Centers for Medicare & Medicaid Services (CMS)
Healthcare Common Procedure Coding System (HCPCS)
Public Meeting Summary Report
Orthotics & Prosthetics
Thursday, May 27, 2010

Introduction and Overview

Approximately 30 people attended. The agenda included 12 items.

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

Joel Kaiser, Director of the Division of Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Policy, provided background information on the DMEPOS payment system and the payment categories utilized by Medicare for DME, prosthetics, orthotics, and supplies. The overview was also provided as a written document to the agenda and is attached to this summary.

Prior to the Public Meetings, over the course of several months, the CMS HCPCS Coding Workgroup convene, discuss, and establish preliminary coding recommendations on all HCPCS code applications. CMS assigns preliminary recommendations regarding the applicable Medicare payment category and methodology that will be used to set a payment amount for the items on the agenda. The preliminary coding and payment recommendations are posted on the CMS HCPCS web site, specifically at http://www.cms.gov/MedHCPCSGenInfo/08_HCPCSPublicMeetings.asp#TopOfPage, as part of the HCPCS public meeting agendas.

Information provided at the CMS HCPCS Public Meetings is considered by the CMS HCPCS Coding Workgroup at a subsequent workgroup meeting. The Workgroup reconvenes after the public meetings, and reconsiders its preliminary coding recommendation in light of any new information provided, and formulates its final coding decisions.

CMS maintains the permanent HCPCS Level II codes, and reserves final decision making authority concerning requests for permanent HCPCS codes. Final decisions regarding Medicare payment are made by CMS and must comply with the Statute and Regulations. Payment determinations for non-Medicare insurers, (e.g., state Medicaid Agencies or Private Insurers) are made by the individual state or insurer.

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

The latest information on the process for developing agendas and speaker lists for the public meetings, as well as the Guidelines for Proceedings at these CMS Public Meetings can be found on the CMS HCPCS web site, specifically at: http://www.cms.gov/MedHCPCSGenInfo/08_HCPCSPublicMeetings.asp#TopOfPage. In addition, the standard application format for requesting a modification to the HCPCS Level II Code Set, along with instructions for completing the application, and background information regarding the HCPCS Level II coding process is available at: http://www.cms.gov/MedHCPCSGenInfo/01_Overview.asp#TopOfPage. The application form is updated annually and posted on the CMS HCPCS web site sometime in the summer. A decision tree, outlining CMS' decision-making criteria is also available at: http://www.cms.gov/MedHCPCSGenInfo/Downloads/decisiontree.pdf.

Centers for Medicare & Medicaid Services (CMS) Healthcare Common Procedure Coding System (HCPCS) Public Meeting Agenda for Orthotics & Prosthetics
Thursday, May 27, 2010, 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 made 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 complete HCPCS code application received by CMS. 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# 10.097
Request to establish 9 codes for outpatient supplies and accessories associated with ventricular assist devices (VAD).

Primary Speaker: Dr. Shashank Desai of Inova Fairfax Hospital

AGENDA ITEM #2
Attachment# 10.095
Request to establish a code for a manual locking control cable for upper extremity prosthesis, trade name: Sure-Lok Cable Lock and Control System.

No Primary Speaker

AGENDA ITEM #3
Attachment# 10.056
Request for a new HCPCS "addition" or "feature" code to identify biaxial electromagnetic shielding, fabric. Trade Name: Umbrellan®.

No Primary Speaker

AGENDA ITEM #4
Attachment# 10.048
Request for a HCPCS code to identify a replacement external abutment used to connect an auditory osseointegrated implant to its partner sound processor. Trade Name: Baha Abutment.

Primary Speaker: Dr. Peter Weber of Cochlear Americas

AGENDA ITEM #5
Attachment# 10.113
Request to establish a code for a tracheostomy and ventilator speaking and swallowing valve, trade name: Passy Muir®.

Primary Speaker: Julie Kobak of Passy-Muir, Inc.

AGENDA ITEM #6
Attachment# 10.023
Request to establish a code, appropriate coverage and reasonable reimbursement for custom thermoplastic wrist supports.

No Primary Speaker

AGENDA ITEM #7
Attachment# 10.090
Request to establish a code to describe a multiple input interface feature used in prosthetic elbows.

Primary Speaker: Todd Anderson of Otto Bock HealthCare Professional Clinical Services

AGENDA ITEM #8
Attachment# 10.041
Request to establish a HCPCS "L" code to describe the function of automatic calibration (and re-calibration) of the wearer's control inputs for an electric hand or Terminal Device (TD). Trade Name: AutoCal.

Attachment# 10.042
Request to establish a code for Automatic Detection of Terminal Device Type. Trade Name: AutoDetect Feature of the U3 Arm prosthesis.

No Primary Speaker

AGENDA ITEM #9
Attachment# 10.088
Request to establish a code for a polycentric design with dynamic external hip rotation feature function of a hip joint.

Attachment# 10.089
Request to establish a code for a hydraulic hip joint with stride length limiter, adjustable feature used in prosthetic hip joints.

Attachment# 10.091
Request to establish a code to identify the hip flexion feature of the Helix^{3D} Hip Joint.

Primary Speaker: Todd Anderson of Otto Bock HealthCare Professional Clinical Services

AGENDA ITEM #10
Attachment# 10.059
Request a new HCPCS "addition" code for a microprocessor controlled orthotic knee joint. Trade Name: Otto Bock® Sensor Walk Knee Joint.

Attachment# 10.092
Request to establish an "addition" code for an electronically activated knee joint used in custom-made KAFOs, trade name: E-MAG Active Knee Joint.

Primary Speaker: Curt Kowalczyk of Otto Bock HealthCare Professional Clinical Services

AGENDA ITEM #11
Attachment# 10.094
Request to revise the verbiage of existing code L5828 which currently reads: ADDITION, ENDOSKELETAL KNEE-SHIN SYSTEM, SINGLE AXIS, FLUID SWING AND STANCE PHASE CONTROL to omit the words "single axis;" and to revise the verbiage of existing code L5818 which currently reads: ADDITION, ENDOSKELETAL KNEE-SHIN SYSTEM, POLYCENTRIC, FRICTION SWING, AND STANCE PHASE CONTROL to omit the words "friction swing, and stance phrase."

Primary Speaker: Alan Kercher of Endolite

AGENDA ITEM #12
Attachment# 10.093
Request to establish a code to describe the function and benefit of a hydraulic ankle foot, trade name: Echelon.

Primary Speaker: Dr. Saeed Zahedi of Endolite

HCPCS Public Meeting Agenda Item #1
May 27, 2010

Attachment# 10.097

Topic/Issue:

Request to establish 9 codes for outpatient supplies and accessories associated with ventricular assist devices (VAD). Applicant's suggested language:

QXXX1 UNIVERSAL BATTERY CHARGER
QXXX2 POWER MODULE PATIENT CABLE
QXXX3 POWER MODULE AC CORD
QXXX4 POWER MODULE DC INPUT CABLE (CAR)
QXXX5 VAD CONSOLIDATED BAG
QXXX6 STABILIZATION BELT
QXXX7 TRAVEL CASE
QXXX8 PUMP TO POWER BASE UNIT CABLE
QXXX9 SYSTEM CONTROLLER BATTERIES (3)

Background/Discussion:

According to the requester, the HeartMate VAD is a prosthetic, life-saving device which requires components to ensure long term function and stabilization. Patients cannot be discharged to the home without the outpatient accessories and supplies required by the FDA to support the VAD. As these items wear out over time, medical professionals need a way to replace these items. The universal battery charger is designed to charge the HeartMate batteries used to power the HeartMate II LVAS during mobile operation. These two components replace the original power base unit (PBU). The power module patient cable connects the power module to the power base unit to the system controller's power leads. The AC cord is compatible with the power module and universal battery charger. The power module DC input cable plugs into the automobile DC power outlet to power the LVAS while traveling by car. The consolidated bag is designed specifically to hold the system controller. The stabilization belt with lead locks is used to immobilize and provide strain relief to the percutaneous lead(s) at the patient exit site. The travel case is designed to carry back up emergency HeartMate equipment. The replacement batteries are for HeartMate II system controller alarms. In 2005 various codes were approved for the existing VADs, but since that time ongoing advancements in VAD therapy have occurred. Some of these advancements have been made in cables, power modules and peripheral equipment. According to the requester, these items serve a different purpose and do not currently fit with any of the existing codes.

CMS HCPCS Preliminary Decisions:

1) Existing code Q0495 "BATTERY/POWER PACK CHARGER FOR USE WITH ELECTRIC OR ELECTRIC /PNEUMATRIC VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY" adequately describes the universal battery charger.

2) Establish Qxxxx POWER MODULE FOR USE WITH ELECTRIC/PNEUMATRIC VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY to describe the power module.

3) The power module patient cable, power module AC cord, stabilization belt, pump to power base unit cable and system controller batteries are furnished when implanted. On the rare occasion they are replaced, existing code Q0505 "MISCELLANEOUS SUPPLY OR ACCESSORY FOR USE WITH VENTRICULAR ASSIST DEVICE" is available for assignment by all insurers if they deem appropriate.

4) Revise existing code Q0499 which currently reads: "BELT/VEST FOR USE WITH ELECTRIC OR ELECTRIC/PNEUMATIC VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY" to instead read: BELT/VEST/BAG FOR USE TO CARRY EXTERNAL PERIPHERAL COMPONENTS OF ANY TYPE VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY. Revised Q0499 adequately describes the VAD consolidated bag.

5) Establish Qxxxx POWER ADAPTER FOR USE WITH ELECTRIC/PNEUMATIC VENTRICULAR ASSIST DEVICE, VEHICLE TYPE. This code adequately describes The Power Module DC input Cable (Car).

6) A national program operating need to establish a code for the travel case was not identified by Medicare, Medicaid or 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:

For Q0495, Q0499, and Q0505, the payment rules associated with the existing codes apply to these products if covered. Pricing = 38

For the power module code, based on our preliminary benefit category analysis, we believe that the item would be paid in accordance with the payment rules that apply to orthotics, prosthetics, prosthetic devices, and vision services if covered.

For the power adaptor (vehicle type), based on our preliminary benefit category analysis, we believe that the item would be paid in accordance with the payment rules that apply to orthotics, prosthetics, prosthetic devices, and vision services if covered. For the travel case, based on our

preliminary benefit category analysis, we believe that 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 coding decision to establish unique HCPCS codes to identify the power module DC input cable (car) and the VAD consolidated bag. The speaker withdrew the request for a unique code to identify the pump to power base unit cable since the item will not be used after 2012. However, the speaker disagreed with the Workgroup's preliminary coding decision to use existing HCPCS code Q0495 (Battery/power pack charger for use with electric or electric/pneumatic ventricular assist device, replacement only) for the universal battery charger since this code was created for the Pneumatic TLC-II battery car charger. To appropriately identify the universal battery charger under HCPCS code Q0495, the speaker suggested deleting the reference to electric VAD from the HCPCS code descriptor and recommended revising the long descriptor to read "battery/power pack charger for use with electric ventricular assist device, replacement only." In addition, the primary speaker disagreed with the Workgroup's preliminary coding decision for the power module patient cable, power module AC cord, stabilization belt, and the system controller batteries. The speaker indicated that the marketing volume for these items have increased since the HCPCS code application was submitted, and believed that HCPCS codes are warranted for these items. Further, the speaker disagreed with the Workgroup's coding decision for the travel case, and stated this item is necessary to transport the accessories that power the VAD. The speaker recommended the creation of a new HCPCS code to describe the travel case and suggested the long descriptor to read "travel case for use with electric or electric/pneumatic ventricular assist device, replacement only." Finally, the primary speaker disagreed with the Workgroup's decision for the power module, and indicated that the current HCPCS code descriptor for Q0489 (Power pack base for use with electric/pneumatic ventricular assist device, replacement only) does not accurately describe the power module. To adequately describe the power module under Q0489, the speaker recommended a revision to the HCPCS code descriptor by including the terms "electric or electric/pneumatic VADs."

HCPCS Public Meeting Agenda Item #2
May 27, 2010

Attachment# 10.095

Topic/Issue:

Request to establish a code for a manual locking control cable for an upper extremity prosthesis, trade name: Sure-Lok Cable Lock and Control System. Applicant's suggested language: "Addition to upper limb prosthetic cable, manual lock for control system".

Background/Discussion:

According to the requester, the Sure-Lok is a manually-controlled locking cable control system developed for use in upper limb prostheses. It includes a unidirectional cable locking and control technology incorporating a manually actuated, self-energizing cam mechanism. The Sure-Lok mounts to the surface of existing or new prostheses to enhance the usefulness of cable operated prosthetic and orthotic devices. It gives the user greater control over their upper limb prosthetic terminal device, and is particularly well-suited for use with voluntary opening and closing devices. The Sure-Lok is intended for use in general activities of daily living, and assists in carrying or holding objects for prolonged periods of time. According to the requester, Sure-Lok is significantly therapeutically distinct from other products because: 1) use of the Sure-Lok lessens the likelihood of developing cumulative trauma injuries and overuse syndrome; and 2) the user may generate up to 60 - 70 pounds of pinch force without artificial constraints. Of all the current HCPCS codes available for upper limb prosthetic componentry, none are applicable for a locking cable control system. Codes that describe part of the design of a locking control system include: L6655 "UPPER EXTREMITY ADDITION, STANDARD CONTROL CABLE, EXTRA" and L6660 UPPER EXTREMITY ADDITION, HEAVY DUTY CONTROL CABLE". However, these codes are not applicable to the Sure-Lok due to the cost and the function of the locking cable control system.

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.

Medicare Payment:

No separate payment for this item. The payment rules associated with the existing code 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 #3
May 27, 2010

Attachment# 10.056

Topic/Issue:

Request for a new HCPCS "addition" or "feature" code to identify biaxial electromagnetic shielding, fabric. Trade Name: Umbrellan®. Requester's Suggested Language: "Addition to prosthetic liner or textile products, biaxial electromagnetic shielding to reduce phantom limb pain."

Background/Discussion:

Umbrellan® is a knitted fabric with biaxial electrical conductivity. It can be woven into a variety of complex shapes, including sock-like structures that encompass a residual limb. Although the precise mechanism of action has not yet been established, the requester claims that incorporation of Umbrellan® into the protective outer covering of a liner provides electromagnetic shielding to the residuum, which has been shown to reduce phantom leg pain (PLP), and even provide ongoing reduction in reported PLP symptoms when the prosthesis has been removed. There is no an existing code category for the unique phantom pain reduction feature of the Umbrellan® material.

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 liners that include electromagnetic shielding. Existing code L5673 "ADDITION TO LOWER EXTREMITY, BELOW KNEE/ABOVE KNEE, CUSTOM FABRICATED FROM EXISTING MOLD OR PREFABRICATED, SOCKET INSERT, SILICONE GEL, ELASTOMERIC OR EQUAL, FOR USE WITH LOCKING MECHANISM" or L5679 "ADDITION TO LOWER EXTREMITY, BELOW KNEE/ABOVE KNEE, CUSTOM FABRICATED FROM EXISTING MOLD OR PREFABRICATED, SOCKET INSERT, SLICONE GEL, ELASTOMERIC OR EQUAL, NOT FOR USE WITH LOCKING MECHANISM" (depending upon whether or not a locking mechanism is available) adequately describes the prosthesis liners that are the subject of your request. The electromagnetic shielding feature is not separately billable.

Medicare Payment:

No separate payment for this item. The cost of materials used in fabricating a prosthetic or accessory for a prosthetic is included in the payment for the prosthetic.

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item #4
May 27, 2010

Attachment# 10.048

Topic/Issue:

Request for a HCPCS code to identify a replacement external abutment, used to connect an auditory osseointegrated implant to its partner sound processor. Trade Name: Baha Abutment. Current code L8690 is only appropriate for the entire Baha system of titanium implant, abutment, and sound processor. The applicant is requesting a new code to extend the current series of HCPCS codes describing a replacement abutment for attaching the sound processor to the implant.

Background/Discussion:

According to the requester, the Baha auditory osseointegrated implant works by implanting a titanium implant into the temporal bone behind the ear which then binds permanently with the bone after healing (osseointegration). The Baha sound processor is affixed to an external abutment which in turn is attached to the implant. This holds the bones of the skull for transmission to the cochlea, allowing patients with malformed or diseased middle ears to regain hearing function. There is currently a HCPCS code for the entire system (implant, abutment, and sound processor), a code for a replacement sound processor, and a code for a Baha system used non-surgically with a headband. The applicant is requesting an expansion of the code set to account for situations in which the patient needs a replacement of the abutment that connects the sound processor to the implant. For example, in some cases, patients are pre-disposed to hypertrophic skin growth (keloid formation) which results in skin occluding the abutment, making it impossible for the patient to attach the sound processor. In these cases, a surgeon will typically reduce the skin overgrowth and replace the abutment with a longer version, to prevent recurrence of this issue in the future.

CMS HCPCS Preliminary Decision:

Establish Lxxxx AUDITORY OSSEOINTEGRATED DEVICE ABUTMENT, ANY LENGTH, REPLACEMENT ONLY

Medicare Payment:

Based on our preliminary benefit category analysis, we believe that the item would be paid in accordance with the payment rules that apply to orthotics, prosthetics, prosthetic devices, and vision service items if covered.

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker agreed with the Workgroup's preliminary decision to establish a new HCPCS code that identifies a replacement external abutment for the Baha Abutment.

HCPCS Public Meeting Agenda Item #5
May 27, 2010

Attachment# 10.113

Topic/Issue:

Request to establish a code for a tracheostomy and ventilator speaking and swallowing valve, trade name: Passy Muir®. Applicant's suggested language: "Tracheostomy and ventilator swallowing and speaking valve".

Background/Discussion:

According to the requester, the Passy-Muir valve is a biased-closed position one-way valve indicated for use by pediatric and adult patients who require a tracheostomy. It may also be used by patients who are receiving mechanical ventilation. The Passy-Muir is placed on the end of the tracheostomy tube. After the patient inhales, the diaphragm easily opens allowing air to flow through the Passy-Muir Valve, tracheostomy tube, mouth and nose. When inhalation stops, and before exhalation begins, the diaphragm relaxes and returns to a completely closed position allowing all exhaled air to flow around the tracheostomy tube, through the vocal cords, and out through the mouth and nose. This restores normal, closed respiratory system and normal aero-digestive physiology and can reverse the physiologic changes and complications caused by the tracheostomy tube. Since the diaphragm closes completely when airflow temporarily stops at the end of inhalation and before exhalation begins, a column of air is maintained in the tracheostomy tube to act as a buffer, prohibiting secretions from entering the tracheostomy tube or the Passy-Muir Valve. According to the requester, the "significant therapeutic benefit" of the biased-closed position, no-leak design of the Passy-Muir valve, (in addition to speech), is the complete restoration of airflow and positive pressure to the upper airway, which could result in improved smell, taste and sensation, more effective cough, swallow and reduced aspiration. Such benefits render the Passy-Muir Valve superior to all other one-way valves. All of these benefits result in reduced hospital length of stay, infection, and overall cost of care, and improved quality of life, making the Passy Muir valve the standard of care for tracheostomized patients. The Passy Muir valve is the only valve that incorporates a biased-closed, no-leak design; is FDA indicated for swallowing and speaking; and is the only valve that can be safely used with mechanical ventilators. For all other open position valves, speech is the only benefit provided. Existing code L8501 "TRACHEOSTOMY SPEAKING VALVE" does not adequately describe Passy-Muir because it provides the same reimbursement for all one-way valves although the therapeutic benefits are not the same.

CMS HCPCS Preliminary Decision:

Existing code L8501 "TRACHEOSTOMY SPEAKING VALVE" adequately describes the product that is the subject of this request.

Medicare Payment:

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

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with the Workgroup's preliminary decision "because the valve is the only one that improves swallowing and has significant therapeutic distinction."

HCPCS Public Meeting Agenda Item #6
May 27, 2010

Attachment# 10.023

Topic/Issue:

Request to establish a code, appropriate coverage and reasonable reimbursement for custom thermoplastic wrist supports. Applicant's suggested language: "Wrist orthosis, without joints, may include soft interface, straps, custom fabricated, custom fitted".

Background/Discussion:

According to the requester, thermoplastic wrist supports provide rigid support, warmth and compression to treat and aid in the prevention of a variety of injuries and ailments including, but not limited to, strains, sprains, arthritis, carpal tunnel syndrome, repetitive movement injuries and paralysis and contractions attributed to strokes, cerebral palsy and other neurological disorders. These wrist supports are cut from sheet neoprene material and thermoplastic panels, based on measurements, tracings or castings provided. Seams are glued, sewn and taped to ensure strength and durability. Many times, straps and closures are utilized to allow for adjustability, added compression and support and easier application and removal. According to the requester, there are currently no codes to describe products that are custom fabricated with a specific individual in mind that also require custom fitting by a medical professional.

CMS HCPCS Preliminary Decision:

Existing codes L3807 WRIST HAND FINGER ORTHOSIS, WITHOUT JOINT(S), PREFABRICATED, INCLUDES FITTING AND ADJUSTMENTS, ANY TYPE or L3908 WRIST HAND ORTHOSIS, WRIST EXTENSION CONTROL COCK-UP, NON MOLDED, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT, depending on the anatomy involved, adequately describes the product that is the subject of this request.-

Medicare Payment:

The payment rules associated with the existing codes apply to these products. Pricing = 38

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, 2010

Attachment# 10.090

Topic/Issue:

Request to establish a code to describe a multiple input interface feature used in prosthetic elbows. Applicant's suggested language: "Addition, upper extremity prosthesis, multiple input interface allowing 4 or more EMG (electromyography) and/or switch control options, microprocessor simultaneous or sequential control of elbow, rotator and terminal device."

Background/Discussion:

According to the requester, the multiple input interface allows a person to have simultaneous control of elbow, wrist and terminal device; up to six individual, independent EMG sites; and two switch inputs to switch between components. Multiple inputs allow the person to simply think about moving a component of the prosthesis. The brain sends a signal to contract the reinnervated muscle, which initiates an electric current to pass down the nerve fiber and is picked up by the electrode at the surface of the skin. The electrode sends output in the form of voltage to the control circuit in the component which interprets this information and runs the motor to actively control the movement of the component. Increasing the number of EMG control signals allows simultaneous and direct control of multiple joints. Multiple Input Interface was developed for persons who have undergone TMR (Targeted Muscle Reinnervation) surgery and are being fit with the Otto Bock DynamicArm TMR. By having TMR surgery and using the Multiple Input Interface, a person can develop multiple control sites in reinnervated muscles which allows for intuitive and direct control of multiple prosthetic joints and reduces the cognitive demand required to control the prosthetic arm. According to the requester, there are no existing codes for a multiple input interface allowing 4 or more EMG and /or switch control options in a prosthetic elbow.

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. Existing code L9900 “ORTHOTIC AND PROSTHETIC SUPPLY, ACCESSORY, AND/OR SERVICE COMPONENT OF ANOTHER HCPCS “L” CODE” adequately describes this feature, as it is included in existing code L7181 "ELECTRONIC ELBOW, MICROPROCESSOR SIMULTANEOUS CONTROL OF ELBOW AND TERMINAL DEVICE,” and as such, it is not separately billable.

Medicare Payment:

No separate payment for this item. 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 and stated that the existing HCPCS codes do not accurately describe TMR functions. The speaker indicated that the current HCPCS codes allow for only two site control, whereas the TMR allows for six site control. In addition, the speaker claimed that prosthetic control with TMR produces more myoelectric signals, more natural movements, and intuitive muscle control. The speaker believed that the benefits of a prosthetic control with TMR is a significant advancement in technology that is not described by existing HCPCS codes, and recommended the establishment of a new HCPCS code specific to TMR.

HCPCS Public Meeting Agenda Item #8
May 27, 2010

Attachment# 10.041

Topic/Issue:

Request to establish a HCPCS "L" code to describe the function of automatic calibration (and re-calibration) of the wearer's control inputs for an electric hand or Terminal Device (TD). Trade Name: AutoCal.

Background/Discussion:

According to the requester, AutoCal is a function of the prosthetic controller which enables the patient to make adjustments to the control settings to compensate for changes in EMG strength during the day. Thus, the patient uses AutoCal to maintain optimal function. The arm wearer can intentionally contract the muscles stronger or weaker, to set the sensitivity higher or lower, as desired, even when not fatigued. The product is primarily used to optimize EMG settings to prevent overexertion and straining when the user is fatigued. Prosthesis wearers sometimes desire lower gains in order to perform careful work, which is also accomplished using AutoCal. AutoCal is appropriate for all myoelectric prosthetic candidates that demonstrate the ability to learn and understand how to perform the AutoCal sequence and have adequate muscle strength and control. Motion Control has offered auto calibration in its ProControl 2, the Utah Arm 3 and the Utah Hybrid Arm products since their release in 1997, 2004, and 2006. AutoCal is a patented technology and is not used by other manufacturers. AutoCal is incorporated into the controller of the prosthesis-thus requires only additional software, compared with a non-AutoCal prosthesis. AutoCal is prescribed by a physician, if they specify the Motion Control type TD to be fitted by a physiatrist or orthopedic rehabilitation specialist. AutoCal provides a functional benefit beyond that provided by any other myoelectric prosthesis, and this benefit is not described by any existing HCPCS "L" code for upper limb prosthetics.

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" adequately describes this feature, as it is included in existing codes L6882 “MICROPROCESSOR CONTROL FEATURE, ADDITION TO UPPER LIMB PROSTHETIC TERMINAL DEVICE” and L7007 “ELECTRIC HAND, SWITCH OR MYOELECTRIC CONTROLLED, ADULT” and as such, is not separately billable.

Medicare Payment:

No separate payment for this item. The payment rules associated with the existing code 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 #8
May 27, 2010

Attachment# 10.042

Topic/Issue:

Request to establish a code for Automatic Detection of Terminal Device Type. Trade Name: AutoDetect Feature of the U3 Arm prosthesis.

Background/Discussion:

According to the Requester, AutoDetect is a feature providing the wearer of the prosthesis interchangeability between manufacturer's TDs, so that the entire range of TD functions are potentially available to the wearer of an electric arm. There are only two methods for connecting the power and control signals. In-Hand controller type, with built in micro-processor, and Motor-direct type (the controller is proximal to the TD-providing a control signal directly to the motor). The controller either detects a "Motor Direct"-type TD, or an "In-Hand Controller"-type TD. AutoDetect is incorporated into the controller of the prosthesis. AutoDetect is not used by any other manufacturers, beyond Motion Control. The Requester states that elbow prosthesis without AutoDetect is not able to provide interchangeability of all brands of TDs, and thus it cannot provide as complete functional capability. AuoDetect is prescribed as part of the U3, U3+, or Hybrid arm prosthesis, by a physician-physiatrist or orthopedic rehabilitation specialist.

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" adequately describes this feature, as it is included in existing codes L6882 “MICROPROCESSOR CONTROL FEATURE, ADDITION TO UPPER LIMB PROSTHETIC TERMINAL DEVICE” and L7007 “ELECTRIC HAND, SWITCH OR MYOELECTRIC CONTROLLED, ADULT” and as such, is not separately billable.

Medicare Payment:

No separate payment for this item. The payment rules associated with the existing code 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 #9
May 27, 2010

Attachment# 10.088

Topic/Issue:

Request to establish a code for a polycentric design with dynamic external hip rotation feature function of a hip joint. Applicant's suggested language, "Addition, lower extremity hip prosthesis, polycentric design with dynamic external hip rotation."

Background/Discussion:

According to the requester, the polycentric design with dynamic external hip rotation feature is a function that allows the Helix^{3D} Hip Joint to rotate contrary to the pelvis to compensate for pelvic rotation during stance and swing. The rotation is directly related to flexion and extension of the hip. This feature prevents high torsion on the prosthetic components, socket, skin and spine. This benefits the patient by reducing strain on the lower spine and potentially reducing back pain. The axis geometry is based on an R-S-S-R mechanism, which makes it possible to link hip flexion and extension to hip joint rotation, which promotes more natural walking pattersn. Approximately six degrees of rotation should be expected when walking. The polycentric design shortens the prosthesis during swing for greater toe clearance, which minimizes falls. The design also provides a more natural, unobtrusive sitting position, and aids stability during stance phase. According the requester, there are not currently any other prosthetic hip joints on the market that provide a Dynamic External Hip Rotation feature. Other prosthetic hip joints have a single-axis design, offering only one place of motion. The Helix^{3D} Hip Joint is unique because of the Dynamic External Hip Rotation it allows. This feature is not found in any other prosthetic hip joint on the market. No existing code describes the function of the Dynamic External Hip Rotation feature.

Attachment# 10.089

Topic/Issue:

Request to establish a code for a hydraulic hip joint with stride length limiter, adjustable feature used in prosthetic hip joints. Applicant's suggested language: "Addition, endoskeletal hydraulic hip joint with stride length limiter, adjustable".

Background/Discussion:

According to the requester, the Helix^{3D} is a prosthetic hip joint that is 1) hydraulically controlled for both swing and stance phase, and 2) provides an ability to control the step length (stride length limiter). It is designed to be used exclusively by people with limb deficiency at the hip joint or above. During swing phase, the hydraulic unit helps to control the step length and allows

the amputee to walk with variable speeds. During stance phase, the hydraulic unit controls the extension speed so that the hip joint does not snap back into extension too aggressively. This reduces the stress on the patient's body by providing a smooth transition from hip flexion to hip extension. The stride length limiter allows the practitioner to adjust the hip joint so the patient 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 flex at the same time. This also helps shorten the overall length of the prostheses during swing phase, which minimizes the risk of falling. According to the requester, no other hip joints offer a hydraulic control, and the Helix^{3D} is unique because of the hydraulic and the ability to adjust the stride length limiter. The requester claims that the Helix^{3D} confers a significantly therapeutic distinction from other products because it consists of a spatial four-axis mechanism with hydraulic stance and swing-through control. This design results in the following biomechanical improvements compared to conventional joints: 1) more stable hip movements during weight transfer, 2) support for swing-through phase initialization, 3) control of hip movements during the swing-through phase, 4) three-dimensional movements in terms of the relationship between hip joint extension/flexion and transversal pelvic rotation.

Attachment# 10.091

Topic/Issue:

Request to establish a code to identify the hip flexion feature of the Helix^{3D} Hip Joint. 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 is a feature that helps to flex the hip joint during the initiation of swing phase. It includes two polyurethane spring elements that store energy during stance phase. To initiate swing phase, this energy is released as soon as knee flexion takes place. Simultaneous hip and knee flexion is more natural and provides greater clearance at mid-swing reducing the potential of stumbles and falls. The hip flexion assist flexes the hip when the prosthesis is un-weighted, greatly reducing the effort and pelvic thrust power necessary when the user initiates walking with the prosthetic limb. The amount of flexion during swing phase is controlled by the hydraulic unit. The hip flexion assist feature is designed to be used exclusively by people with limb deficiency at the hip joint or above. According to the requester, there are currently no other prosthetic hip joints on the market that have a hip flexion assist and there are no existing codes to describe this hip feature.

CMS HCPCS Preliminary Decision applies to all 3 requests for "features" (10.088, 10.089 and 10.091) taken together as a single hip joint:

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. Existing code L5999 "LOWER EXTREMITY PROSTHESIS, NOT OTHERWISE SPECIFIED" is available for assignment by all insurers to be billed once for the entire device, including all features as described in the 3 HCPCS code applications (10.088, 10.089 and 10.091). 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 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 for attachments 10.088, 10.089, and 10.091, and requested assignment of a single HCPCS code to appropriately describe all functions of the device. The speaker suggested that the single HCPCS code should read "endoskeletal hip joint, polycentric design with external hip rotation, hydraulic control with hip flexion assist and stride length limiter."

HCPCS Public Meeting Agenda Item #10
May 27, 2010

Attachment# 10.059

Topic/Issue:

Request a new HCPCS "addition" code for a microprocessor controlled orthotic knee joint. Trade Name: Otto Bock® Sensor Walk Knee Joint. Requester's Suggested Language: "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, the Sensor Walk Knee Joint is a microprocessor controlled orthotic knee joint designed to enable patients to achieve a safer gait. The componentry includes a microprocessor, foot pressure sensors, knee angle sensor, wrap spring clutch, electromechanical release, actuator and battery of all which can be custom fabricated in a Knee-Ankle-Foot-Orthosis (KAFO). According to the requester, KAFOs are intended for patients that present with quadriceps weakness or absent knee extensors to safely support weight during ambulation. Stance Control KAFOs, also known as Stance Control Orthoses, allow the knee joint to flex but block flexion during stance, which is the weight bearing phase of the gait cycle. This action holds the knee in a safe and stable position while walking on the weak, braced leg thus enabling a patient a more normal, energy efficient, and biomechanically safe gait. The Sensor Walk Knee Joint has been further demonstrated to significantly increase walking speed and reduce the compensatory movements of vaulting and hip-hiking. The existing non-microprocessor SCOs have no mechanism to ensure knee joint locking and unlocking at the appropriate time in the gait cycle and require the patient to think about each step they are taking during gait to get the knee joint to unlock for swing. The Sensor Walk, on the other hand, enables ambulation without this distraction. The requester also states that the Sensor Walk Knee Joint differs significantly from the Horton SCOKJ and the Becker E-Knee and requires an add-on code to describe the microprocessor controlled componentry to be used in conjunction with a custom KAFO base 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. 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 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.

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 clarified that the HCPCS coding request was for two unique codes to identify the microprocessor controlled knee joint and the electronically activated knee joint. While the speaker agreed with the Workgroup's preliminary decision to identify the microprocessor controlled knee joint with existing HCPCS code L2999 (Lower extremity orthoses, not otherwise specified), the speaker disagreed with the decision to use this same HCPCS code for the electronically activated knee joint. The primary speaker explained the differences between the two knee joints. Specifically, the speaker asserted that an electronically activated knee joint is different than a mechanically activated knee joint because it uses gyroscopes and accelerometers to monitor a patient's gait pattern, adapts to the calibrated gait pattern, and can be recalibrated if a patient's gait changes. The primary speaker recommended the establishment of a new HCPCS code to appropriately identify the electronically activated knee joint, and proposed the HCPCS code descriptor to read, "Addition to lower extremity stance control orthosis, electronic activation."

HCPCS Public Meeting Agenda Item #10
May 27, 2010

Attachment# 10.092

Topic/Issue:

Request to establish an "addition" code for an electronically activated knee joint used in custom-made KAFOs, trade name: E-MAG Active Knee Joint. Applicant's suggested language: "Addition to lower extremity stance control orthosis, electronic activation."

Background/Discussion:

According to the requester, the E-MAG Active Knee Joint is an electronically activated knee joint with a secure stance phase and free swing phase that is controlled independent of the ankle or sole of the foot. It consists of a controller, gyroscope, accelerometer, battery and wire harness that is custom fabricated into a knee-ankle-foot-orthosis (KAFO). The electronically activated E-MAG Active Knee Joint unlocks KAFOs during the appropriate time in the patient's gait pattern. Gyroscopes and accelerometers monitor the position of the leg as a patient walks. When the leg is in position to come off the ground for swing, a signal is sent to the electromagnet in the knee joint to unlock, enabling the knee to bend and swing, allowing foot clearance. This enables the patient to walk with a more physiological gait and lessens the need for compensatory movements. According to the requester, there is no existing code to describe an electronically activated orthotic knee joint. 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" is a base code that describes a simple stance control mechanism with automatic, mechanical locking and unlocking. Items included in code L2005 are not electronically activated. The electronically activated E-MAG Knee Joint differs significantly from simple stance control devices coded at L2005.

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 L2999 "LOWER EXTREMITY ORTHOSES, 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 clarified that the HCPCS coding request was for two unique codes to identify the microprocessor controlled knee joint and the electronically activated knee joint. While the speaker agreed with the Workgroup's preliminary decision to identify the microprocessor controlled knee joint with existing HCPCS code L2999 (Lower extremity orthoses, not otherwise specified), the speaker disagreed with the decision to use this same HCPCS code for the electronically activate knee joint. The primary speaker explained the differences between the two knee joints. Specifically, the speaker asserted that an electronically activated knee joint is different than a mechanically activated knee joint because it uses gyroscopes and accelerometers to monitor a patient's gait pattern, adapts to the calibrated gait pattern, and can be recalibrated if a patient's gait changes. The primary speaker recommended the establishment of a new HCPCS code to appropriately identify the electronically activated knee joint, and proposed the HCPCS code descriptor to read "Addition to lower extremity stance control orthosis, electronic activation."

HCPCS Public Meeting Agenda Item #11
May 27, 2010

Attachment# 10.094

Topic/Issue:

Request to revise the verbiage of existing code L5828 which currently reads: ADDITION, ENDOSKELETAL KNEE-SHIN SYSTEM, SINGLE AXIS, FLUID SWING AND STANCE PHASE CONTROL to omit the words "single axis;" and to revise the verbiage of existing code L5818 which currently reads: ADDITION, ENDOSKELETAL KNEE-SHIN SYSTEM, POLYCENTRIC, FRICTION SWING, AND STANCE PHASE CONTROL to omit the words "friction swing, and stance phrase."

Background/Discussion:

According to the requester, key benefits for the users of a knee joint identified under code L5828 is the hydraulic yield capacity in stance control, the ability of the user to switch from high resistance to low resistance for swing control, using hydraulics to damp the motion of the knee avoiding excessive heel rise and terminal impact at the end of gait/step cycle. Application of such fluid as stance and swing control should not be restricted to a single axis frame, which acts only as a carrier for these control devices and is only a means to attach the socket and foot. In existing code L5818, the term friction swing and stance phase control referring to a polycentric knee has little significance to the user's function and benefit. According to the requester, this proposed action will not have any impact on current applications of these codes. The re-worded L5828 and L5818 would accurately describe any polycentric swing and stance phase system, like KX06 knees for the future. The KX06 is prosthetic knee device combines the properties of a polycentric knee stance control ideal for short as well as long residual limbs with hydraulic knee wing and stance control hydraulic unit for transfemoral, knee and hip disarticulation amputees. It is designed to enhance the stance control and reduce effort of activation of swing control which enables the lower extremity amputee to safely and comfortably traverse varied terrain, slopes and stairs with ease. The KX06 is designed for K3 - lower extremity amputees that have the ability or potential for ambulation with variable cadence. In terms of a knee joint, the key benefit of polycentric or multi axial knee joint, is generation of a moving center of rotation, more like natural femur and tibia joints, where the instantaneous center of rotation actually moves along a path, ensuring optimum effort and mechanical stability in a primarily uni-directional joint motion. Polycentric joints are multi links to provide a moving center of rotation during stance and swing phase. This still allows L5828 to be applied to any system with fluid swing and stance hydraulic.

CMS HCPCS Preliminary Decision:

Existing code L5840 ADDITION, ENDOSKELETAL KNEE-SHIN SYSTEM, 4-BAR LINKAGE OR MULTIAXIAL, PNEUMATIC SWING PHASE CONTROL" adequately describes the product that is the subject of this request.

Medicare Payment:

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

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with the Workgroup's preliminary decision and maintained that the proposed revisions to HCPCS codes L5818 and L5828 is necessary to accurately describe any polycentric swing and stance phase system associated with knee joints.

HCPCS Public Meeting Agenda Item #12
May 27, 2010

Attachment# 10.093

Topic/Issue:

Request to establish a code to describe the function and benefit of a hydraulic ankle foot, trade name: Echelon. Applicant's suggested language: "Hydraulic ankle, with independent variable plantar and dorsi-flexion adjustment, fluid stance phase control."

Background/Discussion:

According to the requester, Echelon's unique stance phase hydraulic ankle provides independent variable dorsi-flexion and plantar flexion. It is designed for K3 level amputees to facilitate walking on level or uneven ground, up and down inclines, ascending or descending stairs and sitting down and getting up from a chair with ease. The stance phase control provides even distribution of forces on both limbs during standing, on inclines, and reduces risk of degeneration of sound limb joints. The "hydraulic" stance phase control of the ankle is clinically different and distinguishes itself from all other conventional ankle-foot systems by enabling natural body posture for a range of commonly encountered environmental conditions. At heel strike the foot moves into plantar flexion to initiate a stable safe base for loading of the prosthesis during stance phase. When the user walks up or down inclines the hydraulic fluid adjusts the foot to match the gradient. In stair ascent the Echelon moves up to 9 degrees during the first step in stance phase. When descending stairs the hydraulic ankle allows dorsi-flexion during the first step, which permits the user to place the entire prosthetic foot on the subsequent downward step, further enhancing safety. When the user walks on level terrain the Echelon foot remains in a dorsi-flexed position after "toe-off" during the swing phase. This provides greater ground clearance during swing phase, minimizing the risk of catching the toe, and a potential fall. The Echelon foot hydraulic technology is necessary to improve the function of the prosthesis prescribed for individuals with lower extremity limb loss. According to the requester, existing HCPCS codes L5981 "ALL LOWER EXTREMITY PROSTHESES, FLEX-WALK SYSTEM OR EQUAL" and L5968 "ADDITION TO LOWER LIMB PROSTHESIS, MULTIAXIAL ANKLE WITH SWING PHASE ACTIVE DORSIFLEXION FEATURE" do not describe the stance phase feature of the "hydraulic" independent variable control of plantar and dorsi-flexion.

CMS HCPCS Preliminary Decision:

Existing code L5981 "ALL LOWER EXTREMITY PROSTHESIS, FLEX-WALK SYSTEM OR EQUAL" together with code 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 these products.

For L5981, Pricing = 38

For L5968, Pricing = 38

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with the Workgroup's preliminary decision and indicated there is no current HCPCS code for a viscoelastic or yielding ankle to serve the industry. The speaker asserted that a unique HCPCS code is warranted to appropriately describe the stance phase feature of the "hydraulic" independent variable control of plantar and dorsi-flexion that is associated with the Echelon foot technology.

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, fiscal intermediaries and A/B MACs (e.g., claims for DME implanted in an ambulatory surgical center are processed by local carriers). Claims for DME and ostomy, tracheostomy and urological supplies furnished by a home health agency are processed by Regional Home Health Intermediaries (RHHIs) and A/B MACs.

Fee Schedule Payments

Prior to January 1, 1989, payment for most DMEPOS items and services was made on the basis of the reasonable charge methodology. Reasonable charges are calculated using suppliers' charges and are limited by an inflation adjustment factor. Payment is still made on a reasonable charge basis for 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 payment for the ongoing delivery of contents continues for patient owned gaseous or liquid systems.

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

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

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

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

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

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

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

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

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