DRAFT AGENDA

Centers for Medicare & Medicaid Services (CMS) Healthcare Common Procedural Coding System (HCPCS) Public Meeting Agenda for Orthotics & Prosthetics
Tuesday, May 22, 2006, 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 #07.28
Request to establish a code for a halo traction ring and skull pins. Trade name: ReSolve Halo System.

AGENDA ITEM #2
Attachment #07.13
Request to remove the "Vibrant Soundbridge" reference from the current HCPCS code V5095 Semi-Implantable Middle Ear Hearing Prosthesis.

AGENDA ITEM #3
Attachment #07.40
Request to modify the HCPCS code set to add two (2) new codes for Battery Packs used with the Behind-The-Ear (BTE) Speech Processor of the MED-EL Cochlear Implant System.

AGENDA ITEM #4
Attachment #07.58
Request to add a new HCPCS Level II code for the upper extremity prosthetics. Trade Name: Multi-articulating digits for partial hand prosthesis and an upper extremity prosthetic hand with 5 multi-articulating digits. Trade Name: I-LIMB Hand & ProDigits.

AGENDA ITEM #5
Attachment #07.86
Request to establish a new code for a body-powered articulating artificial finger, trade name: X-Finger, X-Tip.

AGENDA ITEM #6
Attachment # 07.114
Request to establish a new code for a prefabricated thumb spica, trade name: RhizoLoc.

AGENDA ITEM #7
Attachment # 07.117
Request to establish a new code for a wrist hand finger orthosis, trade name: SaeboFlex®.

AGENDA ITEM #8
Attachment #07.77
Request to establish (3) three new HCPCS codes for the temporary or preparatory fitting phase of fitting external powered upper extremity prosthetics.

AGENDA ITEM #9
Attachment #07.57
Request to establish a new code for a wireless Bluetooth communication link to allow for adjustments to the microprocessor used with upper extremity prosthetics. General Product Name: Wireless Adjustability, Bluetooth or equal, upgrade. Trade Name: LimbLink™.

AGENDA ITEM #10

Attachment #07.43
Request to establish a code for a prefabricated bracing device for treatment of the elbow joint. Trade name: SADER I Elbow Flexion/Extension Device (static and dynamic and range of motion).

Attachment #07.47
Request to establish a code for a custom bracing device for treatment of the knee. Trade name: SADER IV Knee Flexion/Extension Orthosis (static and dynamic end range of motion).

Attachment #07.48
Request to establish a code for a custom bracing device for treatment of the elbow joint. Trade name: SADER I Elbow Flexion/Extension Device (static and dynamic end range of motion).

Attachment #07.49
Request to establish a code for a custom bracing device for treatment of the wrist, Trade Name: SADER III wrist flexion/extension device (static and dynamic end range of motion).

Attachment #07.50
Request to establish a code for a prefabricated bracing device for treatment of the knee, Trade Name: SADER IV knee flexion/extension orthosis (static and dynamic end range motion).

Attachment #07.51
Request to establish a code for a prefabricated bracing device for treatment of the wrist, Trade Name: SADER III wrist flexion/extension device (static and dynamic end range of motion).

AGENDA ITEM #11

Attachment #07.129
Request to establish a code to identify a custom made hip knee ankle foot orthosis (HKAFO), trade name: Dynamic Lycra HKAFO.

Attachment #07.130
Request to establish a code to identify a custom made elbow wrist hand orthosis (EWHO), trade name: Dynamic Lycra EWHO.

Attachment #07.131
Request to establish a code to identify a compliance and posture monitoring device, trade name: Cricket.

Attachment #07.132
Request to establish a code to identify a custom made Lycra tension-based TLSO, trade name: Dynamic Lycra TLSO.

AGENDA ITEM #12
Attachment #07.61
Request to establish a code for an Electronically Controlled Static Stance Regulator, Adjustable feature used in prosthetic knees.

AGENDA ITEM #13
Attachment #07.90
Request to establish a code to identify a motorized, active prosthetic knee, Trade Name: PowerKnee™, and two additional codes to identify the lithium polymer technology powering it.

Attachment # 07.99
Request to establish a new code for a microprocessor-controlled prosthetic ankle-foot system, trade name: Proprio Foot™.

AGENDA ITEM #14
Attachment #07.78
Request to establish a code for an electronically controlled orthotic knee joint system with sensory feedback, Trade Name: Otto Bock® E-Mag Control.

AGENDA ITEM #15
Attachment #07.112
Request to establish a new code to identify a Patellofemoral, functional, rehabilitative knee brace, trade name: In the Groove™ knee brace.

AGENDA ITEM #16
Attachment #07.20
Request to add a new HCPCS Level II code to describe the Pump It Up prosthetic socket.

AGENDA ITEM #17
Attachment # 07.100
Request to establish a new L code for a manually-activated device that adjusts vertical pylon alignment of lower limb prosthesis, trade name: BRIO.

AGENDA ITEM #18
Attachment # 07.115
Request to establish a new code for a lower limb leg brace, trade name: Step-Smart.

HCPCS Meeting Agenda Item #1
May 22, 2007

#07.28

Topic/Issue:
Request to establish a code for a halo traction ring and skull pins. Trade name: ReSolve Halo System. Requester suggested language: "Addition to Halo Procedures, Nonconductive Ring and Skull Pins".

Background/Discussion:
According to the requester, ReSolve is the first MRI-safe ring and pin set. It employs unique non-conductive materials to insulate halo patients during Magnetic Resonance Imaging and protect them from potential current induction. The use of these advanced non-conductive materials also reduces artifact resulting in superior image resolution.

These products are part of a system generally described as Halo Traction or Halo Vest Systems. A complete system consists of the halo ring, skull pins, superstructure and vest. The halo system is used in the stabilization injuries. The Ring and Skull Pins serve as the rigid fixation point at the head. The vest is secured to the upper torso. The superstructure is used to maintain the prescribed heal and spinal alignment. The patient may wear the unit for six to twelve weeks without removal. During that time the patient may require diagnostic imaging.

According to the applicant, "an additional code is needed to provide reimbursement when newer non-conductive materials are required for patient safety and optimal imaging."

CMS HCPCS Workgroup Preliminary Decision:
Existing code L0859 ADDITION TO HALO PROCEDURE, MAGNETIC RESONANCE IMAGE COMPATIBLE SYSTEMS, RINGS AND PINS, ANY MATERIAL, adequately describes the product that is the subject of this request and is available for assignment by insurers. Inquiries regarding fees associated with codes are not within the jurisdiction of CMS' HCPCS Workgroup and should be submitted directly to the insurer in whose jurisdiction a claim would be filed.

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

HCPCS Meeting Agenda Item #2
May 22, 2007

#07.13

Topic/Issue:
Request to remove the "Vibrant Soundbridge" reference from the current HCPCS code V5095 Semi-Implantable Middle Ear Hearing Prosthesis.

Background/Discussion:
According to the requester, the Soundbridge device, formerly manufactured by Symphonix, is no longer available in the United States. Since it is no longer available, the requester would like to have references to "Vibrant Soundbridge" be eliminated from code V5095. The requester claims that this reference is unnecessary and may cause coding confusion.

The Med-El Corporation has significantly changed the device, and renamed it Vibrant Med-EL. The new device will serve a unique and underserved market, which consists of patients who cannot wear hearing aids, and suffer sensorineural hearing loss. When it is ready for release in the U.S. market, Med-El will apply for a new HCPCS code.

CMS HCPCS Workgroup Preliminary Decision:
Do not revise code V5095 SEMI-IMPLANTABLE MIDDLE EAR HEARING PROSTHESIS. HCPCS codes represent a category of similar products, and are not product-specific. The term "Vibrant Soundbridge" is publisher's annotation in a non-government publication which is not included in the verbiage of code V5095. For removal of this reference, please contact the publisher.

Medicare Payment:
The fee schedule and payment rules associated with the existing code apply.
Pricing = 00

HCPCS Meeting Agenda Item #3
May 22, 2007

#07.40

Topic/Issue:
Request to modify the HCPCS code set to add two (2) new codes for Battery Packs used with the Behind-The-Ear (BTE) Speech Processor of the MED-EL Cochlear Implant System. The MED-EL cochlear implant system is prescribed for individuals suffering from bilateral severe-profound sensorineural hearing. Applicants suggested language: 1) "Battery Pack for use with Cochlear Implant ear level speech processor (straight, angled, children's)"; and 2) "Battery pack for use with Cochlear Implant ear level speech processor (remote)".

Background/Discussion:
According to the requester, the battery pack is a critical component of the MED-EL cochlear implant system. The battery pack provides the power source that enables the BTE Speech Processor to capture sound from the environment, analyze the information, digitize it into a code, and transmit the code across the skin to the implant. Since the implant has no power source of its own, the battery pack is tasked with providing the power necessary for the implanted current source to generate the electrical pulses that stimulate the auditory nerve. The Straight, Angled, Children's and Remote battery pack contain the batteries, the ON/OFF switch for the device and two of the battery packs (an input jack for assistive listening devices). The Angled, Children's and Straight battery packs use three (3) 675 High-Powered zinc air batteries while the Remote battery pack uses one (1) AA battery (disposable or rechargeable). All patients implanted with the MED-EL Cochlear Implanted System require use of the battery pack in order for the implant to function. The battery pack is an essential part of the external component of the MED-EL Cochlear Implant System. The external parts include the BTE Speech Processor, battery pack, coil and coil cable. The BTE Speech Processor consists of one control unit with four different battery packs that can be combined for five different wearing options. The different wearing options are created by connecting a given battery pack with the speech processor. The various configurations facilitate wearing the system comfortably and securely, regardless of age or activity level. According to the applicant, there is not a HCPCS code that specifically describes battery packs for the MED-EL cochlear implant system.

CMS HCPCS Workgroup Preliminary Decision:
These items are included with the initial issue of the device coded at L8614"COCHLEAR DEVICE, INCLUDES ALL INTERNAL AND EXTERNAL COMPONENTS". Existing code L8621 "ZINC AIR BATTERY FOR USE WITH COCHLEAR IMPLANT DEVICE, REPLACEMENT, EACH", adequately describes replacement batteries for the Straight, Angled and Children's Cochlear Implant System. Existing code L8622 "ALKALINE BATTERY FOR USE WITH COCHLEAR IMPLANT DEVICE, ANY SIZE, REPLACEMENT, EACH", adequately describes replacement batteries for the remote. Existing code L7510 "REPAIR OF PROSTHETIC DEVICE, REPAIR OR REPLACE MINOR PARTS" is available for assignment by insurers to identify replacement of a battery pack, when necessary.

Medicare Payment:
The fee schedule and payment rules associated with the existing codes apply to this product.
For L8614, L8621, L8622, Pricing = 38
For L7510, Pricing = 46

HCPCS Meeting Agenda Item #4
May 22, 2007

#07.58

Topic/Issue:
Request to add a new HCPCS Level II code for the upper extremity prosthetics. General Product Name: Multi-articulating digits for partial hand prosthesis and an upper extremity prosthetic hand with 5 multi-articulating digits. Trade Name: I-LIMB Hand & ProDigits.

Background/Discussion;
According to the requester, there are two distinctively different products that are being discussed for the establishment of the same L code. The two products are a new external powered prosthetic hand with individual powered articulating fingers (for patients of amputation levels Wrist Disarticulation and higher); and the other is an external powered prosthetic finger (for patients of amputation level Partial Hand)-both products share the same underlying mechanical characteristics. The hand is called I-LIMB Hand and the fingers are called ProDigits.

The individually articulating fingers of the devices offer users a step-change in functionality and performance, enabling patients to do more with their prosthetic hand. The fingers embrace the very latest in mechanical engineering design. The devices are manufactured using high-strength industrial plastics and injection molding techniques.

The grasping patterns are more like the natural human hand and unlike any other prosthetic hand. These grasping patterns allow a more dexterous and compliant grip, providing an increase in prehension and a decrease in energy expenditure for operation.

Existing codes: L7025 is used to describe the function of the hand. L7499 is used for the multi-articulating of each finger. According to the requester, no other code exists that describes the function and operation of these fingers.

CMS HCPCS Workgroup 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. CMS will be happy to consider an application in a later coding cycle if sales volume increases substantially. In the meantime, 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:
Payment for any covered items will be based on the carriers individual consideration of the claim since no specific code or fee schedule has been established for this item.

HCPCS Meeting Agenda Item #5
May 22, 2007

#07.86

Topic/Issue:
Request to establish a new code for a body-powered articulating artificial finger, trade name: X-Finger, X-Tip. Requester's suggested language: "Body-Powered Articulating Artificial Finger, Each".

Background/Discussion:
According to the requester, the X-Finger is an artificial finger that restores function to a patient that has a lost finger. A patient can slide the X-Finger over the portion of the finger that is remaining and immediately can begin to operate the device as if theirs was still attached. The X-Finger not only offers function very similar to a real finger, it provides similar grip strength as well. Patients can use the X-Finger to perform many of life's daily activities such a picking up objects, opening doors, and writing. Whenever needed, the device can easily be removed for cleaning.

CMS HCPCS Workgroup Preliminary Decision:
Existing code L7499 "UPPER 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. CMS will be happy to consider an application in a later coding cycle if sales volume increases substantially.

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

HCPCS Meeting Agenda Item #6
May 22, 2007

 # 07.114

Topic/Issue:
Request to establish a new code for a prefabricated thumb spica, trade name: RhizoLoc. Requester's suggested language: "Wrist hand finger orthosis, wrist gauntlet with thumb spica, prefabricated"

Background/Discussion:
According to the requester, RhizoLoc is a stabilizing orthosis for the stabilization of the thumb saddle and the first metacarpophalangeal (MCP) joints. An aluminum guard is used for support. Restriction of the thumb mobilization can be adjusted. The limiting flap for positioning the first metacarpophalangeal joint must be fastened under tension at the start of treatment, i.e., the transverse slot in the support must be closed. The orthotic must be individually adapted to the patient by a trained orthopedic technician. RhizoLoc is best used on patients with lateral ligament lesions of the 1st MCP (skier's thumb), and with the irritation in the region of the saddle and first metacarpophalangeal joints of the thumb, (acute/chronic osteoarthritis).

CMS HCPCS Workgroup Preliminary Decision:
Establish code LXXXX "HAND FINGER ORTHOSIS, WITH THUMB SPICA, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT".

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

HCPCS Meeting Agenda Item #7
May 22, 2007

 # 07.117

Topic/Issue:
Request to establish a new code for a wrist hand finger orthosis, trade name: SaeboFlex®. Applicant suggests that verbiage include: "WHFO, dynamic spring assist finger extension, and custom-fabricated"

Background/Discussion:
As described by the requester, SaeboFlex is a dynamic hand splint specifically designed for survivors of a neurological injury who exhibit some shoulder and elbow movement but minimal hand function. Some of these patients will never regain use of their hand and require the SaeboFlex in order to function around their home. Others can regain use of their hand and use the SaeboFlex both in the home and as a conduit in therapy. Saeboflex assists the individual in opening the hand by means of a variable strength finger and thumb spring system. This spring assistance allows individuals to perform functional grasp and release activities that would otherwise be impossible. Saeboflex is made from co-polymer plastic shell, aircraft 2024 aluminum, closed-cell foam (Plastizote), Velcro and steel hardware. The base components of the orthosis, which include the dorsal hand piece and forearm shell, are made of the co-polymer. The sheet of co-polymer is sized and heated. The pieces are vacuum formed over a positive mold. The pieces are then trimmed and finished. The therapist makes the final adjustments and the tensioned springs are chosen on the patient's level of disability/tone. Saeboflex is custom fabricated with use of a forearm shell, a dorsal hand piece, 8 aluminum parts, 8 springs, 5 straps, 5 digit caps & straps, a padded liner, and miscellaneous screws, rings, crimps, and a nylon line.

CMS HCPCS Workgroup Preliminary Decision:
Existing code L3940 "WRIST HAND FINGER ORTHOSIS, DORSAL WRIST, WITH OUTRIGGER ATTACHMENT, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT", adequately describes the product that is the subject of this request and is available for assignment by insurers as they deem appropriate. Most of the components are prefabricated; vacuum forming some components does not meet the definition of a custom fabricated device unique to an individual patient.

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

HCPCS Meeting Agenda Item #8
May 22, 2007

#07.77

Topic/Issue:
Request to establish (3) three new HCPCS codes for the temporary or preparatory fitting phase of fitting external powered upper extremity prosthetics. Applicant' suggested language:
Lxxx1 "Addition to upper extremity prosthesis, external powered, temporary fitting phase, wrist disarticulation or below elbow, molded to patient"
Lxxx2 "Addition to upper extremity prosthesis, external powered, temporary fitting phase, elbow disarticulation or above elbow, molded to patient"
Lxxx3 "Addition to upper extremity prosthesis, external powered, temporary fitting phase, shoulder disarticulation or interscapularthoracic, molded to patient"

Background/Discussion:
According to the requester, due to the advancements in socket design, materials and microprocessor based electronics, more patients are prescribed external powered upper extremity prosthesis as their first prosthesis versus a cable operated device. A problem arises in these fittings because there is no preparatory fitting phase for external powered systems under the current L code system. Providing a phase prior to the fitting of a definitive external powered system, prosthetists are able to adjust the fit of the device as the limb atrophies and edema is controlled. This 3-6 month period is known as the temporary or preparatory phase. Some physicians understand the need for the prosthetic system to be fit during this "golden period" from amputation and are prescribing external powered systems during this period; we request several codes for a temporary fitting phase for external powered prostheses, to reflect the division of amputation levels of the base codes. Existing miscellaneous codes are used to bill for this device. Similar products exist with cable operated and lower extremity, no code exists for external powered upper extremity devices.

CMS HCPCS Workgroup Preliminary Decision:
No insurer (i.e., Medicare, Medicaid, Private Insurance Sector), identified a national program operating need to establish codes for these services. Fitting, including preparation, is included in the base code for the prosthetic. Pricing includes the professional service; therefore separate billing is not appropriate. Existing codes for upper extremity prostheses should be used as appropriate. For coding guidance, contact the insurer in whose jurisdiction a claim would be filed. For private insurers, contact the individual private insurance contractor. For Medicaid, contact the Medicaid Agency in the state in which a claim would be filed. For Medicare, contact the Medicare contractor. Inquiries regarding fees assigned to codes are not within the jurisdiction of the HCPCS workgroup and should be directed to the insurer in whose jurisdiction a claim would be filed.

Medicare Payment:
The fee schedule and payment rules associated with the existing codes apply to this service.
Pricing = 38

HCPCS Meeting Agenda Item #9
May 22, 2007

#07.57

Topic/Issue:
Request to establish a new code for a wireless Bluetooth communication link to allow for adjustments to the microprocessor used with upper extremity prosthetics. General Product Name: Wireless Adjustability, Bluetooth or equal, upgrade. Trade Name: LimbLink™. Applicant's suggested language: LXXXX ADDITION TO MICROPROCESSOR, WIRELESS ADJUSTABILITY, BUILT-IN BLUETOOTH OR EQUAL.

Background/Discussion:
According to the requester, standard external powered microprocessors control terminal devices, wrists, and elbows. Yet, standard systems are limited on adjustability and oftentimes provide poor control of the prosthesis. LimbLink technology enables real time adjustments to some of these microprocessors to offer patients, who at one time were unable to control a prosthesis, the ability to return to work and avocations with an external powered prosthesis. These adjustments are necessary to operate the prosthesis to improve their quality of living. The controllers that use wireless adjustments benefit a small population of wearers who would otherwise not be able to control an external powered prosthesis. Some manufacturers have been using Bluetooth technology to wirelessly communicate to the microprocessor. This feature uses a built-in receiver on the existing microprocessor. For prosthetic use, it does not require an upgrade of an electronics receiver to link the prosthetic microprocessor to the computer so the prosthetist can make the adjustments. According to the requester, no current descriptor matches product design, function, or purpose of the wireless built-in receiver. Existing codes L7499 "UPPER EXTREMITY PROSTHESIS, NOT OTHERWISE SPECIFIED", is used for all billing and L6882 "MICROPROCESSOR CONTROL FEATURE, ADDITION TO UPPER LIMB PROSTHETIC TERMINAL DEVICE", is used for the microprocessor.

CMS HCPCS Workgroup 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 functionality included in the microprocessor code. The appropriate "L" code should be used for the microprocessor. 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 fee schedule and payment rules associated with the existing code apply to this product.
Pricing = 38

HCPCS Meeting Agenda Item #10
May 22, 2007

#07.43

Topic/Issue:
Request to establish a code for a prefabricated bracing device for treatment of the elbow joint. Trade name: SADER I Elbow Flexion/Extension Device (static and dynamic and range of motion). Requester suggested language: "Elbow Orthosis, Combined Flexion and Extension Assist, Range of Motion Limiting and Static Positioning, Pre Fabricated".

Background/Discussion:
According to the requester, this SADER I product is a prefabricated elbow orthosis with combined functions to treat skeletal and soft tissue injuries during the healing process and restore functional range and positioning controls of the elbow joint. It combines all of the necessary treatment combinations available for rehabilitation and to restore normal elbow flexion and extension functions. Combined dynamics forces for flexion and extension, range of motion limiters and positional static locking capabilities allows the treating professional the ability to make changes in the treatment protocol as the patient's healing progresses. This device is designed to provide multiple treatment protocols for the management of post elbow injuries and prevention of contractures of the elbow. It is also used in the post surgical care and rehabilitation of biceps tendon repair, radial head replacement, fracture mobilization, and dislocations. The device combines the ability to use static or dynamic forces in both flexion and extension with combined range of motion limits or static positioning. Treatment uses include an entire range of injuries and surgeries requiring the mobilization of the elbow joint to functional positioning. According to the applicant, there is not an existing code to describe this prefabricated, combined treatment technique.

CMS HCPCS Workgroup Preliminary Decision:
Existing code L3999 UPPER LIMB ORTHOSIS, 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. CMS will be happy to consider an application in a later coding cycle if sales volume increases substantially.

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

HCPCS Meeting Agenda Item #10
May 22, 2007

#07.47

Topic/Issue:
Request to establish a code for a custom bracing device for treatment of the knee. Trade name: SADER IV Knee Flexion/Extension Orthosis (static and dynamic end range of motion). Requester suggested language: "Knee Orthosis, Includes One or More Nontorsion Joints, Combined Dynamic Flexion and Extension Assist, May Include Range of Motion Limiter, Soft Interface, Straps, Custom, Includes Fitting and Adjustment".

Background/Discussion:
According to the requester, this SADER IV product is a custom designed knee orthosis with combined dynamic functions to treat skeletal and soft tissue injuries during the healing process and restore functional range and positioning controls of the knee. It combines all of the necessary treatment combinations available for rehabilitation and to restore normal knee flexion and extension functions. Combined dynamics forces for flexion and extension, range of motion limiters and positional static locking capabilities allows the treating professional the ability to make changes in the treatment protocol as the patient's healing progresses. According to the requester, the principle use of this device is during the post surgical rehabilitation of total knee replacement surgery. This device is designed to help restore normal range of motion to the knee and prevent or reduce contractures during the rehabilitation process. Also according to the requester, there is no current code that allows for or includes a custom device with external elastic bands for flexion and extension, range of motion limiters and static positioning for rehabilitation purposes.

CMS HCPCS Workgroup Preliminary Decision:
Existing code L2999 LOWER LIMB ORTHOSIS, 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. CMS will be happy to consider an application in a later coding cycle if sales volume increases substantially.

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

HCPCS Meeting Agenda Item #10
May 22, 2007

#07.48

Topic/Issue:
Request to establish a code for a custom bracing device for treatment of the elbow joint. Trade name: SADER I Elbow Flexion/Extension Device (static and dynamic end range of motion). Requester suggested language: "Elbow Orthosis, Combined Dynamic Flexion and Extension Assist, Range of Motion Limiting and Static Positioning, Custom Fabricated".

Background/Discussion:
According to the requester, this SADER I product is a custom designed elbow orthosis with combined dynamic functions to treat skeletal and soft tissue injuries during the healing process and restore functional range and positioning controls of the elbow joint. It combines all of the necessary treatment combinations available for rehabilitation and to restore normal elbow flexion and extension functions. Combined dynamics forces for flexion and extension, range of motion limiters and positional static locking capabilities allows the treating professional the ability to make changes in the treatment protocol as the patient's healing progresses. This device is designed to provide multiple treatment protocols for the management of post elbow injuries and prevention of contractures of the elbow. It is also used in the post surgical care and rehabilitation of biceps tendon repair, radial head replacement, fracture mobilization, and dislocations. The device combines the ability to use static or dynamic forces in both flexion and extension with combined range of motion limits or static positioning. Treatment uses include an entire range of injuries and surgeries requiring the mobilization of the elbow joint to functional positioning. Also according to the requester, the current available code L3730 "Elbow orthosis, double upright with forearm/arm cuffs, extension/flexion assist, custom-fabricated", allows for extension or flexion assist and does not include range of motion limiters or static positioning.

CMS HCPCS Workgroup Preliminary Decision:
Existing code L3999 UPPER LIMB ORTHOSIS, NOT OTHERWISE SPECIFIED is available for assignment by insurers as they deem appropriate. Use of code L3730 "ELBOW ORTHOSIS, DOUBLE UPRIGHT WITH FOREARM/ARM CUFFS, EXTENSION/FLEXION ASSIST, CUSTOM FABRICATED is not 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. CMS will be happy to consider an application in a later coding cycle if sales volume increases substantially.

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

HCPCS Meeting Agenda Item #10
May 22, 2007

#07.49

Topic/Issue:
Request to establish a code for a custom bracing device for treatment of the wrist, Trade Name: SADER III wrist flexion/extension device (static and dynamic end range of motion). Requester suggested language**: "**Wrist hand orthoses, includes one or more nontorsion joints, combined dynamic flexion and extension assist, range of motion limiter, may include soft interface, straps, custom, includes fitting and adjustment."

Background/Discussion:
According to the requester, this SADER III product is a custom designed wrist orthosis with combined dynamic functions to treat skeletal and soft tissue injuries during the healing process and restore functional range and positioning controls of the wrist. It incorporates combined treatment options for the treating professional. This device combines all of the necessary treatment combinations available for rehabilitation and to restore normal wrist flexion and extension functions. Combined dynamic forces for flexion and extension, range of motion limiters, and positional static locking capabilities allows the treating professional the ability to make changes in the treatment protocol as the patients healing progresses. According to the requester, there is no current code that allows for or includes a custom device with external elastic bands for flexion and extension, range of motion limiters and static positioning for rehabilitation purposes. Code L3905 is currently being used to describe this product; however, this code is limited to elastic or turnbuckle features which only react in one motion, flexion or extension.

CMS HCPCS Workgroup Preliminary Decision:
Existing code L3999 UPPER LIMB ORTHOSIS, NOT OTHERWISE SPECIFIED is available for assignment by insurers as they deem appropriate. Use of code L3905 "WRIST HAND ORTHOSIS, INCLUDES ONE OR MORE NONTORSION JOINTS, ELASTIC BANDS, TURNBUCKLES, MAY INCLUDE SOFT INTERFACE, STRAPS, CUSTOM FABRICATED, INCLUDES FITTING AND ADJUSTMENT is not 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. CMS will be happy to consider an application in a later coding cycle if sales volume increases substantially.

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

HCPCS Meeting Agenda Item #10
May 22, 2007

#07.50

Topic/Issue:
Request to establish a code for a prefabricated bracing device for treatment of the knee, Trade Name: SADER IV knee flexion/extension orthosis (static and dynamic end range motion). Requester suggested language**: "**Knee orthoses, includes one or more nontorsion joints, combined dynamic flexion and extension assist, may include range of motion limiter, soft interface straps, prefabricated, includes fitting and adjustment".

Background/Discussion:
According to the requester, this SADER IV product is a prefabricated knee or orthosis with combined dynamic functions to treat skeletal and soft tissue injuries during the healing process and restore functional range and positioning controls of the knee. It incorporates combined treatment options for the treating professional. Knee injuries and repairs differ in each aspect of the recovery process. Different injuries require different mobilization techniques. In the past, multiple bracing techniques may have been required during the rehab process in order to accomplish good clinical outcomes. New bracing techniques allow the bracing device to convert to different modes of operation to accommodate the different healing periods. New techniques allow a single bracing device to accomplish many modes of operation independently or in combination. These modes of operation include: variable dynamic flexion assist, variable extension assist, range of motion limiters, and static positioning. According to the requester, "the principle use of this device is during the post surgical rehabilitation of total knee replacement surgery. This device is designed to help restore normal range of motion to the knee and prevent or reduce contractures during the rehab process". The requester claims there are no current codes to cover these prefabricated combined treatment techniques and there are no add-on codes to support base codes.

CMS HCPCS Workgroup Preliminary Decision:
Existing code L2999 LOWER LIMB ORTHOSIS, 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. CMS will be happy to consider an application in a later coding cycle if sales volume increases substantially.

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

HCPCS Meeting Agenda Item #10
May 22, 2007

#07.51

Topic/Issue:
Request to establish a code for a prefabricated bracing device for treatment of the wrist, Trade Name: SADER III wrist flexion/extension device (static and dynamic end range of motion). Requester suggested language**: "**Wrist hand orthoses, includes one or more nontorsion joints, combined dynamic flexion and extension assist, range of motion limiter, may include soft interface, straps, prefabricated, includes fitting and adjustment."

Background/Discussion:
According to the requester, this SADER III product "is a prefabricated designed wrist orthosis with combined dynamic functions to treat skeletal and soft tissue injuries during the healing process and restore functional range and positioning controls of the wrist". It incorporates combined treatment options for the treating professional. Wrist injuries and repairs differ in each aspect of the recovery process. Different injuries require different mobilization techniques. In the past, multiple bracing techniques may have been required during the rehab process in order to accomplish good clinical outcomes. New bracing techniques allow the bracing device to convert to different modes of operation to accommodate the different healing periods. New techniques allow a single bracing device to accomplish many mode of operation independently or in combination. These modes of operation include: variable dynamic flexion assist, variable extension assist, range of motion limiters, and static positioning. According to the requester, no current codes cover these prefabricated combined treatment techniques and there are no add-on codes to support base codes. Currently, L3905 "Wrist hand orthoses, includes one or more nontorsion joints, elastic bands, turnbuckles, may include soft interface, straps, custom fabricated, includes fitting and adjustment" is used to describe this product; however, the requester claims that present codes are limited to custom fabricated designs of unlike products.

CMS HCPCS Workgroup Preliminary Decision:
Existing code L3999 UPPER LIMB ORTHOSIS, NOT OTHERWISE SPECIFIED is available for assignment by insurers as they deem appropriate. Use of code L3909 WRIST ORTHOSIS, ELASTIC, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT (E.G. NEOPRENE, LYCRA) is inappropriate. 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. CMS will be happy to consider an application in a later coding cycle if sales volume increases substantially.

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

HCPCS Meeting Agenda Item #11
May 22, 2007

Attachment: #07.129

Topic/Issue:
Request to establish a code to identify a custom made hip knee ankle foot orthosis (HKAFO), trade name: Dynamic Lycra HKAFO. Applicant's suggested Language: "Tension based dynamic HKAFO, consists of one or more reinforced Lycra (or similar) panels with a tension and line of pull specific to patient needs. Extends bilaterally from the pelvis, and crosses the hip, knee and ankle, may include stirrups and closures. Custom made from measurement, includes evaluation, fitting and adjustments".

Background/Discussion:
According to the requester, the HKAFO is used by pediatric and adult neuromuscular patients with Cerebral Palsy, Post traumatic brain injury, and cerebrovascular accident. The Dynamic HKAFO is a custom made to measurement brace made from computer generated patterns of Lycra. This skin tight fitting material provides strong proprioceptive feedback. Sections of Lycra reinforcements are stitched to a base fabric using specific tensions, directions of pull and types of material and thickness to provide corrective forces to the body segment. The goal in fitting this orthosis is to encourage a more upright standing position and prevent or reduce "scissor" gait by encouraging leg abduction. In doing so the patient should exhibit improved balance and a reduced walking effort. In the case of soft tissue contractures, the device provides a constant stretch toward functional position. The Dynamic assists in reestablishing normal functional position with the use of elasticized and non-elasticized materials by introducing a force along the weakened muscle line of action. Reinforcements are used to prevent the legs from rotating in, and keeping the legs facing forward. The orthosis is worn during waking hours by the patient and is removed for sleeping. According to the requester, a new code is warranted to identify Dynamic's unique ability to provide a controlled stretch in multiple planes of motion, a function not captured in current code descriptions.

CMS HCPCS Workgroup Preliminary Decision:
Existing code L2999 "LOWER EXTREMITY ORTHOSIS, NOT OTHERWISE SPECIFIED" is available for assignment by insurers as they deem appropriate. Your reported sales volume is 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. CMS will be happy to consider an application in a later coding cycle if sales volume increases substantially.

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

HCPCS Meeting Agenda Item #11
May 22, 2007

Attachment: #07.130

Topic/Issue:
Request to establish a code to identify a custom made elbow wrist hand orthosis (EWHO), trade name: Dynamic Lycra EWHO. Applicant's suggested Language: "Tension based dynamic EWHO, consists of one or more reinforced Lycra (or similar) panels with a tension and line of pull specific to patient need. Extending proximal to the elbow, distal to the shoulder, may include zipper, palmer section and fingers. Custom made from measurement, includes evaluation, fitting and adjustments".

Background/Discussion:
According to the requester, the EWHO is used to treat upper extremity needs of neurologically impaired individuals such as those diagnosed with Cerebral Palsy, Post traumatic brain injury, and cerebrovascular accident. This orthosis is used to improve specific postural and tonal issues that affect arm posture and movement. Such improvement leads to greater awareness of the arm and development of spontaneous patterns of reach in daily tasks. Proximal symmetry through the shoulder has also improved which helps in balance and gait patterns. The Dynamic EWHO is a custom made to measurement brace made from computer generated patterns of Lycra. This skin tight fitting material provides strong proprioceptive feedback. Sections of Lycra reinforcements are stitched to a base fabric using specific tensions, directions of pull and types of material and thickness to provide corrective forces to the body segment. The Dynamic assists in reestablishing normal functional position with the use of elasticized and non-elasticized materials by introducing a force along the weakened muscle line of action. It also produces continuous stretch of spastic muscles and has rapid splinting and anti-spastic effects on wrist and fingers in patients with hemiplegia. The orthosis is worn during waking hours by the patient and is removed for sleeping. According to the requester, a new code is warranted to identify Dynamic's unique ability to provide a controlled stretch in multiple planes of motion, a function not captured in current code descriptions.

CMS HCPCS Workgroup Preliminary Decision:
Existing code L3999 "UPPER LIMB ORTHOSIS, NOT OTHERWISE SPECIFIED" is available for assignment by insurers as they deem appropriate. Your reported sales volume is 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 mush 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. CMS will be happy to consider an application in a later coding cycle if sales volume increases substantially.

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

HCPCS Meeting Agenda Item #11
May 22, 2007

Attachment: #07.131

Topic/Issue:
Request to establish a code to identify a compliance and posture monitoring device, trade name: Cricket. Applicant's suggested language: "Temperature and inclination (compliance) monitoring device fit to an existing orthosis. Includes LCD reader, fitting, adjustment, retrieving and interpreting data"

Background/Discussion:
According to the requester, the Cricket is a quarter size monitoring device that fits into an orthosis. It is used primarily by patients with idiopathic and neuromuscular scoliosis as well as various musculoskeletal conditions. It is used in conjunction with any orthotic device that would require compliance monitoring. The device monitors patient compliance and posture; the hours the orthosis is worn and the position of the patient. The sensor measures and stores information on adherence to brace treatment and inclination of the body segment. Appropriate sensors to measure human proximity, as well as inclination, are packaged in a module small enough to be attached to a brace. Compliance is measured by using two temperature sensors and one tilt sensor. One temperature sensor is on the inside of the brace and the other on the outside. The inside sensor measures body surface temperature, and the outside sensor measures ambient temperature. When the brace is being worn the temperatures are consistently different and when not worn, the temperatures are the same. A 2-axis accelerometer is used to measure tilt. Tilt is used to determine whether the person is upright or lying down. The accelerometer is sufficiently accurate to measure the change in these two states. Also, there is a LCD readout on the device so the patient can have a real time display of average hours of wear per week. Wear time can then be adjusted to meet the pre- prescribed wear hours per week. This data is vital in determining the efficacy of the orthosis to the orthotist, prescribing physician, patient and payer. The sensor has 64K memory, which allows 8 months of compliance data and 4 months of compliance and tilt data to be stored. It is packaged using clear plastic, which is vacuum-formed in a custom mold. The compliance sensor is placed on the reader and through software commands the download procedure begins. Data takes 1 minute to download entire 64K memory. The battery is a 3V coin cell battery and will last for approximately 1.5 years running at full capacity.

CMS HCPCS Workgroup Preliminary Decision:
Existing code A9279 "MONITORING, FEATURE/DEVICE, STAND-ALONE OR INGEGRATED, ANY TYPE, INCLUDES ALL ACCESSORIES, COMPONENTS AND ELECTRONICS, NOT OTHERWISE CLASSIFIED" is available for assignment by insurers as they deem appropriate, to identify monitoring features and devices.

Medicare Payment:
The fee schedule and payment rules associated with the existing code apply to this product.
Pricing = 00

HCPCS Meeting Agenda Item #11
May 22, 2007

Attachment: #07.132

Topic/Issue:
Request to establish a code to identify a custom made Lycra tension-based TLSO, trade name: Dynamic Lycra TLSO. Applicant's suggested language: "Tension based dynamic TLSO, consists of one or more reinforced Lycra (or similar) panels with line of pulls specific to patient needs. Extending anteriorly from sternal notch to symphyus pubis, posteriorly from T3 or higher, to sacrococcygeal junction, may include straps and closures. Custom made from measurements, includes evaluation, fitting and adjustments"

Background/Discussion:
According to the requester, these TLSOs are custom made to measure brace made from computer generated patterns of Lycra material. This body forming TLSO consist of sections of Lycra reinforcements stitched to a base fabric using specific tensions, directions of pull, type of material and thickness to provide corrective forces which transfer to the body segment. The patient is able to move without discomfort therefore proving the orthosis to be truly dynamic and patient compliant. This TLSO helps to reestablish normal function and balance with the use of elasticized materials by introducing a force along the weakened muscle line of action. This orthosis provides cylindrical pressure which improves loading on joints leading to improved stability. Increased internal soft tissue pressure leads to enhanced proprioceptive feedback to improve body awareness, improving muscle activation, reduction of any excessive tone, relaxes the patient with possible improvements in posture and gait. In the case of neuromuscular scoliosis, it has been shown to reduce the curve, provide corrective movement, and in turn improve sitting balance. Also, by providing truncal support, and reducing tone, it allows function to be restored to the upper extremities that otherwise would be used to support the body. The orthosis is worn during waking hours by the patient and is removed for sleeping.

CMS HCPCS Workgroup Preliminary Decision:
Existing code L1499 "SPINAL ORTHOSIS, NOT OTHERWISE SPECIFIED" is available for assignment by insurers as they deem appropriate. Your reported sales volume is 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 mush 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. CMS will be happy to consider an application in a later coding cycle if sales volume increases substantially.

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

HCPCS Meeting Agenda Item #12
May 22, 2007

#07.61

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 Regulator, Adjustable feature is designed to be used exclusively by people with limb deficiency at, above, or through the knee joint. This item 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). 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.

Ambulatory people are faced with situations on a daily basis that require them to stand for a period of time. While standing, they typically shift their weight from one side to another. They are required to place most of their weight on their sound side while simultaneously stabilizing the prosthesis. Over time, this places extreme stress on the sound side. The Electronically-Controlled Static Stance Regulator, Adjustable feature 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. According to the requester, the current codes do not describe the Electronically-Controlled Static Stance Regulator, Adjustable feature as it addresses the patient's need to have a flexed knee in a locked position to provide stability while in static stance. Existing codes L5925 is used for (manual locking) and L5848 is used for (stance extension dampening).

CMS HCPCS Workgroup 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 functionality included in the microprocessor code. The appropriate "L" code should be used for the microprocessor. 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 fee schedule and payment rules associated with the existing codes apply to this product.
Pricing = 38

HCPCS Meeting Agenda Item #13
May 22, 2007

#07.90

Topic/Issue:
Request to establish a code to identify a motorized, active prosthetic knee, Trade Name: PowerKnee™, and two additional codes to identify the lithium polymer technology powering it. Requester's suggested language: (1) Addition, electromechanically-powered endoskeletal knee-shin system with sensory control, powered swing and stance phase, including power source; (2) Lithium-polymer charger; and (3) Lithium-polymer battery, replacement.

Background/Discussion:
According to the requester, the Power Knee™ is the first motorized external prosthetic knee. The motor actively initiates and controls all knee movement. No current L-codes refer either explicitly or implicitly to a motorized prosthetic knee. The next-most advanced prosthetic knees – microprocessor-controlled devices – have no motor, and cannot actively initiate knee movement, as they are passive devices. The Power Knee™ is the first prosthetic knee to require lithium-polymer batteries for a power and a lithium-polymer battery charger. No current L-codes refer to this technology. And all other battery-powered prosthetic knees rely on lithium-ion batteries and chargers.

CMS HCPCS Workgroup Preliminary Decision:
Existing code L7368 "LITHIUM ION BATTERY CHARGER" adequately describes the lithium battery charger and is available for assignment by insurers. Existing code L7367 "LITHIUM ION BATTERY, REPLACEMENT" adequately describes the lithium battery replacement, and is available for assignment by insurers. Existing code L5999 "LOWER EXTREMITY PROSTHESIS, NOT OTHERWISE CLASSIFIED" is available for assignment by insurers, as they deem appropriate, to describe the Power Knee. For the Power Knee System, 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. CMS will be happy to consider an application in a later coding cycle if sales volume increases substantially.

Medicare Payment:
The fee schedule and payment rules associated with the existing codes apply to these products.
For L7368 and L7367, Pricing = 46
For L5999, Pricing = 46

HCPCS Meeting Agenda Item #13
May 22, 2007

 # 07.99

Topic/Issue:
Request to establish a new code for a microprocessor-controlled prosthetic ankle-foot system, trade name: Proprio Foot™. Suggested Language: "Addition to lower extremity prosthesis, endoskeletal ankle system, microprocessor control feature, active dorsiflexion and plantar flexion, includes automatic terrain alignment feature, includes power source"

Background/Discussion:
According to the requester, Proprio is the first microprocessor-controlled ankle-foot system available to lower extremity amputees. It automatically and intelligently regulates plantar flexion and dorsiflexion in real time based on the underlying terrain. Proprio foot is indicated for transtibial amputees with at least a K2 functional level. Proprio foot is designed to facilitate walking on level ground, on uneven terrain, up and down inclines/declines, up and down stairs, and standing up from a sitting position. Proprio foot consists of four central elements: 1) an energy-storing prosthetic foot; 2) prosthetic ankle that dorsiflexes and plantar flexes during swing phase; 3) a microprocessor that controls dorsiflexion and plantar flexion; and 4) a lithium-ion battery and charger. Proprio operates the same way as a traditional prosthetic foot in the stance phase portion of the gait cycle, its microprocessor-control feature permits dynamic, real-time adjustments of the ankle-foot complex once the prosthetic foot leaves the ground. When walking on level terrain, Proprio Foot™ dorsiflexes immediately after "toe off" permits greater ground clearance when the user transitions from the flexion to extension portion of swing phase. Before heel strike, the microprocessor then initiates plantar flexion to encourage a symmetrical, smooth transition back onto the user's prosthetic side. No other ankle-foot system can provide this function.

CMS HCPCS Workgroup Preliminary Decision:
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. CMS will be happy to consider an application in a later coding cycle if sales volume increases substantially.

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

HCPCS Meeting Agenda Item #14
May 22, 2007

#07.78

Topic/Issue:
Request to establish a code for an electronically controlled orthotic knee joint system with sensory feedback, Trade Name: Otto Bock® E-Mag Control. Requester's suggested language: "Orthotic Knee Joint, Electronically Controlled Lock/Unlock Feature with Sensory Feedback".

Background/Discussion:
According to the requester, the Otto Bock® E-Mag Control is a new joint with an automatic electronic locking function and a wireless, remotely activated electromagnetic unlocking function with sensory feedback for patients with sensory deficiencies or severe balance challenges. The joint is designed to provide safety and stability for patients with hearing and visual impairments, post-traumatic conditions, post polio syndrome, paralysis or extensor muscle weakness. The wireless unlocking feature is ideal for those patients with decreased upper extremity strength; for those that lack the strength and balance to bend at the waist; or for individuals with compromised stability. Providers have billed using code L2999 "Lower extremity orthoses, not otherwise specified". The applicant is seeking a code to specifically identify this product.

CMS HCPCS Workgroup Preliminary Decision:
Existing code L2999 LOWER LIMB ORTHOSIS, 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. CMS will be happy to consider an application in a later coding cycle if sales volume increases substantially.

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

HCPCS Meeting Agenda Item #15
May 22, 2007

Attachment: #07.112

Topic/Issue:
Request to establish a new code to identify a Patellofemoral, functional, rehabilitative knee brace, trade name: In the Groove™ knee brace. Requester Suggested Language: "Knee orthosis, femoral-tibial alignment, opposing straps, prefabricated".

Background/Discussion:
According to the requester, in Patellofemoral syndrome, the femur is offset from the tibial plateau. The patella cannot track in the femoral condylar groove, trochlear groove, and the underside of the patella scrapes on the femoral condyle damaging both contacting surfaces. In the Groove™ knee brace helps to glide the femoral condyles back into the tibial menisci wells. Back in the wells, the patella can track in the femoral condyle groove. When the patella is in the groove, there is increased mobility, reduction of damage to the femoral condyles, underside of the patella, and the menisci of the tibia. This brace was designed after a Mulligan maneuver, Mobilization with Movement Glide and is specific for patellofemoral syndrome. It will help to rehabilitate the muscles of the knee by maintaining better alignment during exercising the knee joint as in weight bearing activity. After a few months the knee joint muscles are generally rehabilitated and the braces are no longer needed all the time.

According to the applicant, existing code categories describe braces that provide patella control, however, they do not describe femoral-tibial alignment adjustment. The In the Groove™ knee brace is acting on a different anatomical site than the existing braces that put pressure on the patella. When the patella is permitted to move normally, the muscles are strengthened. This in turn helps to maintain better patella tracking and proper knee function. Therefore, the In the Groove™ knee brace also has a significantly better outcome than the braces that fall under existing codes.

CMS HCPCS Workgroup Preliminary Decision:
Existing code L1800 "KNEE ORTHOSIS, ELASTIC WITH JOINTS, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT" adequately describes the item that is the subject of this request.

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

HCPCS Meeting Agenda Item #16
May 22, 2007

#07.20

Topic/Issue:
Request to add a new HCPCS Level II code to describe the Pump It Up prosthetic socket.

Background/Discussion:
According to the requester, the Pump It Up socket design is a custom made pneumatic bladder sandwiched between a custom inner and custom outer socket and is designed for either trans-tibial or trans-femoral amputees. The socket is the most important aspect of the prosthesis because it is worn directly against the body and supports the entire weight of the amputee while ambulating. Amputees frequently experience volume changes, often fluctuating daily. A daily change in volume cannot be accommodated in traditional socket design with rigid walls. Despite the advances in prosthetics, amputees still adjust the fit of their prosthetic sockets by adding or removing prosthetic (stump) socks, sheaths or liners just as they have for the past couple of years. The problem with adding and removing socks, etc. is that it is not only cumbersome but difficult, as the prosthesis must be removed. The Pump It Up accomplishes this easily by allowing the wearer to adjust the fit with a hand-held pump without removing the prosthesis. It also provides increased suspension, additional cushioning, and improves rotational stability of the prosthesis. The bladders which are fabricated (vulcanized) of aircraft grade rubber are durable and can with stand repeated use as can the socket itself. For both trans-tibial and trans-femoral amputees, the Pump It Up socket design provides adjustability and cushioning as well as increased proprioception, which is not available to an amputee in any other socket design. By allowing the amputee to adjust the fit of their socket, they increase the surface area between the residual limb and the socket, which aids in suspension, rotational stability, volume management and general comfort level. According to the applicant, existing codes L5646 and L5648 do not describe a custom-made socket design, which incorporates a custom-made circumferential bladder filled with air, sandwiched between an inner and outer socket. In addition other sockets in these codes are not adjustable by the user.

CMS HCPCS Workgroup Preliminary Decision:
Existing codes **L5637** ADDITION TO LOWER EXTREMITY, BELOW KNEE, TOTAL CONTACT, **L5645** ADDITION TO LOWER EXTREMITY, BELOW KNEE, FLEXIBLE INNER SOCKET, EXTERNAL FRAME and **L5646** ADDITION TO LOWER EXTREMITY, BELOW KNEE, AIR, FLUID, GEL OR EQUAL, CUSHION SOCKET, used together, adequately describe the features of the below knee product. Existing codes **L5648** ADDITION TO LOWER EXTREMITY, ABOVE KNEE, AIR, FLUID, GEL OR EQUAL, CUSHION SOCKET, **L5650** ADDITIONS TO LOWER EXTREMITY, TOTAL CONTACT, ABOVE KNEE OR KNEE DISARTICULATION and **L5651** ADDITION TO LOWER EXTREMITY, ABOVE KNEE, FLEXIBLE INNER SOCKET, EXTERNAL FRAME, used together, adequately describe the features of the above knee product.

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

HCPCS Meeting Agenda Item #17
May 22, 2007

 # 07.100

Topic/Issue:
Request to establish a new L code for a manually-activated device that adjusts vertical pylon alignment of a lower limb prosthesis, trade name: BRIO.

Background/Discussion:
According to the requester, BRIO is a fluid-controlled, push-button operated device that enables the user to adjust the vertical pylon alignment of a lower limb prosthesis to accommodate plantar and dorsiflexion of the foot relative to heel height variation. The BRIO attaches between any standard pyramid top foot and a 30mm pylon. The push button, when depressed, opens a valve which allows the user to set plantar and dorsiflexion for optimal vertical pylon alignment. Once the push button is released the BRIO locks in position. The BRIO provides a single axis of motion with a working range of eleven degrees.

CMS HCPCS Workgroup Preliminary Decision:
Existing code category L5990 "ADDITION TO LOWER EXTREMITY PROSTHESIS, USER ADJUSTABLE HEEL HEIGHT", adequately describes an adjustability feature by any means, including the product that is the subject of this request, and is available for assignment by insurers as they deem appropriate.

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

HCPCS Meeting Agenda Item #18
May 22, 2007

 # 07.115

Topic/Issue:
Request to establish a new code for a lower limb leg brace, trade name: Step-Smart. Applicant's suggested language: "AFO, articulated, with posterior co-planar tension elements and set of compression elements, prefabricated, includes fitting and adjustment"

Background/Discussion:
According to the requester, Step-Smart is lower limb leg brace used by patients with Drop Foot, a condition of shock absorption deficit. The dorsiflexors are also responsible for lowering the foot from heel strike to foot flat. Designed for both swing and stance phase, Step-smart provides clearance during the swing phase, and provides shock absorption during stance phase. The brace joint pre-positions the foot into dorsiflexion during swing phase, and then the pre-loaded feature of the joint (a compression component) absorbs shock and decelerates the foot during loading. A set of compression components comes with every Step-Smart brace. These compression components provide for five different settings of shock absorption (Jacob Joint), which can be tailored. This is done by adjusting the length of the compression elements. For improved gait efficiency, it is essential to individualize the resistance level for the specific patient need. The practitioner can assess and provide the proper level of shock absorption. The Jacob Joint comes with an extra tensor which is slightly longer. The calf section can be angled with respect to the foot section. For some shoe types and leg shapes, this adjustment would allow the calf section to track on the calf. The fitting of the Step Smart can take from 30 minutes to 1 hour. According to the applicant, "existing codes that represent products for the treatment of foot drop are described as one piece orthotics. They do not include a joint or shock absorbers".

CMS HCPCS Workgroup Preliminary Decision:
Existing codes L1971 "ANKLE FOOT ORTHOSIS, PLASTIC OR OTHER MATERIAL WITH ANKLE JOINT, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT" and 1 unit of L2210 "ADDITION TO LOWER EXTREMITY, DORSIFLEXION ASSIST PLANTAR FLEXION RESIST), EACH JOINT", used together, adequately describe the product that is the subject of this request.

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

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 Regional Carriers (DMERCs). 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.