payment for all covered components of a power leg elevation system is included in the fee schedule amounts for the power leg elevation system.

DME HCPCS Public Meeting Agenda Item #1
May 27, 2015

Attachment# 15.110

Topic/Issue:

Request to establish a unique Level II HCPCS code to identify Single Spine Backrest System, trade name: standard Mono Backrest System.

Applicant's suggested language: EXXXX - Wheelchair Accessory, Mono Backrest

Background/Discussion:

Sunrise Medical, LLC submitted a request to establish a new unique HCPCS to identify the Mono Backrest, a Single Spine Backrest System. According to the requester, this system is designed to allow independent seating and positioning of the upper and lower body. The Mono Backrest is a single spine track system that attaches to the base frame of a wheelchair and can be moved within 2" left or right of center. With this system, seat and back widths can be different, which allows independent seating and positioning of the upper and lower body - without back canes to interfere with pads and hardware. With two-post back canes, on the other hand, back tubes are attached by welding; attachment hardware or insertion into side tubes at the frames. As such, the back width and seat width are the same. "Decoupling" of the seat width and back width accommodates persons with wide hips and narrow torso and shoulders; persons with narrow hips and wide shoulders; narrower chair to accommodate narrow spaces; seating needs for persons with asymmetries; changes in a persons' needs over time; and adjustable back angles.

The Mono Backrest system is available in adult and pediatric sizes, and in a standard version (the subject of this request), and a dynamic version (see application 15.111). Both configurations include only the center spine and attaching hardware. The requester claims that the Mono Backrest is an optional feature to the wheelchair base, for which there is an additional charge. Positioning components, seat backs and seat cushions are also not included.

The requester comments that use of the miscellaneous code K0108 "Wheelchair Component or Accessory, Not Otherwise Specified", does not allow utilization tracking; does not ensure appropriate payment; and does not support the development of appropriate coverage policy.

Preliminary Decision:

This backrest is included in the wheelchair base code. Code A9900 "Miscellaneous DME supply, accessory, and/or service component of another HCPCS code" may also be used. Separate billing using K0108 or any other code could be considered unbundling and duplicative.

Medicare Payment:

This is a component of the wheelchair, so separate payment is not allowed for this item.

DME HCPCS Public Meeting Agenda Item #1

May 27, 2015

Attachment# 15.111

Topic/Issue:

Request to establish a unique Level II HCPCS code a dynamic backrest frame component for adult wheelchairs, Trade name: Sunrise Dynamic Back.

Applicant's suggested language: EXXXX - Wheelchair Accessory, Dynamic Backrest

Background/Discussion:

Sunrise Medical, LLC submitted a request to establish a HCPCS code to identify a Dynamic Backrest. According to the requester, the dynamic backrest is designed to be used in conjunction with a wheelchair to accommodate a person's movement and extension. The mechanism allows a person seated in a wheelchair to independently extend at the hip when desired for postural relief or in response to abnormal tone. The dynamic backrest can provide pressure relief, reinforce functional movement patterns, allow strengthening, and encourage active communication by accommodating forward flexion. It is appropriate for use by persons who require a wheelchair and who demonstrate atypical muscle tone, atypical movement patterns in sitting, sheer or skin integrity issues and fatigue in sitting due to active resistance to rigid postural support. Existing code E2295 "manual wheelchair accessory, for pediatric size wheelchair, dynamic seating frame, allows coordinated movement of multiple positioning features" represents a *system* that includes a dynamic component for lower extremity movement. A code is needed for the dynamic backrest *only*, and it should not be limited to use with pediatric wheelchairs. According to the requester, while there are no significant differences among available dynamic backrest technologies, the use of dynamic backrests confers improved outcomes for persons with abnormal tone. The difference between dynamic and static backrests is the result of the hinges and hardware used to allow the back frame to move in relation to the seat frame. The dynamic backrest is available by itself and also for Mono Backrest systems - in which case, the Mono Backrest is separately billed. The requester comments that existing code E2295 does not describe the dynamic backrest component alone, which is currently being billed using code K0108. A unique code would facilitate separate billing for this component for adults; development of coverage policies; utilization tracking; and collection of outcomes data.

Preliminary Decision:

The dynamic backrest is included the wheelchair base code. Code A9900 "Miscellaneous DME supply, accessory, and/or service component of another HCPCS code" may also be used. Separate billing using K0108 or any other code could be considered unbundling and duplicative.

Medicare Payment:

This is a component of the wheelchair, so separate payment is not allowed for this item.

DME HCPCS Public Meeting Agenda Item #2
May 27, 2015

Attachment# 15.104

Topic/Issue:

Request to establish a unique Level II HCPCS code to identify TRU-Balance[®] 2 (TB2[®]) Center Mount Power Articulating Foot Platform, and TRU-Balance[®] 3 (TB3[®]) Center Mount Power Articulating Foot Platform

Applicant's suggested language: Wheelchair accessory, Center Mount Power Elevating Foot Platform, with Articulation.

Background/Discussion:

Pride Mobility Products Corporation submitted a request to establish a HCPCS code to identify a wheelchair accessory: center mount power articulating elevating foot platform. According to the requester, this platform is a single unit leg elevation system that is structurally, operationally and clinically different from non-center mounted power leg elevations systems. The center mounted system is used by persons with significant disabilities and chronic medical conditions who require the ability to elevate and/or reposition their lower extremities independently for a variety of reasons but who cannot use manual or power elevating leg rests. Front riggings for a power wheelchair may include a foot platform, swing-away footrests, manual elevating leg rests, power operated elevating leg rests or a power operated center mount elevating foot platform, with articulation. All of these devices support the wheelchair user's feet and lower legs, contribute their overall postural stability in the chair and can be moved out of the way for transfers.

The requester comments that the center mount power articulating foot platform is not adequately described by existing codes for (non-center mounted) power elevating leg rests because (1) the center mounted system does not include a separate right and left component for it to be considered a pair; (2) manufacturing is substantially different from other power elevating leg rests; and (3) it places the wheelchair user's lower extremities in a different position; and (4) it functions differently from power elevating leg rests.

Preliminary Decision:

Establish EXXXX Wheelchair Accessory, Center Mount Power Elevating Legrest/Platform, Complete System, Any Type

Medicare Payment:

Based on Medicare programs instructions in section 60.3.1 of Chapter 23 of the Medicare Claims Processing Manual, the fee schedule amounts for code E1010 would apply to this new code.

DME HCPCS Public Meeting Agenda Item #3
May 27, 2015

Attachment# 15.105

Topic/Issue:

Request to establish a unique Level II HCPCS code to identify a Power Center Mount Foot Platform with Articulation, Trade Name: Motion Concepts LNX

Background/Discussion:

Motion Concepts submitted a request to establish a HCPCS code to identify its center mount power elevating foot platform with articulation for use with power wheelchairs. According to the requester, the LNX is not described by existing code E1010 "Wheelchair accessory, addition to power seating system, power leg elevation system, including leg rest, per pair", because: the LNX is a center mounted device, as opposed to independent, laterally mounted leg rests; the LNX articulation feature, which is required to maintain proper positioning, is not addressed by E1010; and the LNX is one assembly and not sold as a pair. The LNX is a separate electrical component of a power wheelchair's positioning system. It is fully adjustable and center mounted which precludes the need for bulky independent lateral mounts and results in enhanced in-home mobility due the reduced overall footprint of the power chair, while providing enhanced performance and physiological function. The LNX functions by mirroring the body's natural pivot points and using the geometry of two constantly parallel solid steel links to achieve elevation and articulation. It provides a smooth, constant motion as the lower extremities move from 90 degrees of knee flexion (natural position) to up to 175 degrees of knee extension (full elevation). Those who would benefit by the LNX include but are not limited to persons with: spinal cord injury, amyotrophic lateral sclerosis, multiple sclerosis, muscular dystrophy, traumatic brain injury, lymphedema, lipidema, obesity and edema. The LNX is currently billed using code K0108.

Preliminary Decision:

Establish EXXXX Wheelchair Accessory, Center Mount Power Elevating Legrest/Platform, Complete System, Any Type

Medicare Payment:

Based on Medicare programs instructions in section 60.3.1 of Chapter 23 of the Medicare Claims Processing Manual, the fee schedule amounts for code E1010 would apply to this new code.

DME HCPCS Public Meeting Agenda Item #4
May 27, 2015

Attachment# 15.108

Topic/Issue:

Request to establish a unique Level II HCPCS code to identify a Center Mount Power Elevating Foot Platform with Articulation or Power Elevating Center Mount Leg rests - 170°

Background/Discussion:

Permobil, Inc. submitted a request to establish a HCPCS code to identify a Center Mount Power Elevating Foot Platform (CMPEFP) with articulation. According to the requester, CMPEFP with Articulation allows leg (knee) extension while elevating the lower extremities. It is indicated for individuals who have impaired lower extremity functioning including but not limited to neurological conditions. CMPEFP has the following uses: ground clearance, range of motion/knee biomechanics, management of lower extremity edema and shortens wheelchair 'footprint'/wheelbase. The CMPEFP with Articulation includes one actuator to control the power elevating feature, related electronics to allow user to access/control this power function, flip-up/angle-adjustable footplate(s), calf supports, center-mount articulating strap and related fixed mounting hardware. The differences between CMPEFP and products coded at E1010 "Wheelchair accessory, addition to power seating system, power leg elevation system, including leg rest, pair" are as follows: devices coded at E1010 include a pair of leg rests, rather than a single, center-mounted platform; the unique position of the center-mounted design allows for management of pressure along the lateral aspect of the lower extremities. Additionally, articulation (offered with the center mount system) is necessary to achieve proper extension of the lower extremities at the knees. Without articulation, the knees would flex considerably with elevation, causing abduction/external rotation and possibly negatively impacting pelvic positioning in the seating system.

CMPEFP is currently reported using existing code K0108 "Wheelchair component or accessory, not otherwise specified". A code that identifies CMPEFP with articulation would enhance the efficiency of claims processing systems.

Preliminary Decision:

Establish EXXXX Wheelchair Accessory, Center Mount Power Elevating Legrest/Platform, Complete System, Any Type

Medicare Payment:

Based on Medicare programs instructions in section 60.3.1 of Chapter 23 of the Medicare Claims Processing Manual, the fee schedule amounts for code E1010 would apply to this new code.

DME HCPCS Public Meeting Agenda Item #5
May 27, 2015

Attachment# 15.106

Topic/Issue:

Request to establish two new Level II HCPCS codes: one to identify a portable oxygen delivery system, Trade Name: TransCu O2®; and another to identify a wound dressing intended for use with the TransCu O2 device, Trade Name: OxySpur™.

Applicant's suggested language:

EXXXX - Portable Continuous Diffusion of Oxygen Therapy Device

AXXXX - Portable Continuous Diffusion of Oxygen Dressings and Cannula

Background/Discussion:

On behalf of Electrochemical Oxygen Concepts, Inc. (EO2 Concepts) a fourth request was submitted to establish a new HCPCS code to identify the TransCu O2, a low dose tissue oxygenation system intended for use with wound dressings to treat skin ulcerations, pressure ulcers, infected residual limbs, skin grafts, burns and frostbite. The requester describes the oxygen delivery device as lightweight portable device that delivers a continuous supply of pure oxygen, used in conjunction with moist wound dressings to treat difficult-to-heal wounds. This applicant also requests an additional new code to identify OxySpur™ wound dressings used with the TransCu O2.

The requester comments that existing code E0446 “Topical Oxygen Delivery System, not otherwise specified, includes all supplies and accessories”, does not accurately describe the form and function of the TransCu O2 device or the unique therapy it provides, which it refers to as “Portable Continuous Diffusion of Oxygen (CDO) Therapy”. The applicant suggests, therefore, that the language of the requested new code for the TransCu O2 device read: “*portable continuous diffusion of oxygen therapy device*”.

Preliminary Decision:

Existing code E0446 "Topical oxygen delivery system, not otherwise specified, includes all supplies and accessories", adequately describes this device and all supplies and accessories, including wound dressings.

Medicare Payment:

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

O&P HCPCS Public Meeting Agenda Item #6
May 27, 2015

O&P

Attachment# 15.115

Topic/Issue:

Third request to establish a new Level II HCPCS code to identify a custom Dynamic Response Orthotic Pylon (Strut) “energy storing AFO”.

Background/Discussion:

Bio-Mechanical Composites, Inc. submitted its fourth request to establish a new HCPCS code to identify a custom Dynamic Response Orthotic Pylon (strut) (energy storing AFO). The requester acknowledges the three previous applications for a HCPCS “base code” and differentiates this application as a request for an “add-on L code”, saying that an “addition” code is better suited to this technology. According to the requester, this custom, dynamic response orthotic pylon (energy storing pylon or strut custom for an orthosis) is a flat or round composite structure that is custom made to the height and shape of the patient’s leg. It is also custom made to produce a specific amount of rebound resistance. The amount of resistance needed is determined by an evaluation of the amount of weakness or absence of calf strength the patient displays. When the patient walks the pylon bends, loading energy into the structure and then pushes back against the patient, simulating the force the absent calf muscle would have produced. The ankle foot orthosis consists of a foot section and a calf section with either a flexible, rigid or articulated section that connects the two parts of the orthosis. The device is indicated for patients with weakness or absence of the posterior calf muscle group.

The requester comments that no other ankle foot orthoses on the market compensate for the weakness or absence of the plantar flexion of the foot and ankle, and no code that describes this structural dynamic “in addition to an AFO”. Codes L5985 and L5980 describe prefabricated products and the dynamic response orthotic pylon is customized to match the patient.

Preliminary Decision:

Existing code L1940 “Ankle Foot Orthosis, Plastic or Other Material, Custom-Fabricated” describes the AFO that is the subject of this request, which is included in the custom AFO base code, and as such, separate coding would be duplicative. Code L9900 “Orthotic and prosthetic supply, accessory, and/or service component of another HCPCS “L” code” may also be used.

Medicare Payment:

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

O&P HCPCS Public Meeting Agenda Item #7
May 27, 2015

Attachment# 15.003

Topic/Issue:

Fourth request to establish unique Level II HCPCS “addition” code to separately identify a manual prosthetic cable control and locking system for upper extremity prostheses, Trade Name: Sure-Lok™.

Applicant’s suggested language:

LXXXX-Addition to upper extremity, locking mechanism for primary control cable with manual lock/unlock of terminal device or other, surface or subsurface mount

Background/Discussion:

TRS Inc. AKA Therapeutic Recreation System, Inc. submitted its fifth request to establish a new, unique HCPCS “addition” code to separately identify Sure-Lok® Control Cable Locking System, as opposed to including this cable control system in existing addition codes which describe upper extremity addition control cable designs.

According to the requester, the Sure-Lok™ is the world’s first manually-operated control-cable locking system developed for use in upper limb prosthetics. It includes a unidirectional control cable locking technology incorporating a manually actuated, self-energizing cam mechanism. The Sure-Lok® system enhances the usefulness, safety and therapeutic value of cable-operated prosthetic devices for persons with all levels of unilateral and bilateral upper-extremity absence. It is an improvement over existing cable-operated technology and it gives the user greater control over their upper limb prosthetic terminal device (hand/hook), and is designed to increase the versatility of voluntary opening and voluntary closing devices. The Sure-Lok® Control Cable Locking System mounts directly on or in the voluntary opening (VO) or voluntary closing (VC) prosthesis essentially replacing the user’s primary control cable system with improved, more functional, higher performance technology.

The applicant claims a significant therapeutic distinction when the Sure-Lok® system is used, when compared to use of basic cables based on the following: Sure-Lok® technology offers infinite locking positions and pre-set, secure grasp, and whereas basic cables only transfer excursion forces from the harness to the terminal device and either do not lock, or offer a back-lock feature that works in only a few discreet positions. In addition, users of the Sure-Lok® experience: decreased energy expenditure, improved control of terminal devices, and sustained pinch force with voluntary-closing terminal devices.

The requester comments that existing codes do not describe the Sure-Lok™ system because none describe its product design, function or appropriate reimbursement. The requester refutes previous CMS and Medicare Contractor code determinations that existing codes adequately

describe the Sur-Lok™ system, and stating “we have thoroughly and accurately analyzed [these coding determinations] as being invalid”. The requester has repeatedly stated that, despite prior coding decisions, the manufacturer will continue to recommend use of unlisted procedures code L7499 “Upper extremity prosthesis, not otherwise specified” to identify the Sure-Lok™ in order to ensure appropriate reimbursement for this component.

Preliminary Decision:

The manual cable control locking feature that is the subject of this request is an item that may be included as part of any UE prosthesis using a cable control to operate the prosthesis. When a Sure-Lok is included in an UE prosthesis, it is considered to be included in the payment for the UE harness. As such, existing code L9900 “Orthotic and prosthetic supply, accessory, and/or service *component of another HCPCS “L” code*” is the correct code for separate reporting of the Sure-Lok.

Medicare Payment:

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

Pricing = 38

O&P HCPCS Public Meeting Agenda Item #8
May 27, 2015

Attachment# 15.061

Topic/Issue:

Repeat request to establish a unique Level II HCPCS code to identify injectable implants Prolaryn™ Plus and Prolaryn™ Gel (formerly Radiesse Voice and Radiesse Voice Gel).

Applicant's suggested language: L86XX - Injectable bulking agent, calcium hydroxylapatite or sodium carboxymethylcellulose, vocal fold, 1cc, includes shipping and necessary supplies.

Background/Discussion:

On behalf of Merz North America, a request was submitted to establish a HCPCS code to identify injectable implants Prolaryn™ Plus and Prolaryn™ Gel (formerly Radiesse Voice and Radiesse Voice Gel, respectively). According to the requester, using either a percutaneous or transoral needle that is packaged with the Prolaryn products, the products are injected into the larynx to augment the size of vocal folds as a treatment for vocal fold insufficiency. Vocal fold insufficiency is a condition in which an individual's two vocal folds cannot close completely, which can cause people to be unable to speak above a whisper, to have difficulty breathing, and to cough and choke when swallowing. Prolaryn Plus and Prolaryn Gel augment the size of the vocal folds to allow them to close completely. The requester comments that the products should be treated as prosthetic implants. Prolaryn Plus is provided in a pre-filled syringe containing 1.0cc of Prolaryn Plus. Prolaryn Gel is provided in a pre-filled syringe containing 1.0cc of Prolaryn Gel.

Preliminary Decision:

Establish LXXXXX Injectable bulking agent for vocal cord medialization, 0.1ml

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.

O&P HCPCS Public Meeting Agenda Item #9
May 27, 2015

Attachment# 15.114

Topic/Issue:

Third request to create a distinction, via HCPCS coding, between trachea-esophageal voice prostheses that have a magnetic valve closure (Trade Name: Provox® ActiValve™ Voice Prostheses) and those that do not.

Applicant's suggested language:

Establish new code: Tracheo-esophageal voice prosthesis, *active valve closure type*, inserted by a licensed health care provider; and

Revise existing code L8509 which currently reads: "Tracheo-esophageal voice prosthesis, inserted by a licensed health care provider, *any type*"; to instead read: "Tracheo-esophageal voice prosthesis, *standard type*, inserted by a licensed health care provider".

Background/Discussion:

Atos Medical, Inc. submitted another request to make a distinction, via HCPCS coding, between provider-inserted, indwelling trachea-esophageal voice prostheses that have a magnetic valve closure, and those that do not. The requester asks that the coding distinction be made by revising existing code L8509 for provider inserted tracheo-esophageal voice prostheses, to indicate that the devices in this code are "standard"; and establishing a new code specifically for voice prostheses with active valve closure. According to the requester, the ActiValve device is intended for antegrade insertion in a healed puncture for voice rehabilitation after total laryngectomy. It restores voice function in a narrowly defined subset of post-laryngectomy patients experiencing early leakage or repeated malfunction of standard provider-inserted voice prostheses requiring frequent replacement (less than 4-8 weeks). It reduces the need for frequent replacements in a majority, (but not all) users. The ActiValve consists of an outer housing molded from medical grade silicone, an inner valve seat constructed of a blue fluoroplastic, and a hinge made of medical grade silicone. The magnetic valve closure technology increases resistance to valve opening and facilitates complete and secure valve closure each time negative pressures are generated in the esophagus during swallowing and inhalation. Fluoroplastic is resistant to the build-up of Candida on the device. The requester claims a sharply increased indwelling device operating life and correspondingly much-reduced frequency of device failure and replacement when the ActiValve device is used, when compared with the use of voice prostheses that do not have a magnetic valve closure.

The requester comments that a unique code is warranted for the ActiValve device because it substantially differs from "standard" provider-inserted passive valve closure-type voice prostheses in four respects: design, functionality, FDA approved indication, and therapeutic effectiveness for its unique indicated use.

Preliminary Decision:

Existing code L8509 “Tracheo-esophageal vice prosthesis, inserted by a licensed health care provider, any type” adequately describes the provider-inserted tracheo-esophageal voice prostheses, including the Provox ActiValve.

Medicare Payment:

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

O&P HCPCS Public Meeting Agenda Item #10
May 27, 2015

Attachment# 15.117

Topic/Issue:

Request to modify existing Level II HCPCS code L8621 “Zinc air battery for use with cochlear implant device, replacement (each)” to include use with auditory osseointegrated (AOI) devices.

Applicant's suggested revised language for L8621: Zinc air battery for use with cochlear device implant and auditory osseointegrated device sound processors replacement (each).

Background/Discussion:

Cochlear Americas submitted a request to revise existing HCPCS code L8621, which describes zinc air batteries for use with cochlear implant devices, to also specify use with auditory osseointegrated (AOI) devices. The zinc air battery is a disposable battery used to power a sound processor for a cochlear implant or AOI. Two zinc air batteries provide a cochlear implant up to 60 hours of battery life; and one provides AOI between 5 to 7 days of battery life. Cochlear implants are intended for use in adults who have bilateral, pre, peri or post linguistic sensorineural hearing impairment and obtain limited benefit from appropriate binaural hearing aids. AOIs are used to help individuals 5 years of age and older with chronic ear infections, congenital external auditory canal atresia and single sided deafness that cannot benefit from conventional hearing aids.

The requester comments that the text of existing code L8621 should be expanded because the current descriptor limits use of the code to describe batteries only for use with cochlear implants.

Preliminary Decision:

Revise existing code L8621 which currently reads: “Zinc air battery for use with cochlear implant device, replacement, each” to instead read: “Zinc air battery for use with cochlear implant device *and auditory osseointegrated sound processors*, replacement, each”.

Medicare Payment:

The payment rules associated with the existing code apply these products if covered.
Pricing = 38

O&P HCPCS Public Meeting Agenda Item #11
May 27, 2015

Attachment# 15.116

Topic/Issue:

Repeat request to establish 4 unique Level II HCPCS codes to identify Argus II Retinal Prosthesis System (Argus II) external patient-worn components.

Applicant's suggested language:

XXXX1 - Head mounted telemetry and video data collection system (glasses mounting)

XXXX1 - Video processing unit (VPU) for use with retinal prosthesis vision system

XXXX3 - VPU battery charger with AC adapter for use with retinal prosthesis vision system

XXXX4 - VPU rechargeable batteries for use with retinal prosthesis vision system

Background/Discussion:

On behalf of Second Sight, a request was submitted to create 4 HCPCS codes to identify external replacement components of the Argus II Retinal Prosthesis System: head mounted telemetry and video data collection system, video processing unit (VPU), VPU battery charger with AC adapter for use with retinal prosthesis vision system and VPU rechargeable batteries for use with retinal prosthesis vision system.

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 aphakic or pseudophakic. 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 requester comments new HCPCS codes are necessary to identify replacement components that are the subject of this application.

Preliminary Decision:

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 Prosthesis, Includes All Internal and External Components” are available for assignment by insurers if they deem appropriate to describe the entire system, including all components, on initial issue.

Existing code V2799 “Vision item or service, miscellaneous” is available for assignment by insurers to identify replacement head mounted telemetry system and replacement VPU.

Information provided in the application was insufficient to reach a code decision regarding replacement batteries and charger.

Medicare Payment:

The payment rules associated with the existing code apply these products if covered.

Pricing = 46

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.

