Centers for Medicare & Medicaid Services (CMS)
Summary Report
HCPCS Public Meeting
Thursday, April 27, 2006

Introduction and Overview

Michael Barron, CMS Office of Operations Management, moderated the meeting. Approximately 50 people attended. The agenda included 14 items.

CMM staff Joel Kaiser presented an educational overview of the variety of methods used for setting the payment amount for items, and when the different methods are used. The overview was also provided as a written attachment to the agenda. For additional information, the DME payment rules are located at Section 1834 (a) of the Social Security Act. The Medicare fee schedule for DME, Prosthetics, Orthotics and Supplies, and background information, can be accessed and downloaded free of charge at: http://www.cms.hhs.gov/DMEPOSFeeSched/LSDMEPOSFEE/list.asp?filterType=none&filterByDID=0&sortByDID=3&sortOrder=descending.

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

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

Following the public meeting, the CMS HCPCS workgroup will use the input provided at the Public Meeting to reconsider its preliminary coding recommendations, and CMS staff will reconsider its pricing recommendations. The CMS HCPCS workgroup is the entity that 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.

Public Meetings are not CMS HCPCS workgroup meetings. Final decisions are not made at the public meetings. All requestors will be notified in writing, in November, of the final decision regarding the HCPCS code request(s) they submitted.

The process for developing agendas and speaker lists for the public meetings, and Guidelines for Proceedings at CMS' Public Meetings are posted on the official HCPCS world wide web site at: http://cms.hhs.gov/medhcpcsgeninfo in a document entitled: "Alpha-Numeric HCPCS Coding Recommendation Format. The standard application format for requesting a modification to the HCPCS Level II Coding System, along with instructions for completion and background information regarding the HCPCS Level II coding process is available on the same web site.

Meeting Agenda Item #1
April 27, 2006
HCPCS Request #06.24

Topic/Issue:
Request to establish a code for a halo traction ring and skull pins, trade name: ReSolve Halo System, recommended description: Addition to Halo Procedures, non-conductive ring and skull pins.

Background/Discussion:
According to the requester, the Halo System provides external cervical immobilization for unstable cervical spine injuries. It can be both an alternative to surgery and an adjunct when stability is required during a procedure. The System permits ambulation during the healing process. 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 and the vest is secured to the upper torso. The superstructure is used to maintain the prescribed head and spinal alignment. Patients may wear the unit for six to twelve weeks without removal. During that time the patient may require diagnostic imaging. Even though code L0859 was implemented in 2006 in response to a prior request to code this product; the requester claims that "a new code is needed to provide reimbursement when newer non-conductive materials are required for patient safety and optimal imaging. Even though code L0859 ADDITION TO HALO PROCEDURE, MAGNETIC RESONANCE IMAGE COMPATIBLE SYSTEMS, RINGS AND PINS, ANY MATERIAL was implemented in 2006 in response to a prior request to code this product; the requestor claims that "a new code is needed to provide reimbursement when newer non-conductive materials are required for patient safety and optimal imaging. The new code would compensate for the increased expense of high-tech, insulative materials."

CMS HCPCS Workgroup Preliminary Decision:
Continue to use existing code L0859 ADDITION TO HALO PROCEDURE, MAGNETIC RESONANCE IMAGE COMPATIBLE SYSTEMS, RINGS AND PINS, ANY MATERIAL, which adequately describes the product that is the subject of your request. Pricing inquiries are not within the purview of the HCPCS code set maintainers, and should be submitted directly to insurers. It is inappropriate to use L0999 or any other miscellaneous codes.

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

Primary Speaker:
On behalf of Jerome Medical, the primary speaker disagreed with the workgroup's statement that the current code adequately describes the product. The speaker requested that L0859 addition to halo procedure be revised to specify "image-safe" instead of "image compatible", and to include the term "non-conductive" and omit "any material".

According to the speaker, this would acknowledge the need for designating patient safety and diagnostically variable imaging with halo devices over ambiguous terminology such as “Magnetic Resonance Imaging Compatible System, Any Material”, which may be used solely to designate protection of the MRI equipment.

Meeting Agenda Item #2
April 27, 2006
HCPCS Request #06.10

Topic/Issue:
Request to establish a code for a cervical collar back piece, trade name: Miami Occian Collar Back.

Background/Discussion:
According to the requester, the Occian Collar Back is indicated for patients who are at risk for occipital skin breakdown, or for any patient who must wear a collar during sleep and desires a comfortable alternative. It consists of pressure-relieving visco-elastic material inside a breathable, waterproof cover. Immersion of the occiput in the visco-elastic material envelops the back of the head and minimizes pressure points without sacrificing critical immobilization. The Occian Back is an accessory to a standard collar and there is no separate code for a pressure-relieving back piece. Both the pad and shell of the Occian back may be cleaned. This item is used in in-patient facilities.

CMS HCPCS Workgroup Preliminary Decision:
This item is exclusively used in the hospital inpatient setting. For Medicare, it is included in the DRG payment. For Medicaid coding guidance, submit inquiries to the Medicaid agency in the state in which the claim would be filed. For coding inquiries for private insurers, contact the individual private insurance contractor.

Primary Speaker:
On behalf of Jerome Medical, the primary speaker disagreed with the workgroup's preliminary decision that the Occian Back is exclusively used in the hospital inpatient setting, and offered the following reasons:

- The Occian Back is an accessory to a standard collar
- The Occian Back is not typically stocked in hospital. It is stocked by an O&P provider.
- The Occian Back is typically applied by an orthotist on a physician's prescription.
- The Occian Back may be worn by a hospital in-patient. However, it is also worn or prescribed upon discharge for the duration of collar wear.
- The Occian Back may be prescribed for post-operative patients who are discharged.
- The same clinical usage standards as all coded cervical orthotics apply.
- No L-code exists for a separate, specialty back piece or the visit required to apply it.
- Existing collar codes only reimburse for a standard collar.
- The patient's original collar code still applies, because a standard collar is worn while ambulating end the Occian Back is worn while supine.

Jerome Medical reiterated its request that a new L-code be established for a pressure-relieving collar back piece.

Meeting Agenda Item #3
April 27, 2006
HCPCS Request #06.11

Topic/Issue:
Request to establish a code for a cervical thoracic lumbo-sacral orthosis, trade name: Papoose Infant Spinal Immobilizer.

Background/Discussion:
According to the requester, the Papoose is a cervical thoracic lumbo-sacral orthosis (CTLSO) is intended for use with suspected or diagnosed spinal injury resulting from trauma or delivery complications; tumor impinging on spine; or temporary immobilization for IV placement. The Papoose provides stabilization of the child's head and spine. It consists of an anatomically shaped shell with an occipital offset to maintain spinal and airway alignment, and prevent plagiocephaly, Sorbatex padding, and the front of a Miami Jr. P0 collar to be worn as indicated. Both the pad and shell may be cleaned. This item is used in in-patient facilities.

CMS HCPCS Workgroup Preliminary Decision:
This item is exclusively used in the hospital inpatient setting. For Medicare, it is included in the DRG payment. For Medicaid coding guidance, submit inquiries to the Medicaid agency in the state in which the claim would be filed. For coding inquiries for private insurers, contact the individual private insurance contractor.

Primary Speaker:
On behalf of Jerome Medical, the primary speaker disagreed with the workgroup's preliminary decision that the papoose is exclusively used in the hospital inpatient setting, and offered the following reasons:

- No L-code exists for an off-the-shelf CTLSO or the visit required to apply it
- Molding or casting a "custom" infant CTLSO is dangerous, costly and time-consuming. It places the infant at unnecessarily increased risk of permanent injury.
- The Papoose is not typically stocked in the hospital. It is stocked by an O&P provider.
- The Papoose is typically applied by an orthotist on a physician's prescription.
- The Papoose may be worn by a hospital in-patient. However, it is also worn or prescribed upon discharge for the duration of orthotic wear.
- The same clinical usage standards as all coded cervical orthotics apply.
- Existing CTO and TLSO codes are for adults and older children and do not adequately cover the indications for a CTLSO. Existing collar codes only reimburse for a standard collar. Existing CTLSO codes are custom codes for adult devices. There are no provisions for the special requirements of sizing and fitting an infant.
- The Papoose offers additional benefits for the infant including: Anterior-Posterior-Lateral Control, Airway Alignment, Plagiocephaly Prevention, Breathable, Removable, Washable Interface material and a Peroneal Strap.

- The Papoose permits patient-caregiver interaction, by allowing the child to be picked up while maintaining immobilization.

Jerome Medical reiterated its request that a new code be established for a cervico-thoracic lumbo-sacral (CTLSO) for infants.

Meeting Agenda Item #4
April 27, 2006
HCPCS Request #06.92

Topic/Issue:
Request to establish a code for a static wrist hand finger orthosis (WHFO).

Background/Discussion:
According to the requester, the WHFO-static is a rigid anterior or posterior framed orthosis with soft straps and closures initiating distal to the elbow, crossing the wrist, and metacarpal phalangeal joints. WHFOs are used to protect medical conditions of the wrist, hand, and fingers during the healing process and/or to prevent contractures and stiffness of the wrist, hand, and/or fingers. The orthosis is custom fabricated, and includes fitting, training, and a limited number of size and position modifications. It does not include modifications that necessitate additional material for patient's changing anatomical, medical, and post surgical needs. There are no codes that adequately describe this type of orthosis. Custom orthoses are individually fabricated to the patient, and are custom designed to address patient variables, including edema, injury, wounds, external and internal hardware, and boney prominences. WHFO-static is durable with a life span of 1-5 years, depending on intended purpose and patient care of orthosis. Its adjustability for repeated use is as follows: In low temperature materials, 2-5 modification can be made to the existing orthosis for size changes due to fluctuations in inflammation and/or position alterations secondary to changes in the status of healing process. Number of adjustments can depend on the nature of low temp plastic utilized and the extent of the adjustments needed. High temperature materials have minimal adjustability. Recommended language: WHFO (wrist/hand/finger orthosis), static.

CMS HCPCS Workgroup Preliminary Decision:
Establish a code:
Lxxxx WRIST HAND FINGER ORTHOSIS, RIGID WITHOUT JOINTS, MAY INCLUDE SOFT INTERFACE MATERIAL, STRAPS, CUSTOM FABRICATED, INCLUDES FITTING AND ADJUSTMENT

Medicare Payment:
Fee schedule amounts are established by the DMERCs in accordance with CMS gap-filling instructions.
Pricing = 38

Primary Speaker:
There was no Primary Speaker for this item.

Meeting Agenda Item #5
April 27, 2006
HCPCS Request #06.93

Topic/Issue:
Request to establish a code for a dynamic wrist hand finger orthosis (WHFO).

Background/Discussion:
According to the requester, the WHFO-dynamic is a rigid anterior or posterior framed orthosis with soft straps and closures initiating distal to the elbow, crossing the wrist, and metacarpal phalangeal joints and may or may not cross the IP joins. This WHFO will have a dynamic or static progressive component (springs, rubber-bands, hinges, turn keys or static progressive pull) at the wrist and/or digits. WHFOs are used to protect medical conditions of the wrist, hand, and fingers during the healing process and/or to prevent contractures and stiffness of the wrist, hand, and/or fingers. The orthosis is custom fabricated, and includes fitting, training, and a limited number of size and position modifications. It does not include modifications that necessitate additional material for patient's changing anatomical, medical, and post surgical needs. WHFO-dynamic is durable with a life span of 1-5 years, depending on intended purpose and patient care of orthosis. Its adjustability for repeated use is as follows: In low temperature materials, 2-5 modifications can be made to the existing orthosis for size changes due to fluctuations in inflammation and/or position alterations secondary to changes in the status of healing process. Number of adjustments can depend on the nature of low temp plastic utilized and the extent of the adjustments needed. High temperature materials have minimal adjustability. Recommended language: WHFO (wrist/hand/finger orthosis), dynamic.

CMS HCPCS Workgroup Preliminary Decision:
Establish a code:
Lxxxx WRIST HAND FINGER ORTHOSIS, INCLUDES ONE OR MORE NONTORSION JOINT(S), ELASTIC BANDS, TURNBUCKLES, MAY INCLUDE SOFT INTERFACE MATERIAL, STRAPS, CUSTOM FABRICATED, INCLUDES FITTING AND ADJUSTMENT

Medicare Payment:
Fee schedule amounts are established by the DMERCs in accordance with CMS gap-filling instructions.
Pricing = 38

Primary Speaker:
There was no Primary Speaker for this item.

Meeting Agenda Item #6
April 27, 2006
HCPCS Request #06.44

Topic/Issue:
Request to establish a code for a dynamic wrist elbow device, trade name: Carp-X Dynamic Lateral Epicondylitis Orthosis.

Background/Discussion:
According to the requester, Carp-X is a unique product for the treatment of lateral epicondylitis (severe tennis elbow). This orthotic device is worn at the wrist to allow the extensor muscle to be at rest during normal daily activities. Carp-X employs usage of the flexor muscles for function in flexion, returning the hand to the extension position without the use of the extensor muscle. There by allowing the tendon fibers to realign. Carp-X is fitted to a patient and recommended usage is six to twenty-four weeks depending on the severity of the patient's condition.

CMS HCPCS Workgroup Preliminary Decision:
No insurer identified a national program operating need to establish a new code to distinguish this item from other products coded in the L3908 code category. Existing code L3908 WHFO, WRIST EXTENSION CONTROL COCK-UP, NON MOLDED, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT adequately describes the item that is the subject of the application. Use of L3906 or L3999 or other miscellaneous codes is not appropriate.

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

Primary Speaker:
There was no Primary Speaker for this item.

Meeting Agenda Item #7
April 27, 2006
HCPCS Request #06.45

Topic/Issue:
Request to establish a code for a functional wrist orthosis, trade name: C.Ti. Custom Wrist Brace Model.

Background/Discussion:
According to the requester, dorsal wrist orthosis designed to help restore functional and structural characteristics of the wrist that have been compromised by injury or surgery. C.Ti. has a bi-articulating hinge system that enables controlled movement of the wrist specific to the patient's range-of-motion. If necessary, ulnar and radial deviation can also be limited. Adustable extension clips, ranging from 0-60°, allow C.Ti to accommodate improvements in patient range-of-motion during rehabilitation. C.Ti. is used post-inury and/or post-surgery to limit and control patient movement, thereby protecting the integrity of the surgery and helping to prevent injury during rehabilitation.

CMS HCPCS Workgroup Preliminary Decision:

Establish code:
Lxxxx WRIST HAND ORTHOSIS WITH JOINTS, MAY INCLUDE SOFT INTERFACE MATERIAL, STRAPS, PREFABRICATED, INCLUES FITTING AND ADJUSTMENT. This is not considered a custom-made orthosis.

Medicare Payment:
Fee schedule amounts are established by the DMERCs in accordance with CMS gap-filling instructions.
Pricing = 38

Primary Speaker:
On behalf of Innovation Sports, Inc., the primary speaker agreed with the workgroup's preliminary decision to establish a code, but disagreed with the workgroup's statement that the CTi Custom Wrist Orthosis is not considered a custom made orthosis. The speaker stated that CTi is truly a wrist orthosis; completely hand fabricated using a positive cast-mold of the patient's hand, wrist and forearm. As a result, this unique orthosis can be constructed to fit anatomical abnormalities of the hand and wrist that have been compromised by injury or surgery.

Meeting Agenda Item #8
April 27, 2006
HCPCS Request #06.46

Topic/Issue:
Request to establish a code for a functional wrist orthosis, trade name: C.Ti. Wrist Brace Off-the-Shelf Model.

Background/Discussion:
According to the requester, C.Ti wrist brace is a rigid, dorsal wrist orthosis designed to help restore functional and structural characteristics of the wrist that have been compromised by injury or surgery. C.Ti. has a bi-articulating hinge system that enables controlled movement of the wrist specific to the patient's range-of-motion. If necessary, ulnar and radial deviation can also be limited. Adustable extension clips, ranging from 0-60°, allow C.Ti to accommodate improvements in patient range-of-motion during rehabilitation. C.Ti. is used post-inury and/or post-surgery to limit and control patient movement, thereby protecting the integrity of the surgery and helping to prevent injury during rehabilitation.

CMS HCPCS Workgroup Preliminary Decision:
Establish code:
Lxxxx WRIST HAND ORTHOSIS, WITH JOINTS, MAY INCLUDE SOFT INTERFACE MATERIAL, STRAPS, PREFABRICATED, INCLUES FITTING AND ADJUSTMENT

Medicare Payment:
Fee schedule amounts are established by the DMERCs in accordance with CMS gap-filling instructions.
Pricing = 38

Primary Speaker:
There was no Primary Speaker for this item.

Meeting Agenda Item #9
April 27, 2006
HCPCS Request #06.64

Topic/Issue:
Request to establish a code for a dynamic ankle foot orthosis, trade name: Foot-Up Ankle Foot Orthosis.

Background/Discussion:
According to the requester, the Foot-Up is a lightweight ankle-foot orthosis designed to provide dynamic support for drop foot and associated neurological conditions affecting active dorsiflexion. The orthosis provides visible improvement in gait by providing support the moment the foot is raised. As dynamic support, the Foot-up enables the user to improve gait without wearing a static, rigid, plastic AFO which impedes range-of-motion and is uncomfortable against the skin and inside the shoe. Foot-up consist of two main parts, an ergonomic ankle wrap and a plastic shoe inlay. The plastic inlay fits discretely between the tongue and laces of the shoe and attaches to the ankle wrap via a powerful elastic strap featuring a quick-release clip. The cushioned ankle wrap is breathable 3-layer material, which can be worn comfortably for long periods of time without causing skin irritation or impeding the foot's range-of-motion. Foot-Up is indicated for patients who have experienced nerve damage due to a traumatic injury or post surgical nerve damage, CVA or degenerative nerve conditions causing palsy and the condition of drop foot.

CMS HCPCS Workgroup Preliminary Decision:
No insurer identified a national program operating need to establish a code to identify this item. It is not an orthotic. For Medicare, there is no benefit category, and code A9270 NON-COVERED ITEM OR SERVICE should be used. For guidance regarding appropriate coding for Private Sector health insurance systems, please contact the individual private insurance contractor. For Medicaid systems, please contact the Medicaid Agency in the state in which the claim is being filed. Use of code L codes or miscellaneous codes is inappropriate.

Medicare Payment:
This product is not covered.

Primary Speaker:
There was no Primary Speaker for this item.

Meeting Agenda Item #10
April 27, 2006
HCPCS Request #06.60

Topic/Issue:
Request to establish a code to identify pelvic rotation function for a reciprocating gait orthosis (RGO), trade name: Otto Bock RGO Hip Joint System.

Background/Discussion:
According to the requester, this hip control system utilizes a single push/pull cable to create a reciprocating gait motion. Unlike all other reciprocating gait orthosis hip joints, this feature provides for and accommodates pelvic rotation in addition to flexion and extension allowing for a smoother and more energy efficient gait pattern because there is less vertical and horizontal displacement of the Center of Mass during the gait cycle. It also has a unique unlocking mechanism that allows for safer and easier sitting. This is accomplished through a two-step process: pushing a button to engage the unlocking system, then squaring their body in front of a chair and with a slight hip extension moment, releasing the mechanism hip lock. This will not engage unless both hip joints are in complete alignment as an added safety feature. The RGO Hip Joint System includes a tubular metal pelvic band that is all that needs to be replaced to accommodate any patient growth, saving the additional cost of hip joint replacement and associated labor. It also includes special hip joints, vertical uprights, thoracic belt, prefabricated system attached to a custom RGO/HKAFO system.

CMS HCPCS Workgroup Preliminary Decision:
Use existing code L2999 LOWER EXTREMITY ORTHOSIS, NOT OTHERWISE SPECIFIED. No insurer identified a national program operating need to create a code to identify this device. Due to low volume of documented use, the administrative burden of establishing a new code is not warranted.

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

Primary Speaker:
There was no Primary Speaker for this item.

Meeting Agenda Item #11
April 27, 2006
HCPCS Request #06.47

Topic/Issue:
Request to establish an add-on code for dj Orthopedics FourcePoint Hinge. Applicant's Suggested language: L2XXX – "Addition to lower extremity orthoses, directional resistance knee joint, adjustable, each"

Background/Discussion:
According to the requester, the FourcePoint Hinge is a novel technology intended to improve knee stability and movement patterns. It behaves similarly to a polycentric knee joint (with unrestricted range-of-motion) up to the last 25-degrees of extension, where a mechanism engages that gradually resists further knee extension. The FourcePoint Hinge has both engagement and resistance adjustment. The hinge provides improved knee stability and function for patients and those with knee instability or ligament reconstruction.

CMS HCPCS Workgroup Preliminary Decision:
Use existing L codes to identify the brace without using add-ons. The joint is included in the brace. Prefabricated devices are coded as complete devices, and use of add-on codes is inappropriate.

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

Primary Speaker:
On behalf of dj Orthopedics, the primary speaker disagreed with the workgroup's preliminary decision and reiterated his request for the establishment of a HCPCS code as follows:

L2xxx Addition to lower extremity orthosis, directional resistance knee joint, adjustable, each.

The speaker stated that a new add-on code is needed and that FourcePoint™ Hinge is not adequately described by any current code because it is functionally and therapeutically different from joints described by all existing codes. The speaker claims that improved stabilization, knee Range of Motion (ROM) and gait normalization is unique to the FourcePoint Hinge. The speaker also claims that none of the joints described by current codes allow unrestricted, full ROM and apply gradually increasing resistance during extension.

Meeting Agenda Item #12
April 27, 2006
HCPCS Request #06.106

Topic/Issue:
Request to establish a code for an orthotic knee, trade name: Horton's Stance Control Orthotic Knee™ Joint System or SCOKJ® System.

Background/Discussion:
According to the requester, SCOKJ is an innovative type of external knee joint that automatically prevents knee collapse during stance phase, but releases to permit normal knee motion during swing phase. Because it only uses a patented one-way cam mechanism, the Horton's system is the only mechanical orthotic stance control option that always permits the knee to extend freely. It is not a lock, but is instead a biomechanically sophisticated component that prevents the knee from collapsing regardless of flexion angle without interfering with either knee extension or swing phase knee motion. SCOKJs are primarily intended for incorporating into custom KAFOs, and have also been used successfully for selected prosthetic patients with chronic problems with knee control. For amputee cases, the Horton's joints are applied adjacent to the patient's knee and incorporated into the custom prosthesis. "Last years new L2005 code does not accurately accommodate the versatility of Horton's SCOKJ® system and is much better suited for single stance control joint designs than the dual stance control configuration that is unique to Horton's design." Recommended language is Mechanical stance control knee joints that block knee collapse into flexion while permitting free knee extension, with automatic release for swing phase flexion, using any mechanical actuation method.

CMS HCPCS Workgroup Preliminary Decision:
When used as an orthotic, 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, adequately describes this device. L2005 encompasses the total KAFO, including stance control. Use of miscellaneous or add-on codes is inappropriate. When used as on prosthetic, code L5999 LOWER EXTREMITY PROSTHESIS, NOT OTHERWISE SPECIFIED may be used.

Medicare Payment:
Fee schedule and payment rules associated with existing code apply to this product.
Pricing = 38 (L2005) Pricing = 46 (L5999)

Primary Speaker:
There was no Primary Speaker for this item.

Meeting Agenda Item #13
April 27, 2006
HCPCS Request #06.121

Topic/Issue:
Request to establish a code for an orthotic knee, trade name: Becker 9001 E-Knee.

Background/Discussion:
According to the requester, Becker E-Knee is an electrically controlled orthotic knee joint component, with associated hardware, that must be incorporated into a custom-made lower limb orthosis for patient use. The knee joint provides a lock against flexion that can be disengaged when appropriate but always permits free extension. An intelligent controller, via input from the foot sensor, determines when it is safe to release the knee flexion lock allowing unrestricted knee motion during swing phase. E-Knee is indicated for individuals with complicated physical disabilities including quadriceps weakness or paralysis. Individuals that have significantly impaired voluntary hip control, in addition to impaired knee and ankle stability, can use the 9001 E-Knee safely and effectively. Recommended language is Addition to custom made lower limb orthoses, stance control knee joint mechanism that is automatically engaged during stance phase and disengaged during swing phase, electronically activated.

CMS HCPCS Workgroup Preliminary Decision:
Use existing code L2999 LOWER EXTREMITY ORTHOSES, NOT OTHERWISE SPECIFIED. No insurer identified a national program operating need to create a code to identify this device. The administrative burden of establishing a new code is not warranted due to low volume of documented use.

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

Primary Speaker:
On behalf of Becker Orthopedic, the primary speaker disagreed with the workgroup's preliminary decision and reiterated his original request that a HCPCS code be granted to identify this electronic stance control component for a custom-made knee ankle foot orthosis. The speaker stated that mechanical stance control devices represent significant biomechanical advances over the historical "locked knee brace" that was the prior state of the art. Mechanical stance control options differ in complexity, cost, and biomechanical sophistication however they have overlapping clinical indications and are all designed for individuals with knee paralysis or weakness. According to the speaker, patients with complicated physical disabilities that have significantly impaired voluntary hip control, in addition to impaired knee and ankle stability, can use the 9001 E-Knee safely and effectively.

Meeting Agenda Item #14
April 27, 2006
HCPCS Request #06.95

Topic/Issue:
Request to establish a code for a dynamic patella traction brace, trade name: Q Lok Dynamic Patella Traction Brace.

Background/Discussion:
According to the requester, Q-Lok is a device used as part of an overall treatment/rehab program for anterior knee pain resulting from maltracking patella. The Q-Lok reduces pain by applying a force to increase the surface contact area within the patellofemoral joint. It also stretches the lateral retinaculum with the Calibrated Patella Traction strap. The calibrated patella traction strap is adjustable which allows varying pressure to be applied to the patella thus increasing the patellofermoral articular surface contact area. By using this intermittent medial traction force long-term, results can be achieved to relocate the patella in its proper tracking pattern. Q-Lok is clinically indicated for anterior knee pain that affects approximately 25% of the population. Recommended language: Knee orthosis, double uprights, adjustable calibrated patella traction, intermittent medial/lateral traction control, prefabricated, includes fitting and adjustment.

CMS HCPCS Workgroup Preliminary Decision:
Existing code L1820 KNEE ORTHOSIS, ELASTIC, WITH CONDYLAR PADS AND JOINTS, WITH OR WITHOUT PATELLAR CONTROL, PREFBRICATED, INCLUDES FITTING AND ADJUSTMENTS, adequately describes this device. Use of add-on codes for prefabricated orthoses is inappropriate. "Patella control", as in L1820, means patella control by any method.

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

Primary Speaker:
On behalf of Cropper Medical, Inc., the primary speaker disagreed with the workgroup preliminary decision. The speaker claimed that code L1820 does not describe the Q Lok device, and claimed differences in function and indications between the Q Lok and devices coded at L1820 as follows:

- The Q Lok™ Brace treats a mal-tracking patella providing correction to the lateral tracking patella thus reducing the incidences of surgical intervention the L1820 code does not.
- The Q Lok has a progressive patellar traction treatment program. L1820 is not dynamic, in that it does not apply an adjustable force.

The speaker requested that the workgroup reconsider the creation of a code for the Q Lok Brace.

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.