Centers for Medicare & Medicaid Services (CMS)
Healthcare Common Procedure Coding System (HCPCS)
Public Meeting Summary Report
Orthotics and Prosthetics
Tuesday, May 6, 2008

Introduction and Overview

Approximately 40 people attended. The agenda included 12 items.

Cindy Hake provided an overview of the HCPCS public meeting process and the overall HCPCS process.

Prior to 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 website at: www.cms.hhs.gov/medhcpcsgeninfo, as part of the HCPCS public meeting agendas.

Following the public meeting, CMS HCPCS workgroup reconvenes and considers all input provided at the Public Meeting regarding 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.

A DMEPOS Medicare Payment overview was 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: www.cms.hhs.gov/FeeScheduleGenInfo/.

The process for developing agendas and speaker lists for the public meetings, and Guidelines for Proceedings at CMS' Public Meetings is posted on the official HCPCS website at: www.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 www.cms.hhs.gov/medhcpcsgeninfo/Downloads/2009Alpha.pdf. A decision tree outlining CMS' coding criteria is available at www.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
Tuesday, May 6, 2008, 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 #08.75
Request to establish a new "J" code for dextranomer/hyaluronic acid copolymer, Trade Name: Deflux®.

Primary Speaker: Martha Christian of Princeton Reimbursement Group

AGENDA ITEM #2
Attachment #08.140
Request to establish a code and "right" and "left" code modifiers to identify a cervical collar device, trade name: Neuro Flex Restorative Kentucky Kollar (Ky Kollar).

Primary Speaker: Brian King of Restorative Medical, Inc.

AGENDA ITEM #3
Attachment #08.128
Request to establish a code for an articulating artificial finger for upper extremity partial hand prosthetics: trade name: X-Finger.

Primary Speaker: Dan Didrick of Didrick Medical, Inc.

AGENDA ITEM #4
Attachment #08.78
Request to establish a code for a motorized multi-articulating electronic prosthetic digit, trade name: i-Limb™ ProDigits™.

Primary Speaker: Rob Kistenberg of Georgia Institute of Technology

AGEDNA ITEM #5
Attachment #08.106
Establish an add-on code for a multi-flex wrist feature to be used in conjunction with existing code L6621.
OR
Establish a new code to be used in place of L6621 when the MultiFlex (flexible wrist plus locking feature) is utilized, trade name: MultiFlex Wrist.

Primary Speaker: Harold Sears of Motion Control, Inc.

AGENDA ITEM #6
Attachment #08.100
Request to establish a code for dynamic molded prosthetic liners.

No Primary Speaker

AGENDA ITEM #7
Attachment #08.65
Request to establish a code for Hypobaric Sealing Membrane (HSM), a flexible elastomeric ring bonded to the exterior of the liner circumferentially.

No Primary Speaker

AGEDNA ITEM #8
Attachment #08.52
Request to establish a code for the microprocessor-controlled ankle function of Proprio Foot.

Primary Speaker: David McGill of Ossur Americas

AGENDA ITEM #9
Attachment #08.138
Request to establish a code for an upper extremity ratchet action joint kit, trade name: Close Contour Series Kit.

Primary Speaker: Timothy Pansiera of OTS Corporation

AGENDA ITEM #10
Attachment #08.137
Request to include an orthotic lower extremity dynamic stance control knee joint, trade name: DynaPak, in existing code L2005.

Primary Speaker: Timothy Pansiera of OTS Corporation

AGENDA ITEM #11
Attachment #08.63
Request to establish a code for an Electronically Controlled Static Stance Regulator, Adjustable, feature used in prosthetic knees.

Primary Speaker: Peter Nohre of Otto Bock

AGENDA ITEM #12
Attachment #08.37
Request to establish a code for a limb brace, Trade Name: VACO®ped.

Primary Speaker: Christian Marten of OPED, Inc.

HCPCS Public Meeting Agenda #1
May 6, 2008

Attachment #08.75

Topic/Issue:
Request to establish a new "J" code for dextranomer/hyaluronic acid copolymer, Trade Name: Deflux® .
Applicant's suggested language:
Injectable bulking agent, dextranomer/hyaluronic acid, 1mL syringe.

Background/Discussion:
According to the requester, Deflux® injectable gel is a dextranomer/hyaluronic acid copolymer implant material used as a bulking agent in the treatment of vesicoureteral reflux (VUR). VUR is a common childhood anomaly of the urinary tract system and ranges in severity from grade I (mild) to V (severe). Deflux is a sterile, viscous gel of dextranomer microspheres (50mg/mL) in a carrier gel of non-animal, stabilized hyaluronic acid (NASHA 17mg/mL) constituting a biocompatible and biodegradable implant. Deflux injectable gel is supplied in a 1mL pre-filled single use, disposable syringe. The requester states that in keeping with established CMS policy this hyaluronate product, Deflux (dextranomer/hyaluronic acid) which is dispensed and used in the same manner as other drugs, satisfies the Medicare definition of a drug and should be granted its own unique HCPCS code as described.

CMS HCPCS Preliminary Decision:
Establish Lxxxx "INJECTABLE BULKING AGENT, DEXTRANOMER/HYALURONIC ACID COPOLYMER IMPLANT, URINARY TRACT, 1 ML, INCLUDES SHIPPING AND NECESSARY SUPPLIES"

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. Pricing =38

Summary of Primary Speaker Comments at the Public Meeting:
The primary speaker agreed with the workgroup's preliminary coding decision and suggested that APC payment be established by CMS' Division of Outpatient Care.

HCPCS Public Meeting Agenda #2
May 6, 2008

Attachment #08.140

Topic/Issue:
Request to establish a code and "right" and "left" code modifiers to identify a cervical collar device, trade name: Neuro Flex Restorative Kentucky Kollar (Ky Kollar).

Background/Discussion:
According to the requester, KyKollar™ is custom fit to the patient's specific needs considering the degree of lateral flexion and the intensity of their neurological tone. This device provides low load passive stretch to increase range of motion, and flex properties that reduce neurological tone and spasticity. The process of working through the tone typically occurs approximately 15 to 30 minutes after donning. The device could be remolded if appropriate as the patient's range of motion increases. People who would benefit from this device are patients from infant age to the oldest adults who develop Torticollis or who have left leaning of the head from some type of neurological injury or disease process. Diagnoses that might be associated with this type of condition are after a stroke, Whip Lash injury, end stage Alzheimer's disease, ALS, Multiple Sclerosis, Traumatic Brain Injury, Spinal Cord Injury and Parkinson's disease. According to the requester there is no existing HCPCS code that describes this product.

CMS HCPCS Preliminary Decision:
Existing code L0140 CERVICAL, SEMI-RIGID, ADJUSTABLE (PLASTIC COLLAR) adequately describes the product that is the subject of your request.

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

Summary of Primary Speaker Comments at the Public Meeting:
The primary speaker disagreed with the workgroup's preliminary decision. The speaker stated that the Ky Kollar is twice as long as the standard collar and comes up to the ear, and that the Ky Kollar has a unique leaf-spring design. This product can be heated using a standard industrial heat gun by a physical therapist. The speaker also stated that there is no existing code to describe this product, however, code L0130 has the "closest" description, and is currently used when billing.

HCPCS Public Meeting Agenda #3
May 6, 2008

Attachment #08.128

Topic/Issue:
Request to establish a code for an articulating artificial finger for upper extremity partial hand prosthetics: trade name: X-Finger. Applicant's suggested language: "Body-Powered Articulating Finger, Each."

Background/Discussion:
According to the requester, the X-Finger is an artificial finger that restores function to a patient that has lost a finger. The device allows users to independently control the flexion and extension movements of each replaced phalange. The X-Finger is the first mechanical artificial finger that articulates bone-like components creating movement similar to a real finger. A patient is able to control the movement of the X-Finger using the same motion he used to control his prior finger. The X-Finger simply slides over the patient's residual finger and stabilizes itself to the patient's hand. Once the device is applied to the patient's hand, the downward movement of the patient's residual finger forces the X-Finger to articulate in a similar manner as an actual finger. The movement of the residual finger not only controls the movement of both the flexion and extension movements but also the combined lateral movements as well. Patients can control the X-Finger to perform many of life's daily activities such as picking up objects, opening doors, and writing. Currently there are no existing codes in place for a functional artificial finger. There are approximately 40,000 finger amputations in the U.S. each year. Only 8% of all amputated fingers are successfully reattached and 88-90% of amputated fingers are finger tips, leaving approximately 4,000 patients annually, from an X-finger.

CMS HCPCS Preliminary Decision:
The workgroup requires more information on sales volume before it can determine whether the level reported in your application is sufficient to support your request for revision to the national code set. In accordance with the 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 or modified code enhances the efficiency of the electronic processing of claims and justifies the administrative burden of adding or modifying the code. The HCPCS workgroup would like an opportunity to consider additional information regarding the universe of patients that would use this device, the total number of patients that received one or more prosthetic fingers (as opposed to the total number of prosthetic fingers sold), and the proportion of claims submitted to the various insurer types (e.g., Medicaid, Medicare, Commercial Private Insurer (workman's compensation and non-), and Military).

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:
The primary speaker reported the universe of patients that could use this technology (between 2,500 and 4,000 patients annually, in the U.S.); the total number of patients that received one or more prosthetic fingers (108); and the proportion of claims submitted to various insurer types (92 of 108 patients to Workman's Compensation).

HCPCS Public Meeting Agenda #4
May 6, 2008

Attachment #08.78

Topic/Issue:
Request to establish a code for a motorized multi-articulating electronic prosthetic digit, trade name: i-Limb™ ProDigits™. Applicant's suggested language: "Addition to upper limb prosthesis, motorized electronic digit, each"

Background/Discussion:
According to the requester, i-Limb™ ProDigits™ is the world's first electronically powered finger and thumb module suitable for use by persons with partial hand amputations. Each i-Limb ProDigits is a stand-alone functional unit with its own independent electric motor that can be controlled by myoelectric signals from remnant muscles or by electronic switch mechanisms. The i-Limb ProDigits offer selected persons with partial hand deficiencies the restoration of active grasp and release with nearly normal speed and strength of finger movement. Each finger/thumb has multiple articulations, similar to the human digit, and is powered by a single electric micro-motor. i-Limb ProDigits must be incorporated into a custom-made prosthesis for selected persons having partial or full hand deficiencies secondary to tumor, trauma, infection, or traumatic injury. Candidates must be able to independently control the myoelectric signal from two muscle remnant sites or to actuate electronic switches in lieu of one or both myo signals. Due to space requirements, i-Limb cannot be used when part of the finger remains; it is only prescribed for persons with complete loss of one or more digits. i-Limb can be used for the absence of a single finger, multiple fingers, or just the thumb remaining. These multi-articulated fingers provide a versatile grasp pattern that effectively stabilizes a wide array of objects more effectively than body powered alternatives, offering cylindrical, spherical, lateral and tip pinch patterns. The myoelectric signals generated from remnant muscles provide both voluntary opening and voluntary closing of the digits with minimal physical effort by the amputee. Currently there are no existing codes available that describe individually-powered electronic fingers.

CMS HCPCS Preliminary Decision:
The workgroup requires more information on sales volume before it can determine whether the level reported in your application is sufficient to support your request for revision to the national code set. In accordance with the 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 or modified code enhances the efficiency of the electronic processing of claims and justifies the administrative burden of adding or modifying the code. The HCPCS workgroup would like an opportunity to consider additional information regarding the universe of patients that would use this device, the total number of patients that received one or more prosthetic fingers (as opposed to the total number of prosthetic fingers sold), and the

proportion of claims submitted to the various insurer types (e.g., Medicaid, Medicare, Commercial Private Insurer (workman's compensation and non-), and Military).

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:
The primary speaker reported the universe of patients that could use this technology (average 161 individuals per year with trans-metacarpal amputation); the total number of units sold (30, but unsure if this is 30 fingers or 30 patients); and the proportion of claims submitted to various insurer types (21% of 30 (or 6 patients), to private insurers, and the balance either to the VA or Workman's Compensation or not reported).

HCPCS Public Meeting Agenda #5
May 6, 2008

Attachment #08.106

Topic/Issue:
Request to either:

1) Establish an add-on code for a multi-flex wrist feature to be used in conjunction with existing code L6621 "UPPER EXTREMITY PROSTHESIS ADDITION, FLEXION/EXTENSION WRIST WITH OR WITHOUT FRICTION, FOR USE WITH EXTERNAL POWERED TERMINAL DEVICE"

OR

2) Establish a new code to be used in place of L6621 when the MultiFlex (flexible wrist plus locking feature) is utilized, trade name: MultiFlex Wrist.

Background/Discussion:
According to the requester, flexible wrist is used with an electric hand or other terminal device, incorporating a passive lock allowing a fixed flexion position in three positions (30 degrees of flexion or extension, and neutral position). Multi-Flex is indicated for persons who have suffered an amputation of the upper extremity, at some level between wrist disarticulation and complete shoulder loss. The Multi-Flex Wrist enhances the function of an electric hand or electric terminal device by allowing better security of grip, and better comfort for activities which require the wrist to move in a wide range of motion, more like the natural wrist (i.e. turning a steering wheel, bicycling, pushing a wheelbarrow, etc.). The Multi-Flex Wrist, while unlocked, will move in a natural range of motion as an object is grasped in an electric hand. This improves comfort greatly, by reducing reaction forces on the wearer's socket and reducing the awkward reposition of the shoulder and/or elbow required when the wrist is not flexible. Also, security of gripping is improved, since the object being pushed or pulled will not tend to pull out of the hand or terminal device. The Multi-Flex Wrist may also be "locked" in three flexion/extension positions, so tasks requiring a stiff wrist may also be performed. Candidates for the multi-flex wrist include transradial and transhumeral amputees using an electronic prothesis who use their prostheses actively. Existing L6621 "Upper extremity prosthesis addition, flexion/extension wrist with or without friction, for use with external powered terminal device" does not describe a product that provides flexibility in the wrist combined with the flexion/extension lock. Also, the Multi-Flex wrist is more costly than products included in L6621. According to the requester, this design is more complex, includes the new mechanism for the heavy duty spring return, and incorporates optional locking. Multi-Flex is integrated into the hand or terminal device when manufactured, so it is integral to the device.

CMS HCPCS Preliminary Decision:
Revise existing code L6621 which currently reads: "UPPER EXTREMITY PROSTHESIS ADDITION, FLEXION/EXTENSION WRIST WITH OR WITHOUT FRICTION, FOR USE WITH EXTERNAL POWERED TERMINAL DEVICE" to

instead read: "UPPER EXTREMITY PROSTHESIS ADDITION, FLEXION/EXTENSION WRIST WITH OR WITHOUT FRICTION, WITH OR WITHOUT LOCKING FEATURE, FOR USE WITH EXTERNAL POWERED TERMINAL DEVICE". The proposed revision to the code clarifies that L6621 adequately describes the product that is the subject of your request. The locking feature was considered at the time code L6621 was established. The Multi-Flex Wrist feature is, infact, the predicate product for code L6621.

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

Summary of Primary Speaker Comments at the Public Meeting:
The primary speaker stated that the existing code can only be used for wrists in a locked position. According to the speaker, most users keep this device in the unlocked position and use the locking feature when necessary. The MultiFlex wrist unlocks, locks in 3 positions and bends 30 degrees in every direction. The speaker suggested that language for a new code to include “with spring return to neutral, for use with external powered Terminal Device”. The speaker also indicated that the revision to the existing code (with or without locking feature”) was unnecessary, because all devices should have a locking feature.

HCPCS Public Meeting Agenda #6
May 6, 2008

Attachment #08.100

Topic/Issue:
Request to establish a code for dynamic molded prosthetic liners.

Background/Discussion:
According to the requester, Dynamic molded prosthetic liners have multiple layers, one of which is a dynamic moldable layer which will adapt to the persons leg as they ambulate. This liner is used for pressure relief, force redistribution, maximized comfort and to reduce risk of pathological developments of the leg. It is a functional padding which provides shock resistance from the forces of walking. The liquid phase (initial phase) of the liner uses chemicals, contained in multiple liner pouches. The liquid chemicals flow to the regions of least resistance, thus molding to the contour of the leg. This process eliminates the pressure points of the leg. The liquid chemical sets into a solidified soft accommodative gel material similar in density to the pre molded liner material. According to the requester based on differences in pressure relief and comfort, L5673 and L5679 do not adequately describe this product."

CMS HCPCS Preliminary Decision:
No insurer (i.e., Medicare, Medicaid, Private Insurance Sector) identified a national program operating need to establish a code to identify this product that has not yet been marketed. For coding guidance once the product is marketed, contact the entity 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 later coding cycle when sales data is available.

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 #7
May 6, 2008

Attachment #08.65

Topic/Issue:
Request to establish a code for Hypobaric Sealing Membrane (HSM), a flexible elastomeric ring bonded to the exterior of the liner circumferentially. Applicant's suggested language: "Addition to lower extremity, below knee/above knee hypobaric sealing membrane, excludes socket insert."

Background/Discussion:
According to the requester, the hypobaric sealing membrane is an added feature to the liner portion of the transtibial and transfemoral seal-in liner. The liner portion is already separated coded at L5679 "Addition to lower extremity, below knee/above knee, custom fabricated from existing mold or prefabricated, socket insert, silicon gel, elastomeric or equal, not for use with locking mechanism". The hypobaric sealing membrane is a flexible elastomeric ring bonded to the exterior of the liner circumferentially. The HSM creates an air-tight seal with a high co-efficient of friction between liner and socket. This reduces motion between the residual limb and the prosthesis, preventing prosthetic rotation on the residual limb. The HSM offers the user better control and suspension of the prosthesis without the drawbacks inherent in other systems. According to the requester, existing codes do not accurately describe the HSM feature, or a socket insert that utilizes a hypobaric sealing membrane in conjunction with a cushion liner to optimize control of a prosthetic socket. The requester points out that there are HCPCS codes describing other systems, such as the pin system (L5673); the lanyard system (L5671); and the knee sleeve (l5685).

CMS HCPCS Preliminary Decision:
No insurer (i.e., Medicare, Medicaid, Private Insurance Sector), identified a national program operating need to establish a separate code for this product. This product is included in the base code L5679 "ADDITION TO LOWER EXTERMITY, BELOW KNEE/ABOVE KNEE, CUSTOM FABRICATED FROM EXISTING MOLD OR PREFABRICATED, SOCKET INSERT, SILICONE GEL, ELASTOMERIC OR EQUAL, NOT FOR USE WITH LOCKING MECHANISM" or L5681 "ADDITION TO LOWER EXTREMITY, BELOW KNEE/ABOVE KNEE, CUSTOM FABRICATED SOCKET INSERT FOR CONGENITAL OR ATYPICAL TAUMATIC AMPUTEE, SILICONE GEL, ELASTOMERIC OR EQUAL, FOR USE WITH OR WTIHOUT LOCKING MECHANISM, INITIAL ONLY (FOR OTHER THAN INITIAL, USE CODE L5673 OR L5679)". As such, HCPCS code L9900 "ORTHOTIC AND PROSTHETIC SUPPLY, AND/OR SERVICE COMPONENT OF ANOTHER HCPCS "L" CODE" may be used to identify this product and the use of miscellaneous or add-on codes is inappropriate. 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.
For L5679 & L5681, Pricing = 38
For L9900, Pricing = 46

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

HCPCS Public Meeting Agenda #8
May 6, 2008

Attachment #08.52

Topic/Issue:
Request to establish a code for the microprocessor-controlled ankle function of Proprio Foot. Applicant's suggested language: "Addition to lower extremity prosthesis, endoskeletal ankle system, microprocessor control feature, dorsiflexion and plantarflexion, includes automatic terrain alignment feature, includes power source."

Background/Discussion:
According to the requester, Proprio Foot is the first electronic, microprocessor-controlled prosthetic ankle-foot system for lower-extremity amputees. Proprio foot is indicated for transtibial amputees with a functional level of K2 or K3. 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 parts: 1) an energy storing prosthetic foot, 2) a battery-powered prosthetic ankle that dorsiflexes and plantarflexes during swing phase, 3) a micro-processor that controls dorsiflexion and plantarflexion in real time and in response to changes in the underlying terrain by sampling ankle position more than 1,000 times per second; and 4) a lithium-ion battery and charger. Existing L codes describe all components of the Proprio Foot except the microprocessor-control feature. Its software allows it to intelligently respond to the underlying terrain. The resulting ability of Proprio Foot to adjust to uneven ground, ramps, stairs, and other environmental obstacles distinguishes it from all other ankle-foot systems, which are purely mechanical and passive. 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 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. When the user walks up or down a hill, Proprio Foot raises or lowers the prosthetic toe to adjust the gradient. The intelligent interpretation of data regarding the slope of the hill by the Terrain Logic™ software permits Proprio Foot to adjust to surface gradients of up to 20 degrees. During stair ascent, Proprio Foot dorsiflexes up to 6 degrees after the first step, depending on how the prosthetist programs the device. Similarly, when descending stairs, the microprocessor-controlled dorsiflexion after the first step permits the user to place the entire prosthetic foot on the subsequent downward step.

CMS HCPCS Preliminary Decision:
No insurer (i.e., Medicare, Medicaid, Private Insurance Sector), identified a national program operating need to establish a separate code for this product. Existing code L5999 "LOWER EXTREMITY PROSTHESIS, NOT OTHERWISE SPECIFIED" is available for assignment by insurers, as they deem appropriate. 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 later 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 disagreed with the workgroup's preliminary decision. The speaker stated that they have met the minimal sales threshold and has sold products to more than 3 % of the affected patient population. According to the speaker, this is based on sale to 3.7% of a total eligible population of 8171 that would use K2, K3 device. The speaker did not provide a breakdown of sales by insurer type although did state that 99% of sales have been to a non-Medicare population. The speaker also stated that the microprocessor control feature is present in every Proprio Foot, is not sold separately, and is a feature that is currently not identified in existing codes.

HCPCS Public Meeting Agenda #9
May 6, 2008

Attachment #08.138

Topic/Issue:
Request to establish a code for an upper extremity ratchet action joint kit, trade name: Close Contour Series Kit.

Background/Discussion:
According to the requester, Close Contour is an orthotic upper extremity ratchet action joint used to permit stretching or positioning of the wrist or elbow. This lightweight joint, sold in a kit, includes a free motion component similar to the StepLock knee joint, which has previously been assigned code L2430. However, Close Contour differs from the existing code in three ways: 1) it is lighter and is not designed for weight bearing application, but only for upper extremity use; 2) it is sold in both an extension version for stretching and a reverse action version for positioning of the elbow; and 3) it is sold in an extended ratchet version for wrist articulation. In addition to being smaller and lighter than other upper extremity joints available on the market, it is also less expensive. The Close Contour is manufactured from a metal alloy and the ratcheting action is designed to lock at 10 degree intervals as the joint is extended (or in the case of the reverse elbow, contracted). In its wrist version, the extension action begins at 90 degrees of flexion and ratchets upward to 30 degrees of extension to allow stretching of the wrist beyond its functional extension position. The extension elbow version is similar to the wrist, but the orientation of the beginning and end of the ratchet is from full flexion through 120 degrees of extension. These joints have many clinical applications, including cerebral palsy, spinal cord injuries, and stroke. According to the requester, they are a cost effective alternative to serial casting. Existing codes are inadequate to describe the item because its ratchet action is only addressed in lower extremity codes.

CMS HCPCS Preliminary Decision:
Existing code L3740 "ELBOW ORTHOSIS, DOUBLE UPRIGHT WITH FOREARM/ARM CUFFS, ADJUSTABLE POSITION LOCK WITH ACTIVE CONTROL, CUSTOM-FABRICATED" adequately describes the product that is the subject of your request.

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

Summary of Primary Speaker Comments at the Public Meeting:
The primary speaker stated that he would be happy with code L3740, but requested that the code text be revised to include “wrist/hand”. Other solutions proposed by this speaker include either a new “L” code “providing reasonable reimbursement” or assignment to existing code L3890, and “provide reasonable reimbursement”.

HCPCS Public Meeting Agenda #10
May 6, 2008

Attachment #08.137

Topic/Issue:
Request to include an orthotic lower extremity dynamic stance control knee joint, trade name: DynaPak, in existing code L2005 "KNEE ANKLE FOOT ORTHOSIS, ANY MATERIAL, SINGLE OR DOUBLE UPRIGHT, STANCE CONTROL, AUTOMATIC LOCK AND SWING PHASE RELEASE, MECHANICAL ACTIVATION, INCLUDES ANKLE JOINT, ANY TYPE, CUSTOM FABRICATED".

Background/Discussion:
According to the requester, DynaPak is a hydraulic joint sold in a kit which includes all the necessary hardware. It is similar to many manufacturers' stance control joints, but differs from other joints in that it is never locked in extension. The hydraulic system supports the weight of the patient, but allows for travel on an inclined slope, over uneven ground, or up and down stairs with a normal gait. DynaPac is manufactured from a metal alloy and is located on the calf cuff of the orthosis. It is connected by a very small diameter hydraulic hose to the specially modified bail lock type knee joints on the medial and lateral sides. The orthotist can control three functions. In stance phase, the knee joint will slowly flex. The orthotist can control the speed of knee flexion. The joint allows 38 degrees of range of motion to permit the patient to traverse a ramp or uneven ground. During swing phase, a strong die spring provides extension assistance. The orthotist can control both the strength and extension speed of the die spring. These joints have many clinical applications, including cerebral palsy, spinal cord injuries, stroke, as well as for the gradual stretching to allow burn patients to attain mobility. According to the requester, they are a cost alternative to serial casting. While the applicant requested inclusion in L2005, the applicant also states that existing code L2005 is inadequate to describe the item because its hydraulic action is never locked in stance phase. Clarification was requested.

CMS HCPCS Preliminary Decision:
No insurer, (i.e., Medicare, Medicaid, Private Insurance Sector) identified a national program operating need to establish a code for these devices. 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. Existing code L2999 "LOWER EXTREMITY ORTHOSIS, NOT OTHERWISE SPECIFIED" is available for assignment by all payers. 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 disagreed with the workgroup's preliminary decision. The speaker stated that the DynaPak is unique because it is an orthotic lower extremity knee joint that never locks. The speaker suggested assignment of the DynaPak to code L2005, with a revision to the code language to omit "automatic lock" and replace it with "stance phase support and extension assist". The speaker stated that currently, there are 40 DynaPaks in the field. All are under Beta testing.

HCPCS Public Meeting Agenda #11
May 6, 2008

Attachment #08.63

Topic/Issue:
Request to establish a code for an Electronically Controlled Static Stance Regulator, Adjustable, feature used in prosthetic knees. Applicant's suggested language: "Addition to Lower Extremity, Electronically-Controlled Static Stance Regulator, Adjustable".

Background/Discussion:
According to the requester, the Electronically-Controlled Static Stance Regulators, Adjustable, is a function that stabilizes a prosthetic knee at any flexion angle between 7 and 70 degrees while the patient is in static stance (standing). In order to engage this feature, the user simply flexes the knee to the desired angle and holds that position for 1 second. Mild extension then activates this feature. The feature also does not require any additional steps to "unlock" the knee after it has been stabilized. Unlike other manual locking features, this new feature allows the user to freely extend the knee at any time, thereby unlocking it and returning it to its normal function. This feature allows the patient to stabilize the knee in a locked position and therefore put weight on the knee, taking pressure off the sound side and providing added stability. It gives the natural ability of "shifting weight" back to the amputee. This ability has the potential of reducing falls, saving energy and reducing stresses to the sound side. The current codes do not describe the Electronically-Controlled Static Stance Regulator, Adjustable feature. L5925 is not appropriate as it does not allow movement once it is locked and can only be locked in a full extension. L5848 would not be appropriate is it is referring to the dynamic phase of walking.

CMS HCPCS Preliminary Decision:
No insurer (i.e., Medicare, Medicaid, Private Insurance Sector), identified a national program operating need to establish a separate code for this product. This is an enhancement of a component already included in the microprocessor code L5856 "ADDITION TO LOWER EXTREMITY PROSTHESIS, ENDOSKELETAL KNEE-SHIN SYSTEM, MICROPROCESSOR CONTROL FEATURE, SWING AND STANCE PHASE, INCLUDES ELECTRONIC SENSOR(S) ANY TYPE". As such, code L9900 "ORTHOTIC AND PROSTHETIC SUPPLY, AND/OR SERVICE COMPONENT OF ANOTHER HCPCS "L" CODE" may be used to identify this component, and the use of miscellaneous or add-on codes is inappropriate. 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.
For L5856, Pricing = 38
For L9900, Pricing = 46

Summary of Primary Speaker Comments at the Public Meeting:
The primary speaker disagreed with the workgroup's preliminary decision. The speaker stated that all microprocessor knees vary in their control design. According to the speaker, a new code is needed for this prosthetic knee because it has a unique feature (static stance).

HCPCS Public Meeting Agenda #12
May 6, 2008

Attachment #08.37

Topic/Issue:
Request to establish a code for a limb brace, Trade Name: VACO®ped.

Background/Discussion:
According to the requester, VACO®ped is a cast replacement system for the treatment of injuries of the lower leg and foot that can be used for the entire rehabilitation after ankle fractures and other injuries. VACO®ped can be used as a pre- or postoperative splint, a cast replacement, and/or a functional orthosis. A self-adjusting vacuum cushion conforms to the patient's anatomy and in conjunction with a rigid lattice frame provides cast-like stabilization. It is a pre-fabricated, orthotics, modular system that allows treatment for multiple injury types with only one product. One VACO®ped can replace a pre-and/or post-operative splint, one or a series of casts and also a walking boot. It is available in three sizes. According to the requester, there are no existing HCPCS codes that describe a modular orthotic system that replaces casting, acts as a functional orthotic and/or can be used as a splint to immobilize.

CMS HCPCS Preliminary Decision:
Revise existing code L4360 which currently reads: "WALKING BOOT, PNEUMATIC, WITH OR WITHOUT JOINTS, WITH OR WITHOUT INTERFACE MATERIAL, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT" to instead read: "WALKING BOOT, PNEUMATIC AND/OR VACUUM, WITH OR WITHOUT JOINTS, WITH OR WITHOUT INTERFACE MATERIAL, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT". Revised code L4360 adequately describes the product that is the subject of this request and clarifies that the VACO®ped is included in this category of devices which perform a similar function.

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

Summary of Primary Speaker Comments at the Public Meeting:
The primary speaker disagreed with the workgroup's preliminary decision. The speaker stated that VACOped is distinguished from other products in L4360 because it is a 3-in-1 product (splint, cast, orthosis). The speaker stated that this device is not a walking boot, but a "functional cast replacement system with unique characteristics and features". According to the requester, VACOped replaces conventional casting and eliminates serial casting. The speaker also stated that reimbursement under code L4360 is inadequate for VACOped and could only sustain simplistic products "likely having inferior quality" in the L4360 code category. The speaker suggested alteration of HCPCS to allow rental and recycling of the VACOped.

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. An additional payment is made for those beneficiaries who require portable oxygen. The beneficiary takes over ownership of the equipment after the 36th monthly payment is made, after which payment for delivery of contents continues for patient owned gaseous or liquid systems.

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

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

- **Pricing = 36 Capped Rental Items**
  Payment is made on a monthly rental fee schedule basis. For items furnished on or after January 1, 2006, the beneficiary takes over ownership of the item after the 13th rental payment is made. The rental fee for capped rental items 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.