Centers for Medicare & Medicaid Services (CMS)
Healthcare Common Procedure Coding System (HCPCS)
Public Meeting Summary Report
Orthotics & Prosthetics
Wednesday, May 27, 2009

Introduction and Overview

Approximately 56 people attended. The agenda included 16 items.

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

Joel Kaiser of CMM presented an educational overview of the methods used for setting the payment amount for items, and when the different methods are used. The overview was also provided as a written attachment to the agenda and is also attached to this summary. For additional information, the DME payment rules are located at Section 1834 (a) of the Social Security Act. The Medicare fee schedule for DME, Prosthetics, Orthotics and Supplies, and background information, can be accessed and downloaded free of charge at: http://www.cms.hhs.gov/feeschedulegeninfo.

Prior to the Public Meetings, CMS HCPCS workgroup meets to review all HCPCS code applications and makes preliminary coding recommendations. CMS also makes preliminary recommendations regarding the applicable Medicare payment category and methodology that will be used to set a payment amount for the items on the agenda. The preliminary coding and payment recommendations are posted on the HCPCS world-wide web site at www.cms.hhs.gov/medhcpcsgeninfo, as part of the HCPCS public meeting agendas.

Following the public meetings, CMS HCPCS workgroup reconvenes, and considers all the input provided at the Public Meetings regarding its preliminary coding recommendations. CMS also reconsiders its Medicare payment recommendations. CMS maintains the permanent HCPCS Level II codes, and reserves final decision making authority concerning requests for permanent HCPCS codes. Final decisions regarding Medicare payment are made by CMS and must comply with the Statute and Regulations. Payment determinations for non-Medicare insurers, (e.g., state Medicaid Agencies or Private Insurers) are made by the individual state or insurer.

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

The process for developing agendas and speaker lists for the public meetings, and Guidelines for Proceedings at CMS' Public Meetings are posted on the official HCPCS world wide web site at: http://cms.hhs.gov/medhcpcsgeninfo/downloads/2008guidelines.pdf . The standard application format for requesting a modification to the HCPCS Level II Coding System, along with

instructions for completion and background information regarding the HCPCS Level II coding process is available at: http://cms.hhs.gov/medhcpcsgeninfo/downloads/2009_alpha.pdf. A decision tree, outlining CMS' decision-making criteria is also available at: http://cms.hhs.gov/medhcpcsgeninfo/downloads/decisiontree.pdf.

Centers for Medicare & Medicaid Services (CMS) Healthcare Common Procedure Coding System (HCPCS) Public Meeting Agenda for Orthotics & Prosthetics
Wednesday, May 27, 2009, 9:00 am – 5:00 pm
CMS Auditorium
7500 Security Boulevard
Baltimore (Woodlawn), Maryland 21244-1850

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

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

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

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

AGENDA ITEM #1
Attachment #09.031
Request to reinstate codes L2860 "ADDITION TO LOWER EXTREMITY JOINT, KNEE OR ANKLE, CONCENTRIC ADJUSTABLE TORSION STYLE, MECHANISM, EACH" and L3890 "ADDITION TO UPPER EXTREMITY JOINT, WRIST OR ELBOW, CONCENTRIC ADJUSTABLE TORSION STYLE MECHANISM, EACH" and to revise the descriptors of both of these codes.

Primary Speaker: Mark DeHarde of Ultraflex Systems

AGENDA ITEM #2
Attachment #09.038
Request to establish six codes for an implanted phrenic nerve stimulator and replacement parts as follows: 1) Breathing Pacemaker system (complete package); 2) Mark IV Transmitter; 3) 1-110A Std Receiver; 4) E-377-05 Electrode; 5) 902 A Antenna; and 6) Transtelephonic monitoring and service. Trade name: Breathing Pacemaker System and replacement components.

No Primary Speaker

AGENDA ITEM #3
Attachment #09.113
Request to establish a replacement battery code specific to Lithium Ion replacement batteries for use with Left Ventricular Assist Systems (LVAS).

Primary Speaker: Terry Johnson of Quality Assured Services

AGENDA ITEM #4
Attachment #09.019
Request to establish a new add-on code (similar to L5858) for microprocessor controlled orthotic knee joints used in custom-made knee-ankle-foot orthoses (KAFOs), trade name: Otto Bock Sensor Walk.

No Primary Speaker

AGENDA ITEM #5
Due to an error on our part this agenda item has been moved to the next day.
Attachment #09.059
Request to establish a code for a dynamic dorsal night splint, trade name: D2 Night Splint.

AGENDA ITEM #6
Attachment #09.092
Request to establish a code to describe major parts required to repair a prosthesis.

No Primary Speaker

AGENDA ITEM #7
Attachment #09.042
Request to establish 2 codes for an auditory osseointegrated device with headband, trade name: Baha with Softband.

Attachment #09.046
Request to establish a code for a replacement audio cable for auditory bone conducting device, trade name: Baha Cordelle II Audio Cable.

Primary Speaker: Erik Tolsma of Cochlear Americas

AGENDA ITEM #8
Attachment #09.048 A-E
Request to establish 5 codes for modular sound processor individual components (magnet, controller, battery holder, earhook and cable). Trade names: A) Freedom Coil Magnet; B) Freedom Controller; C) Freedom Battery Holder; D) Freedom Earhook; and E) Freedom Coil Cable

Primary Speaker: Ginger Grant of Cochlear Americas

AGENDA ITEM #9
Attachment #09.117
Request to establish a code for a nipple prosthesis, trade name: ReForma.

No Primary Speaker

AGENDA ITEM #10
Attachment #09.066
Request to establish a code for an attachable external breast prosthesis, trade name: Amoena Comfort + External Breast Prosthesis.

Primary Speaker: Steve Stranne, M.D.

AGENDA ITEM #11
Attachment #09.016
Request to establish a code for a feature of a prosthetic controller that enables interchangeability of Terminal Devices (TDs) from various manufacturers on the same electric arm prosthesis, trade name: AutoDetect.

Attachment #09.017
Request to establish a code for a feature of a prosthetic controller that automatically calibrates sensitivity to EMB (muscle) signals, trade name: AutoCal .

No Primary Speaker

AGENDA ITEM #12
Attachment #09.029
Request to establish a code for a cable locking and control system, trade name: Sure-Lock or Sure-Lok Cable Lock & Control System.

Primary Speaker: Robert Radocy of Therapeutic Recreation Systems

AGENDA ITEM #13
Attachment #09.056
Request to establish a code to identify a myoelectric hand, trade name: i-LIMB hand.

No Primary Speaker

AGENDA ITEM #14
Attachment #09.082
Request to establish an addition code for a hip flexion assist feature used in Helix-3D prosthetic hip joints.

Attachment #09.083
Request to establish an addition code for a polycentric, hydraulic hip joint with stride length limiter, adjustable feature used in Helix-3D prosthetic hip joints.

Attachment #09.084
Request to establish an addition code for a dynamic external hip rotation feature used in Helix-3D prosthetic hip joints.

Primary Speaker: Todd Anderson of Otto Bock Healthcare

AGENDA ITEM #15
Attachment #09.089
Request to establish a code for an external prosthetic ankle-foot system, trade name: Proprio Foot.

Primary Speaker: David McGill of Ossur Americas, Inc.

AGENDA ITEM #16
Attachment #09.053
Request to establish a code to describe the function and benefit of the Echelon foot.

Primary Speaker: Alan Kercher of Endolite

HCPCS Public Meeting Agenda Item #1
May 27, 2009

Attachment: #09.031

Topic/Issue:
Request to reinstate codes L2860 "ADDITION TO LOWER EXTREMITY JOINT, KNEE OR ANKLE, CONCENTRIC ADJUSTABLE TORSION STYLE MECHANISM, EACH" and L3890 "ADDITION TO UPPER EXTREMITY JOINT, WRIST OR ELBOW, CONCENTRIC ADJUSTABLE TORSION STYLE MECHANISM, EACH" and to revise the descriptors of both of these codes. Applicant's suggested language: L2860 "Addition to lower extremity custom orthosis; adjustable dynamic assist and/or resist hip, knee, ankle or metatarsophalangeal (MTP) component, each" and L3890 "Addition to upper extremity custom orthosis; adjustable dynamic assist and/or resist elbow, wrist or metacarpophalangeal (MCP) component, each."

Background/Discussion:
According to the requester, codes L2860 and L3890 describe removable dynamic components used in custom orthoses manufactured by Ultraflex Systems, Inc. since 1990. These components incorporate an adjustable and removable dynamic "power assist". The power assist add-on component is mounted to conventionally functioning elbow, wrist, hip, knee or ankle components within custom orthoses to add the prescribed function to dynamic assist/resist as required. Over 53,000 US patients have used these components in custom orthoses since 1997 to improve functions like walking and reach, grasp, pinch and release. The majority of these patients are pediatric with chronic conditions like spastic cerebral palsy. According to the requester, with the deletion of L2860 and L3890, no remaining "L" codes will describe functions provided by Ultraflex technology used in custom orthoses.

CMS HCPCS Preliminary Decision:
Establish 2 codes:
Lxxx1 ADDITION TO LOWER EXTREMITY JOINT, KNEE OR ANKLE, CONCENTRIC ADJUSTABLE TORSION STYLE MECHANISM FOR CUSTOM FABRICATED ORTHOSES ONLY, EACH"
Lxxx2 ADDITION TO UPPER EXTREMITY JOINT, WRIST OR ELBOW, CONCENTRIC ADJUSTABLE TORSION STYLE MECHANISM FOR CUSTOM FABRICATED ORTHOSES ONLY, EACH"

Medicare Payment:
Since these codes are invalid for Medicare submission, we believe there would be no Medicare payment for these codes.

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker supported the workgroup's preliminary decision to establish codes and stated that inclusion of input by all payers is appreciated. However, the speaker requested that: 1) the words "custom-fabricated" in the text of the proposed codes be revised to instead read "custom-fitted"; 2) that the proposed code language also be revised to describe additional joints not included in the prior (discontinued) codes (specifically, MCP, MTP and hip joints); and 3) that CMS implement the new codes no later than July 1, 2009.

HCPCS Public Meeting Agenda Item #2
May 27, 2009

Attachment: #09.038

Topic/Issue:
Request to establish six codes for an implanted phrenic nerve stimulator and replacement parts as follows: 1) Breathing Pacemaker system (complete package); 2) Mark IV Transmitter; 3) 1-110A Std Receiver; 4) E-377-05 Electrode; 5) 902 A Antenna; and 6) Transtelephonic monitoring and service. Trade name: Breathing Pacemaker System and replacement components.

Background/Discussion:
According to the requester, the Avery Breathing Pacemaker System is a diaphragmatic or phrenic nerve stimulator. It consists of surgically implanted receivers and electrodes mated to an external transmitter by antennas worn over the implanted receivers. A transtelephonic monitor is also provided to allow for evaluation of device function over a telephone. Phrenic nerve pacing provides ventilatory support for patients with chronic respiratory insufficiency whose diaphragm, lungs, and phrenic nerves have residual function. Typically, these patients have high spinal cord injuries, central sleep apnea or other central, neurological disorders, or paralyzed diaphragm(s). The patient population includes quadriplegics, CCHS patients, and patients whose phrenic nerve may have been damaged during a surgical procedure. Some of these patients require assistance from health professionals on a regular basis whether they are in an institution or at home. Other patients may be able to manage without such assistance. For example, some patients with CCHS only need to use the system while sleeping. High functioning quadriplegic patients may be able to function without significant assistance. Individuals with nerve paralysis, but who are otherwise mobile, may also function at home without additional medical or nursing support. The system is originally sold as a package, including transmitter, receiver, electrode, antenna, transtelephonic monitoring and service, carrying case and battery. However, individual components may need replacement, particularly the antennas, because of the long period of time the device is used. Therefore, HCPCS codes are being sought for the complete package as well as for replacement components.

CMS HCPCS Preliminary Decision:
A national program operating need to establish unique codes to identify external replacement parts (transmitter, antenna and battery) was not identified by Medicare, Medicaid or the Private Insurance sector. Your reported sales volume of these components is insufficient to support your request for a revision to the national code set. In accordance with HCPCS criteria as published on CMS' HCPCS website, there must be sufficient claims activity or volume, as evidenced by 3 months of marketing activity, so that adding a new code enhances the efficiency of the system and justifies the administrative burden of adding a code. Existing code A9999 "MISCELLANEOUS

DME SUPPLY OR ACCESSORY, NOT OTHERWISE SPECIFIED" is available for assignment by all payers to identify the battery and antennas. Existing code E1399 "DURABLE MEDICAL EQUIPMENT, MISCELLANEOUS" is available for assignment by all payers to identify the replacement transmitter. CMS will be happy to consider an application in a subsequent coding cycle if sales volume for these components increases substantially.

Implantable components, including electrodes and receiver are included in the DRG and are not separately billable.

Existing code A9279 "MONITORING FEATURE/DEVICE, STAND-ALONE OR INTEGRATED, ANY TYPE, INCLUDES ALL ACCESSORIES, COMPONENTS AND ELECTRONICS, NOT OTHERWISE CLASSIFIED" adequately describes the telephonic monitor. The service component of telephonic monitoring should be identified using CPT codes.

Medicare Payment:

The payment rules associated with the existing codes apply to these products.
For E1399, Pricing = 46
For A9999, Pricing = 46
For A9279, Pricing = 00

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item #3
May 27, 2009

Attachment: #09.113

Topic/Issue:
Request to establish a replacement battery code specific to Lithium Ion replacement batteries for use with Left Ventricular Assist Systems (LVAS). Applicant's suggested language: Qxxxx "Battery for use with un-tethered electric ventricular assist device, lithium-ion, replacement only"

Background/Discussion:
According to the requester, these rechargeable batteries are for left ventricular assist systems. This request has been driven by recent technological advances in battery cell chemistry and an industry shift to lithium-ion batteries with Cobalt as the active ingredient. When LVAS were first developed, manufacturers depended on older battery technology such as sealed lead acid and nickel-based technology. As technology advanced into portable equipment requiring critically timed field-responses, manufactures directed their attention to new power cell technology focusing on smaller, lighter devices. Options included addition of fuel gauges and battery management components with the ability to communicate with the host device resulting in increased management capabilities of the medical device and increased safety for the patient. The varying cell chemistries created significant therapeutic distinctions during un-tethered outpatient operation of the LVAS which is not reflected in current coding. Also, the wide ranging costs to manufacture and distribute the batteries are not reflected in the assigned reimbursement. According to the requester, the concurrent availability of three different power packs with distinctly different cell chemistries, features, advantages, therapeutic benefits and costs is strongly suggestive of the need for distinct "Q" codes for each type of power pack. The single existing code Q0496 "BATTERY FOR USE WITH ELECTRIC OR ELECTRIC/PNEUMATIC VENTRICULAR ASSIST DEVICE, REPLACEMENT, ONLY" does not differentiate between these characteristics nor does it provide adequate reimbursement.

CMS HCPCS Preliminary Decision:
1) Revise existing code Q0496 which currently reads: "BATTERY FOR USE WITH ELECTRIC OR ELECTRIC/PNEUMATIC VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY" to instead read "BATTERY, OTHER THAN LITHIUM-ION, FOR USE WITH ELECTRIC OR ELECTRIC/PNEUMATIC VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY"
2) Establish Qxxxx "BATTERY, LITHIUM-ION, FOR USE WITH ELECTRIC OR ELECTRIC/PNEUMATIC VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY

Medicare Payment:
Based on guidance contained in an informal benefit category determination, we believe that the item would be paid in accordance with the payment rules that apply to orthotics, prosthetics, prosthetic devices and vision services.

Summary of Primary Speaker Comments at the Public Meeting:
The primary speaker agreed with the workgroup's preliminary decision.

HCPCS Public Meeting Agenda Item #4
May 27, 2009

Attachment: #09.019

Topic/Issue:
Request to establish a new add-on code (similar to L5858) for microprocessor controlled orthotic knee joints used in custom-made knee-ankle-foot orthoses (KAFOs), trade name: Otto Bock Sensor Walk. Applicant's suggested language: LXXXX "Addition to lower extremity orthosis, microprocessor stance control feature knee joint, limitless knee flexion block in stance, includes sensors, any type"

Background/Discussion:
According to the requester, Sensor Walk is a microprocessor controlled knee joint designed to help KAFO wearers achieve a safer, more physiologically correct gait. It includes an onboard microprocessor, foot pressure sensors, knee angle sensor and battery, all of which are included in a custom fabricated in a Knee-Ankle-Foot Orthosis (KAFO). KAFOs are medically indicated for patients that present with quadriceps weakness or absent knee extensors to safely support body weight during ambulation. "Stance Control" KAFOs, also known as Stance Control orthoses (SCOs), allow the knee joint to flex, but block flexion during stance, which is the weight bearing phase of the gait cycle. The Sensor Walk offers distinct differences that set it apart from non-microprocessor controlled orthoses. The microprocessor enables the Sensor Walk to receive signals from the foot and knee. When the load on the plantar surface of the foot goes down, the microprocessor interprets that the limb is ready to go into swing phase. It signals an actuator to release the flexion blocking mechanism. The patient does not have to unload the joint or compensate their gait pattern to get the joint to release. Non microprocessor SCOs require the patient to think about each step they are taking during gait to get the knee joint to unlock for swing, thus, the patient is distracted from their environment and can be more susceptible to mishap. The Sensor Walk microprocessor control knee joint enables the patient to ambulate without the need to concentrate on whether or not the knee joint will lock or unlock during gait. With the use of the Sensor Walk: 1) the locking mechanism can release under load; 2) knee joint stability is not dependent on the foot making contact with the ground; 3) knee flexion contractures of 15 degrees can be accommodated (all other SCOs have a limit of 10 degrees); 4) microprocessor control ensures appropriate timing for release and reengagement of the locking mechanism; and 5) the Sensor Walk knee joint accommodates up to 300 lbs., whereas non-microprocessor devices can only accommodate up to 265lbs. According to the requester, there are no codes describing microprocessor control features that monitor the wearer's gait and ensure that the knee joint blocks flexion and allows swing at the appropriate phase of the gait cycle. All current coding refers to mechanical activated knee joints that are not

microprocessor controlled to ensure appropriate time of release and reengagement. Non microprocessor controlled mechanical activation does not ensure locking and unlocking of the knee joint.

CMS HCPCS Preliminary Decision:

A national program operating need to establish a code for this product was not identified by Medicare, Medicaid or the Private Insurance sector. Your reported sales volume was insufficient to support your request for a revision to the national code set. In accordance with HCPCS coding criteria as published on CMS' HCPCS website, there must be sufficient claims activity or volume, as evidenced by 3 months of marketing activity, so that adding a new code enhances the efficiency of the system and justifies the administrative burden of adding the code. For coding guidance, contact the insurer in whose jurisdiction a claim would be filed. For private insurers, contact the individual private insurance contractor. For Medicaid, contact the Medicaid Agency in the state in which a claim would be filed. For Medicare, contact the Medicare contractor. CMS will be happy to consider an application in a subsequent coding cycle if sales volume increases substantially.

Medicare Payment:

Payment for any covered items will be based on the carrier's individual consideration of the claim since no specific code or fee schedule has been established for this item.

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

Due to an error on our part this agenda item has been moved to the next day.

HCPCS Public Meeting Agenda Item #5
May 27, 2009

Attachment: #09.059

Topic/Issue:
Request to establish a code for a dynamic dorsal night splint, trade name: D2 Night Splint. Applicant's suggested language: Lxxxx "Dynamic ankle foot orthosis, including soft interface material, adjustable for fit, for positioning, may be used for minimal ambulation/maintaining rom, prefabricated, includes fitting and adjustment"

Background/Discussion:
According to the requester, D2 night splints are intended to stretch the plantar fascia and foot/calf musculature while the patient rests or sleeps. However, the D2 night splint allows a more gradual stretch, and allows the patient to progress as their tolerance in increased. The low-load stretching also allows the patient to maintain their gains in range of motion. An adjustable dynamic cord and an articulating dorsal shell control the degree of stretch. There are multiple cord hooks on the anterior side of the splint to allow adjustment of the cord tension. The cord hooks are numbered, allowing the patient to follow their progress. The range of motion indicator (markings on the hinge) allows the patient to monitor and the physician to document progress. The D2 is intended for patients with plantar fasciitis, achilles tendonitis, post-operative immobilization of the ankle, plantar flexion contractures, tendon repair, stroke/foot drop, tibial tendonitis, etc. The D2 night splint is made of foam, Primaflex, HTH 745, binding, elastic shock cord, zipper pull, rigid shell, and mesh. According to the requester, code L4396 "STATIC ANKLE FOOT ORTHOSIS, INCLUDING SOFT INTERFACE MATERIAL, ADJUSTABLE FOR FIT, FOR POSITIONING, PRESSURE REDUCTION, MAY BE USED FOR MINIMAL AMBULATION, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT" describes a static night splint, however; no code exists to describe a dynamic night splint that provides a progressive stretching of the muscles, maintains range of motion, and has a range of motion indicator.

CMS HCPCS Preliminary Decision:
Revise code L4396 which currently reads: "STATIC ANKLE FOOT ORTHOSIS, INCLUDING SOFT INTERFACE MATERIAL, ADJUSTABLE FOR FIT, FOR POSITIONING, PRESSURE REDUCTION, MAY BE USED FOR MINIMAL AMBULATION, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT" to instead read “STATIC OR DYNAMIC ANKLE FOOT ORTHOSIS, INCLUDING SOFT INTERFACE MATERIAL, ADJUSTABLE FOR FIT, FOR POSITIONING, MAY BE USED FOR MINIMAL AMBULATION, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT”. This revision is intended to clarify that this code is

also intended for use for dynamic devices. In fact, the predicate product for this code is a dynamic device. Revised code L4396 adequately describes this product.

Medicare Payment:

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

HCPCS Public Meeting Agenda Item #6
May 27, 2009

Attachment: #09.092

Topic/Issue:
Request to establish a code to describe major parts required to repair a prosthesis. Applicant's suggested language: "Repair of prosthetic device, repair or replace major parts"

Background/Discussion:
According to the requester, repairs of prosthetic devices can often exceed the scope of the existing code descriptor of L7510 "REPAIR OF PROSTHETIC DEVICE, REPAIR OR REPLACE MINOR PARTS." The proposed code would be used to describe major parts that are required to facilitate the repair of a prosthesis (for example, replacement of a microprocessor). According to the requester, associated costs for major repairs are not adequately described by the "minor" repair code.

CMS HCPCS Preliminary Decision:
A national program operating need to establish a code for this product was not identified by Medicare, Medicaid or the Private Insurance sector. For coding guidance, contact the entity in whose jurisdiction a claim would be filed. For Medicaid, contact the Medicaid Agency in the state in which a claim would be filed. For private insurance, contact the individual insurance contractor. For Medicare, contact the Medicare contractor.

Medicare Payment:
Payment for any covered items will be based on the carrier's individual consideration of the claim since no specific code or fee schedule has been established for these items.

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

HCPCS Public Meeting Agenda Item #7
May 27, 2009

Attachment: #09.042

Topic/Issue:
Request to establish 2 codes for an auditory osseointegrated device with headband, trade name: Baha with Softband. Applicant's suggested language: xxxx1 "Headband for auditory bone processor with headband" xxxx2 "Auditory bone conduction device, external sound processor with headband"

Background/Discussion:
According to the requester, Baha with Softband is intended for patients who have conductive or mixed hearing loss, and can benefit from sound amplification. It is used for babies and small children who can benefit from an auditory bone conducting sound processor but who are too young or not appropriate for surgery for an auditory osseointegrated implant. It is also indicated for adults who lack the bone strength to support osseointegration. The Softband combines an elastic band with a snap connector disk to which the sound processor is attached. The velcro fastening on the band allows it to be adjusted to fit. The headband presses the snap connector disk against the skin behind the ear. Amplified vibrational sound is transmitted transcutaneously to the bones of the skull for transmission to the cochlea. According to the requester, current codes L8690 "AUDITORY OSSEOINTEGRATED DEVICE, INCLUDES ALL INTERNAL AND EXTERNAL COMPONENTS" and L8691 "AUDITORY OSSEOINTEGRATED DEVICE, EXTERNAL SOUND PROCESSOR, REPLACEMENT" are only appropriate for reporting bone conducting hearing devices for patients whose bone is strong enough to support an osseointegrated implant.

CMS HCPCS Preliminary Decision:
Establish Lxxxx AUDITORY OSSEOINTEGRATED DEVICE, EXTERNAL SOUND PROCESSOR, USED WITHOUT OSSEOINTEGRATION, BODY WORN, INCLUDES HEADBAND OR OTHER MEANS OF EXTERNAL ATTACHMENT".

Medicare Payment:
Based on guidance contained in section 1862(a)(7) of the Social Security Act, we believe there would be no Medicare payment for this item.

Summary of Primary Speaker Comments at the Public Meeting:
The primary speaker agreed with the workgroup's preliminary decision and thanked the HCPCS Workgroup.

HCPCS Public Meeting Agenda Item #7
May 27, 2009

Attachment: #09.046

Topic/Issue:
Request to establish a code for a replacement audio cable for auditory bone conducting device, trade name: Baha Cordelle II Audio Cable. Applicant's suggested language: LXXXX "Transmitting cable for use with auditory bone conducting device, replacement"

Background/Discussion:
According to the requester, Baha auditory osseointegrated implants work by implanting a titanium implant into the bone behind the ear. This implant attaches to a sound processor that transmits sound via the bones of the skull allowing the patient to hear. Baha is currently covered by Medicare as a prosthetic device. The Baha Cordelle II is the most powerful Baha sound processor. It is designed for patients with severe mixed hearing losses who need a stronger device. It consists of a head worn transducer and a body worn sound processor. The audio cord transmits sound from the Baha Cordelle II sound processor to the transducer, which is attached to the implant by an abutment. Patients receiving their first Baha Cordelle II receive the audio cord as part of the device kit. As with electronic devices, certain components occasionally need repair or replacement. If the audio cord is severed, damaged, or fails for other reasons, patients will need a replacement cord in order to regain the functionality of the bone conduction sound processor. Although several codes exist for accessories to auditory devices like cochlear implants, the current HCPCS code set does not include any codes for accessories to auditory bone conducting devices.

CMS HCPCS 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 this transmitting cable. Existing code L7510 "REPAIR OF PROSTHETIC DEVICE, REPAIR OR REPLACE MINOR PARTS" is available for assignment by all payers.

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

Summary of Primary Speaker Comments at the Public Meeting:
The primary speaker disagreed with the workgroup's preliminary decision. The speaker suggested that there is a need for clarification of the distinction between "minor" and "major" parts, and the intended use of code L7510. The speaker claimed that there has been difficulty using this code because some insurers either do not accept it (because it is a "miscellaneous" code); or do not accept it for "swap-out" of minor parts, if not part of a repair. The speaker also suggested revising code L7510 to instead read: "repair or replace minor parts of a prosthetic device."

HCPCS Public Meeting Agenda Item #8
May 27, 2009

Attachment: #09.048 A-E

Topic/Issue:
Request to establish 5 codes for modular sound processor individual components (magnet, controller, battery holder, earhook and cable). Trade names: A) Freedom Coil Magnet; B) Freedom Controller; C) Freedom Battery Holder; D) Freedom Earhook; and E) Freedom Coil Cable

Background/Discussion:
According to the requester, the Nucleus Freedom cochlear implant is an electronic device providing hearing to severe to profoundly deaf individuals by converting sound into digital signals. Generally, cochlear implants are composed of two main components. An external unit captures sound, sends it to the processor which converts sound into digital signals, and transmits those digital signals to the implant. An internal implant is surgically placed to stimulate the hearing nerve in the inner ear. The Nucleus Freedom external unit is composed of the following individual components: A) Freedom Coil Magnet: sits in the middle of the Coil and connects with a magnet on the other side of the skin. B) Freedom Controller: sits behind the ear, attaches to the sound processor, and controls the processor. C) Freedom Battery Holder: sits inside the controller, holds the batteries. D) Freedom Earhook: soft, plastic piece sits above the ear to securely hold the processor in place behind the ear. E) Freedom Coil Cable: unit connects the sound processor to the implant on the other side of the skin. These components collectively work together with the sound processor to function as the external cochlear implant system. At the time of surgery the patient receives the complete system, however; each component can be replaced individually after warranty. Existing replacement part codes are: L8615 for a headpiece, L8616 for a microphone, L8617 for a transmitting coil, L8618 for a transmitter cable, L8619 replacement external sound processor. These codes do not describe replacement parts for external cochlear implant systems.

CMS HCPCS Preliminary Decision:
Existing code L7510 "REPAIR OF PROSTHETIC DEVICE, REPAIR OR REPLACE MINOR PARTS" is available for use by all insurers to code the minor parts, such as the battery holder, ear hook and coil magnet. The major parts are included in existing code L8615 "HEADSET/HEADPIECE FOR USE FOR USE WITH COCHLEAR IMPLANT DEVICE, REPLACEMENT."

Medicare Payment:
The payment rules associated with the existing codes apply to these products.
For L8615, Pricing = 38
For L7510, Pricing = 46

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with the workgroup's preliminary decision. The speaker requested clarification of the distinction between "minor" and "major" parts. Specifically, whether L8615 can be used to report "replacement of a component only, or an entire headset/headpiece of which these components are a part." The speaker reiterated the original request for two separate codes to identify the major parts: the processor controller and the cable.

HCPCS Public Meeting Agenda Item #9
May 27, 2009

Attachment: #09.117

Topic/Issue:
Request to establish a code for a nipple prosthesis, trade name: ReForma.

Background/Discussion:
According to the requester, ReForma is a reusable self-adhering Nipple prosthesis. It allows post status nipple and breast reconstruction patients to feel whole again, by giving them natural looking breast. It improves quality of life, self-esteem and self-image. ReForma is indicated for patients who undergo mastectomies and breast reconstruction. It is composed of a washable reusable self-sticking adhesive. It can be used daily over several months. Currently, code L8039 "BREAST PROSTHESIS, NOT OTHERWISE SPECIFIED" is being used with lengthy predetermination. According to the requester, a specific code for an external nipple prosthesis would provide breast cancer survivors the means to return their breasts to as original a form as possible, either prior to, or as an alternative to nipple reconstruction.

CMS HCPCS Preliminary Decision:
Establish Axxxx NIPPLE PROSTHESIS, REUSABLE, ANY TYPE, EACH

Medicare Payment:
Based on guidance contained in an informal benefit category determination, we believe that the item would be paid in accordance with the payment rules that apply to orthotics, prosthetics, prosthetic devices and vision services.

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

HCPCS Public Meeting Agenda Item #10
May 27, 2009

Attachment: #09.066

Topic/Issue:
Request to establish a code for an attachable external breast prosthesis, trade name: Amoena Comfort + External Breast Prosthesis. Applicant's suggested language: "Attachable external breast prosthesis"

Background/Discussion:
According to the requester, Amoena Comfort is an external prosthesis used to replace the natural breast after a mastectomy due to breast cancer. These prostheses are composed of a layer of adhesive silicone gel, a layer of polymeric phase change material that functions to assist in regulating body temperature, a layer of lightweight silicone to form the front of the prosthesis and a polyurethane film encasement. It has the unique ability to adhere to the patient's chest wall across the entire underside of the prosthesis without degrading the skin surface. Attachment to the chest is achieved through the use of an enhanced adhesive silicone gel shaped in "pearls" on the underside of the prosthesis. Attachable breast prostheses provide a more natural function and shape and permit the patient to carry the weight of the breast prosthesis in a more natural manner, removing pressure that would otherwise be concentrated at the shoulder. Achieving a more normal weight distribution for the prosthesis is especially important for patients with lymphedema, spinal abnormalities or larger pre-surgical natural breasts. These prostheses are indicated for patients who have undergone unilateral or bilateral mastectomy procedures. According to the requester, Amoena Comfort is different from similar products because other breast prosthesis do not include the enhanced technologies that promote full attachment to the patient's chest wall, but are non-attachable and rely on the mastectomy bra to support the weight of the prosthesis. These prostheses are lumped into the general code for external silicone breast prostheses (L8030 BREAST PROSTHESIS, SILICONE OR EQUAL). The absence of a separate code undermines patient access to attachable prostheses that provide the most natural option with respect to both structure and function.

CMS HCPCS Preliminary Decision:
Existing code L8030 "BREAST PROSTHESIS, SILICONE OR EQUAL" together with existing code A4280 "ADHESIVE SKIN SUPPORT ATTACHMENT FOR USE WITH EXTERNAL BREAST PROSTHESIS, EACH" adequately describe the product that is the subject of this request.

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

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with the workgroup's preliminary decision but was happy that CMS recognizes that there is an extension to existing code L8030. However, the speaker stated that "a separate code is merited and remains the best alternative for both payers and patients" on the basis that the Amoena product provides a "distinct structure and function" that confers "meaningful benefits" to patients. The speaker also claimed that this "advanced technology" is more cost-effective over time. According to the speaker, the option recommended by CMS could be a viable option if there is clarification of how to bill for multiple adhesive skin supports under A4280 in a manner that reflects the long-lasting technology that is incorporated within attachable external breast prostheses.

HCPCS Public Meeting Agenda Item #11
May 27, 2009

Attachment: #09.016

Topic/Issue:
Request to establish a code for a feature of a prosthetic controller that enables interchangeability of Terminal Devices (TDs) from various manufacturers on the same electric arm prosthesis, trade name: AutoDetect.

Background/Discussion:
According to the requester, the AutoDetect is incorporated into the controller of the prosthesis. It is a feature that enables the wearer of the prosthesis to use a range of terminal devices (TDs) without restriction to a single manufacturer or connection type. AutoDetect is automatically triggered upon turning on the electric arm prosthesis. The controller either detects a "Motor Direct" type TD, or an "In-Hand controller" type TD and automatically provides the appropriate connections. AutoDetect has been a feature of the Utah U3, U3+ and Hybrid arms since 2004 and 2006, respectively. "Other elbow prostheses, even if offering microprocessor control of the TD, are not able to offer AutoDetect, and thus are not able to provide for interchangeability of all brands of TDs." There are currently no codes available to describe the AutoDetect feature of a prosthetic controller.

CMS HCPCS 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 this product. It is included in the base code for the Terminal Device. Existing code L9900 "ORTHOTIC AND PROSTHETIC SUPPLY, ACCESSORY, AND/OR SERVICE COMPONENT OF ANOTHER HCPCS "L" CODE" is available for assignment by all payers as they deem appropriate. For coding guidance, contact the insurer in whose jurisdiction a claim would be filed. For private insurers, contact the individual private insurance contractor. For Medicaid, contact the Medicaid Agency in the state in which a claim would be filed. For Medicare, contact the Medicare contractor.

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

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

HCPCS Public Meeting Agenda Item #11
May 27, 2009

Attachment: #09.017

Topic/Issue:
Request to establish a code for a feature of a prosthetic controller that automatically calibrates sensitivity to EMB (muscle) signals, trade name: AutoCal

Background/Discussion:
According to the requester, AutoCal is a function of the prosthetic arm controller which enables wearers to make adjustments to the control settings to compensate for changes in EMG muscle strength. Auto calibration has been offered with the Pro Control 2, the Utah Arm 3, and the Utah Hybrid arm since their release in 1997, 2004 and 2006, respectively. The wearer uses AutoCal to maintain optimal function by triggering an "AutoCal event" whenever they desire to change, or re-calibrate the sensitivity of the terminal device (TD) on their prosthesis. Once AutoCal is triggered, the wearer contracts the control muscles to open and close the TD. The AutoCal algorithm automatically adjusts the EMG gains in order to provide maximum output based on EMG signal strength. The most common use of AutoCal is after a period of heavy use, when the muscles become fatigued and the wearer's strength is reduced, requiring greater effort to open and close the TD. In this scenario, AutoCal is used to restore efficient function by raising the EMG gains. The wearer can intentionally set the sensitivity higher or lower, depending on the type of work they desire to perform. According to the requester, there are no codes to describe the AutoCal feature of a prosthetic controller.

CMS HCPCS 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 this product. It is included in the base code for the Terminal Device. Existing code L9900 "ORTHOTIC AND PROSTHETIC SUPPLY, ACCESSORY, AND/OR SERVICE COMPONENT OF ANOTHER HCPCS "L" CODE" is available for assignment by all payers as they deem appropriate. For coding guidance, contact the insurer in whose jurisdiction a claim would be filed. For private insurers, contact the individual private insurance contractor. For Medicaid, contact the Medicaid Agency in the state in which a claim would be filed. For Medicare, contact the Medicare contractor.

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

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

HCPCS Public Meeting Agenda Item #12
May 27, 2009

Attachment: #09.029

Topic/Issue:
Request to establish a code for a cable locking and control system, trade name: Sure-Lock or Sure-Lok Cable Lock & Control System. Applicant's suggested language: "Cable Locking and Control System; manually operated, mechanical, self-energizing cam mechanism, new or retrofit, including ancillary 0.063-inch diameter cable, housing, liner, ferrules, and mounting hardware".

Background/Discussion:
According to the requester, the Sure-Lok is a manually actuated, unidirectional cable locking system developed for use in prostheses that leverages an innovative self-energizing cam mechanism, a fray-and crush-resistant cable, and other advances to give users greater control over their appliance. When engaged, the device maintains tension in a user's cable to sustain grasp, while allowing the user to relax their muscles. By effectively locking the user's terminal device at the desired prehension force, the Sure-Lok reduces energy output and fatigue, and increases the versatility, functional range of motion and prehension capabilities of any cable-driven terminal device and prosthetic system, including both voluntary-opening (v/o) and voluntary-closing (v/c) varieties. The Sure-Lok is primarily intended for body-powered arm prostheses as a replacement for existing conventional cable controls. Current codes L6672, L6675, L6676 and L6677 identify only simple cable systems and associated basic hardware. They do not adequately describe the Sure-Lok locking system or the energy savings and improved control it conveys to users.

CMS HCPCS 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 this product. This is a component included in the harness code L6675 "UPPER EXTREMITY ADDITION, HARNESS, (E.G. FIGURE OF EIGHT TYPE), SINGLE CABLE DESIGN." As such, code L9900 "ORTHOTIC AND PROSTHETIC SUPPLY, ACCESSORY, AND/OR SERVICE COMPONENT OF ANOTHER HCPCS "L" CODE" is available for assignment by all payers as they deem appropriate. CMS would be interested in clinical information substantiating the claims of reduction of energy output and fatigue, and improved control.

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

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with the workgroup's preliminary decision. The speaker provided an update of sales data and presented testimonials related to actual usage of the technology. He also provided a physical demonstration to illustrate the technology's features and function. The speaker reiterated the request for a new code.

HCPCS Public Meeting Agenda Item #13
May 27, 2009

Attachment: #09.056

Topic/Issue:
Request to establish a code to identify a myoelectric hand, trade name: i-LIMB hand.

Background/Discussion:
According to the requester, i-Limb hand is the first prosthetic hand to include digits that articulate like those of the natural human hand. Like other electromechanical hands, the i-Limb is controlled by myoelectric signals from the user's muscles. However, unlike all other hands, the i-limb provides much more function than a simple pinch-type grip between the thumb and two fingers. The i-Limb hand articulates at 9 joints and operates with 5 motors independently, allowing the digits to open fully at extension. It has five articulating fingers that can be configured in a variety of positions, such as pointing the index finger or wrapping the fingers around an object. These different grip patterns allow a more dexterous and compliant grip than other hands, providing an increase in rehabilitation and functionality and a decrease in unnatural body posture for the user. Other myoelectric hands have only one motor, articulate at only one joint, provide only a basic function of gripping objects between the tip of the thumb and the tip of the first two fingers, and when fully extended can achieve only a "c"-type of shape. According to the requester, no code describes the functionality provided by the i-Limb.

CMS HCPCS Preliminary Decision:
A national program operating need to establish a code for this product was not identified by Medicare, Medicaid or the Private Insurance sector. Your reported sales volume was insufficient to support your request for a revision to the national code set. In accordance with HCPCS coding criteria as published on CMS' HCPCS website, there must be sufficient claims activity or volume, as evidenced by 3 months of marketing activity, so that adding a new code enhances the efficiency of the system and justifies the administrative burden of adding the code. For coding guidance, contact the insurer in whose jurisdiction a claim would be filed. For private insurers, contact the individual private insurance contractor. For Medicaid, contact the Medicaid Agency in the state in which a claim would be filed. For Medicare, contact the Medicare contractor. CMS will be happy to consider an application in a subsequent coding cycle if sales volume increases substantially.

Medicare Payment:
Payment for any covered items will be based on the carrier's individual consideration of the claim since no specific code or fee schedule has been established for this item.

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

HCPCS Public Meeting Agenda Item #14
May 27, 2009

Attachments 09.082, 09.083 and 09.084

Attachment: #09.082

Topic/Issue:
Request to establish an addition code for a hip flexion assist feature used in Helix-3D prosthetic hip joints. Applicant's suggested language "Addition, endoskeletal hip system, hip disarticulation or hemipelvectomy, hip flexion assist"

Background/Discussion:
According to the requester, the Hip Flexion Assist feature includes two Polyurethane Spring Elements that store energy during stance phase. This energy is then released early in swing phase, flexing the hip joint at the appropriate time in the gait cycle. This hip flexion occurs as the knee joint begins to flex, which results in shortening of the overall prosthesis. This provides greater toe clearance at mid-swing, reducing the potential for stumbles and falls. The Hip Flexion Assist feature flexes the hip when the prosthesis is unweighted. This greatly reduces the effort and pelvic thrust power necessary when the user initiates walking with the prosthetic limb from a standing position. The amount of flexion during swing phase is controlled by the hydraulic unit. There are no codes that describe the Hip Flexion Assist feature.

Attachment: #09.83

Topic/Issue:
Request to establish an addition code for a polycentric, hydraulic hip joint with stride length limiter, adjustable feature used in Helix-3D prosthetic hip joints. Applicant's suggested language "Addition, endoskeletal hydraulic hip joint, polycentric with stride length limiter, adjustable"

Background/Discussion:
According to the requester, the Polycentric, Hydraulic Hip Joint with Stride Length Limiter is a prosthetic hip joint that: 1) is polycentric in design, 2) is hydraulically controlled for both swing and stance phase; and 3) provides an ability to control the step length (stride length limiter). The following describes the functions of the Polycentric Hydraulic Hip Joint, Adjustable feature: 1) The polycentric design or four-bar structure shortens the overall length of the prosthesis during swing phase. This allows for more foot clearance; reduced risk of falling and increased security. This design also aids in stability during stance phase. 2) During swing phase, the hydraulic unit helps to control the step length and allows the amputee to walk with variable speed. During stance phase, the hydraulic unit controls the speed of extension so that the hip joint does not snap back into extension too aggressively. This reduces the stress on the amputee's body by providing a smooth transition from hip flexion to hip extension. 3) The stride length

limiter allows the practitioner to adjust the hip joint so the amputee may walk with step lengths that are equal from the prosthetic side to the sound side. This also allows the hip joint to flex more easily at the beginning of swing phase so that the hip and knee joints may be flexing at the same time. This also helps to shorten the overall length of the prosthesis during swing phase increasing foot clearance and reducing the risk of falling. This feature was developed to further meet the daily needs of hip disarticulation and hemipelvectomy amputees. The current codes do not describe the Polycentric, Hydraulic Hip Joint with Stride Length Limiter, Adjustable feature. There are not currently any other hip joints on the market that provide this same function.

Attachment: #09.84

Topic/Issue:
Request to establish an addition code for a dynamic external hip rotation feature used in Helix-3D prosthetic hip joints. Applicant's suggested language "Addition, lower extremity hip prosthesis, dynamic external hip rotation"

Background/Discussion:
According to the requester, Dynamic External Hip Rotation is the feature that provides three dimensional movement of the Helix-3D Hip Joint during walking, which reproduces normal hip joint movement. This feature is in the polycentric frame design of the Helix-3D Hip Joint. The axis geometry makes it possible to link hip flexion and extension to hip joint rotation. The rotation angle (transversal movement) depends on the flexion angle (sagittal movement). The dependency is nonlinear so that a physiological geometry is achieved, for example while sitting, so that a normal, unobtrusive sitting position can be assumed. Approximately six degrees of rotation should be expected when walking. The Dynamic External Hip Rotation feature allows the Helix-3D Hip Joint to rotate contrary to the pelvis to compensate for pelvic rotation during stance and swing that provides stabilization while walking. The rotation is directly related to flexion and extension of the hip. This prevents high torsion on the prosthetic components, socket, skin and spine, and benefits the patient by reducing strain on the lower spine and potentially reducing back pain. The patient also benefits by having a more normal gait pattern which involves three dimensional movement like the anatomical hip joint, with inward and outward rotation as well as abduction and adduction during stance and swing phase. In contrast, conventional prosthetic hip joints have a single axis, comparable to a normal door hinge. They allow movement in one plane: flexion and extension. Currently no codes exists to describe the function of the dynamic external hip rotation feature.

CMS HCPCS Preliminary Decision:
A national program operating need to establish a code for this product was not identified by Medicare, Medicaid or the Private Insurance sector. Your reported sales volume was insufficient to support your request for a revision to the national code set. In accordance with HCPCS coding criteria as published on CMS' HCPCS website, there must be sufficient claims activity or volume, as evidenced by 3 months of marketing activity, so that adding a new code enhances the efficiency of the system and justifies the administrative burden of adding the code. Code L5999 "LOWER EXTREMITY

PROSTHESIS, NOT OTHERWISE SPECIFIED" is available for assignment by all insurers to bill for the entire device, including all features. For coding guidance, contact the insurer in whose jurisdiction a claim would be filed. For private insurers, contact the individual private insurance contractor. For Medicaid, contact the Medicaid Agency in the state in which a claim would be filed. For Medicare, contact the Medicare contractor. CMS will be happy to consider an application in a subsequent coding cycle if sales volume increases substantially.

Medicare Payment:

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

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker provided updated sales information. The speaker also indicated that although the original request was for 3 codes to describe the 3 different features of the helix 3-D hip joint, a single code that encompasses all features would also be acceptable, and proposed language for a single code.

HCPCS Public Meeting Agenda Item #15
May 27, 2009

Attachment: #09.089

Topic/Issue:
Request to establish a code for an external prosthetic ankle-foot system, trade name: Proprio Foot.

Background/Discussion:
According to the requester, the Proprio Foot is the first electronic, microprocessor-controlled prosthetic ankle-foot system for lower-extremity amputees. It is designed to facilitate walking on level ground, on uneven terrain, up and down inclines and declines, up and down stairs, and standing up from a sitting position. Proprio Foot consists of four elements (1) an energy-storing prosthetic foot; (2) a battery-powered prosthetic ankle and plantarflexes and dorsiflexes; (3) a microprocessor that samples ankle position more than 1,000 times per second to control plantarflexion and dorsiflexion based on the underlying terrain, all of which occurs in real time; and (4) a lithium-ion battery and charger. While the Proprio Foot operates the same way as a traditional prosthetic foot in the stance phase portion of the gait cycle, its microprocessor-control feature permits dynamic, real-time adjustments of the ankle-foot complex once the prosthetic foot leaves the ground. When the user walks on level terrain, Proprio Foot dorsiflexes immediately after "toe-off." This permits greater ground clearance when the user transitions from the flexion to the extension portion of swing phase. Before heel strike, the microprocessor then initiates plantarflexion to encourage a symmetrical, smooth transition back onto the user's prosthetic side. No other ankle-foot system can provide this function. As a result, there are no existing codes that describe its characteristics. The most analogous code is L5856, which describes microprocessor-controlled knees, not ankle-foot systems.

CMS HCPCS Preliminary Decision:
Establish Lxxxx ADDITION, ENDOSKELETAL ANKLE FOOT SYSTEM, MICROPROCESSOR CONTROLLED FEATURE, DORSIFLEXION AND/OR PLANTAR FLEXION CONTROL, INCLUDES POWER SOURCE

Medicare Payment:
Based on guidance contained in an informal benefit category determination, we believe that the item would be paid in accordance with the payment rules that apply to orthotics, prosthetics, prosthetic devices, and vision service items.

Summary of Primary Speaker Comments at the Public Meeting:
The primary speaker agreed with the workgroup's preliminary decision.

HCPCS Public Meeting Agenda Item #16
May 27, 2009

Attachment: #09.053

Topic/Issue:
Request to establish a code to describe the function and benefit of the Echelon foot.

Background/Discussion:
According to the requester, the Echelon is a new prosthetic device that combines the properties of a dynamic, energy storing foot with integrated hydraulic ankle function. It is designed to allow self alignment which enables the lower extremity amputee to safely and comfortably traverse varied terrain, slopes and stairs with ease. The Echelon has demonstrated the ability to reduce pain and discomfort at the socket interface as well as reduce the risk of fall through increased knee stability in many cases. Studies show use of the Echelon promotes balanced loading of the prosthesis and the intact side, which is known to reduce the risk of secondary complications. The ankle enables independent hydraulic controlled plantar and dorsi-flexion, which provides up to 9 degrees of dampened motion. Combined with deflection of the dynamic springs, the Echelon returns normal range of ankle motion to the user. The Echelon is designed for K3 - lower extremity amputees that have the ability or potential for ambulation with variable cadence. Amputees that spend a considerable amount of time on uneven ground, stairs, slopes and or standing for extended periods of time will derive the most benefit from this new device. According to the requester, code L5968 does not adequately describe the self aligning feature of the Echelon which provides continuous hydraulic adjustment of both plantar and dorsi-flexion.

CMS HCPCS Preliminary Decision:
Existing code L5981 "ALL LOWER EXTREMITY PROSTHESIS, FLEX-WALK SYSTEM OR EQUAL" together with L5968 "ADDITION TO LOWER LIMB PROSTHESIS, MULTIAXIAL ANKLE WITH SWING PHASE ACTIVE DORSIFLEXION FEATURE" adequately describes the product that is the subject of this request.

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

Summary of Primary Speaker Comments at the Public Meeting:
The primary speaker commented that the two existing codes, while not problematic, still do not recognize or specifically enable additional reimbursement for the hydraulic self-alignment feature. The self-alignment during stance phase feature distinguishes the Echelon from other conventional ankle-foot systems. This feature enables continuous adjustment to terrain, providing better distribution of forces at the interface from prosthesis to body, which in turn increases knee stability, safety and confidence, and hence "the risk of fall is significantly reduced." The speaker reiterated the request for a unique "L" code to describe the self-aligning feature, and proposed code language.

PAYMENT FOR DMEPOS

DMEPOS

The term DMEPOS, which stands for durable medical equipment (DME), prosthetics, orthotics and supplies, is used in the Medicare program to describe a set of Medicare Part B device and supply benefits for which claims are processed by four DME Medicare Administrative Contractors (DME MACs). The Part B device benefits covered by this term include:

- DME – equipment used in the home which can withstand repeated use, is primarily and customarily used to serve a medical purpose, and is generally not useful in the absence of an illness or injury;
- Prosthetic Devices – devices that replace all or part of an internal body organ, including ostomy, tracheostomy and urological supplies, parenteral and enteral nutrients, equipment and supplies (PEN), intraocular lenses (IOLs), and one pair of conventional eyeglasses or contact lenses after each cataract surgery;
- Prosthetics – artificial legs, arms, and eyes;
- Orthotics – rigid or semi-rigid leg, arm, back, and neck braces;
- Home Dialysis Supplies and Equipment
- Surgical Dressings
- Therapeutic Shoes and Inserts

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

Fee Schedule Payments

Prior to January 1, 1989, payment for most DMEPOS items and services was made on the basis of the reasonable charge methodology. Reasonable charges are calculated using suppliers' charges and are limited by an inflation adjustment factor. Payment is still made on a reasonable charge basis for home dialysis supplies and equipment and for IOLs inserted in a physician's office. There is a monthly limit per beneficiary on payments for home dialysis supplies and equipment. Payment for most of the other DMEPOS items and services is based on the lower of the actual charge for the item or a fee schedule amount. The Part B deductible and 20 percent coinsurance both apply to the DMEPOS items and services described above.

The Social Security Act requires that the DMEPOS fee schedule amounts be established based on average reasonable charges made during a base period (e.g., July 1, 1986 thru June 30, 1987 for prosthetic devices, prosthetics and orthotics). The fee schedule amounts are increased by annual update factors. Because the reasonable charge data required by the law in establishing fee schedule amounts does not exist for new DMEPOS items, the fee schedule amounts for new DMEPOS items are "gap-filled" using fees for comparable items, supplier price lists, manufacturer suggested retail prices, or wholesale prices plus a markup. The gap-filling methodology is used to estimate the average reasonable charge for the item from the base period.

DMEPOS Payment Categories/HCPCS Pricing Indicators

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

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

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

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

- **Pricing = 33 Oxygen and Oxygen Equipment**
  Monthly fee schedule payments are made for furnishing oxygen and oxygen equipment. 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 monthly payments for the ongoing delivery of contents continue 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. For items furnished on or after January 1, 2006, the beneficiary takes over ownership of the item after the 13th rental payment is made. The rental fee for capped rental items for each of the first 3 months of rental is equal to 10 percent of the purchase fee for the item. The rental fee for months 4 through 13 is equal to 7.5 percent of the purchase fee for the item. Power wheelchairs can be purchased in the first month.

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

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

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

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

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

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