Centers for Medicare & Medicaid Services (CMS)
HCPCS Public Meeting Summary Report for:
Orthotics and Prosthetics Public Meeting
June 7, 2005

Public Meeting Introduction and Overview

Michael Barron, CMS Office of Operations Management, moderated the meeting. Approximately 50 people attended. The agenda included 23 items.

Cindy Hake provided an overview of the public meeting process and the overall HCPCS process. She also discussed the survey of stakeholders regarding needed changes to the HCPCS process, the nature of responses to the survey, and the nature of changes already made, as well as pending changes, included in the reformation of the HCPCS process. Monitor the HCPCS world-wide website for announcement of changes to the HCPCS coding process at www.cms.hhs.gov/medicare/hcpcs.

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. This 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://cms.hhs.gov/providers/pufdownload/default.asp#dme.

CMS HCPCS Public Meetings provide an opportunity for CMS to share its preliminary coding decisions and payment recommendations, and an opportunity for interested parties to make oral presentations and submit written comments in reaction to CMS' these coding and pricing recommendations.

Prior to the Public Meetings the CMS HCPCS workgroup meets to review the coding requests on the public meeting agenda, and to make a preliminary coding decision. CMS also makes preliminary decisions regarding the applicable 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 included in the public meeting agendas.

Following the public meeting, the CMS HCPCS workgroup will reconsider its preliminary coding decisions based on the input heard at the Public Meetings. Afterwards, the workgroup will decide on its final recommendations. CMS maintains the permanent HCPCS level II codes, and reserves final decision making authority concerning requests for permanent HCPCS codes. Final decisions regarding Medicare payment are made by CMS and must comply with the Statute and Regulations. Payment determinations for non-Medicare insurers, (e.g., state Medicaid Agencies or Private Insurers) are made by the individual state or insurer.

HCPCS Public Meetings are not workgroup meetings. No final decisions are made at the public meetings. All requestors will be notified in writing, in early November, of the workgroup's 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 for new supplies are posted on the official HCPCS world wide web site at: http://cms.hhs.gov/medicare/hcpcs/default.asp. The standard application form 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.

Public Meeting Summary

The following information includes a detailed summary of each request on the Public Meeting Agenda, along with CMS' preliminary decisions and rationale, and summaries of presentations made by primary speakers.

Meeting Agenda Item #1
June 7, 2005
HCPCS Request #05.109

Background/Discussion:
Kathy Dodson of American Orthotic and Prosthetic Association submitted a request to establish a code for the "addition to Knee Ankle Foot Orthosis, articulation at ankle joint." According to the requester, the addition to a Knee Ankle Foot Orthosis (KAFO), allows free plantar and dorsiflexion motion at the ankle. This allows many clinical options for treating the patient's ankle foot pathologies when using a KAFO to address knee instability. Further description includes the application of components and modification to the ankle area of KAFO to allow motion at the ankle in the plantarflexion or dorsiflexion range of motion. The allowance of motion at the ankle can be valuable in several ways. Without this plantarflexion, the knee would be translated forward due to solid nature of the foot/ankle portion of the KAFO. This would significantly increase the risk of falls. Also dorsiflexion range allowance at the ankle can be beneficial to the flaccid paralytic, to maintain passive dorsiflexion range of motion which will contribute to the reduced risk of plantarflexion contractures.

CMS HCPCS Workgroup preliminary decision: To use existing codes L2036 (knee ankle foot orthosis, full plastic, single upright, free knee with or without free motion ankle, custom fabricated); L2037 (knee ankle foot orthosis, full plastic, single upright, free knee, with or without free motion ankle, custom fabricated); or L2039 (knee ankle foot orthosis, full plastic, single upright, poly-axial hinge, medial lateral rotation control, with or without free motion ankle, custom fabricated) as appropriate.

Codes L2036, L2037 and L2039 were revised effective January 1, 2005 to include the language "WITH OR WITHOUT FREE MOTION ANKLE". These revised codes adequately describe the item that is the subject of your request.

Primary Speaker – Kathy Dodson of America Orthotic and Prosthetic Association asked CMS to reconsider its decision and AOPA's request that a new code be created to accommodate those situations where an ankle joint is needed. Ms. Dodson expressed some concern that "with or without" phrasiolgy makes it difficult for payers to know what they are buying. She is concerned that free motion ankle was not factored into the base code, then suppliers are expected to give away components or that the device is not provided to patients "because Medicare is unable to reimburse us for it".

Meeting Agenda Item #2
June 7, 2005
HCPCS Request #05.113

Background/Discussion:
Kathy Dodson of American Orthotic and Prosthetic Association submitted a request to establish a new "L" code with the following requested language: "Knee Ankle Foot Orthosis (KAFO), full plastic, with knee joint, multi-axis ankle, (Lively Orthosis or Equal), custom fabricated". According to the requester, this device is differentiated from other orthoses that cross the knee ankle and foot (KAFO's) by its design and componetry. Its most unique characteristic is its ankle joint, which permits movement in a saggital, transverse and coronal planes. It also embodies a knee joint component, which by utilizing one of the various knee joint additions, imparts specific range of motion control to the knee. Its body panels would consist of thermo-formable or thermosetting plastics and would be rigid so as to effectively transfer force across the knee and ankle joints. Finally, a strapping system is designed to effectively keep the orthosis in close contact with the extremity. According to the applicant, in 2005, the descriptor for L2038 was changed to read "without knee joint", and, since there are times when a knee joint is utilized, to manage both knee and ankle contractures, and a code is needed to describe a device provided with a knee joint.

CMS HCPCS Workgroup preliminary decision: To use revised code L2038 to read: knee ankle foot orthosis, full plastic with or without knee joint, multi-axis ankle, custom fabricated.

The "Lively" Orthosis was a predicate product for code L2308. However, the brand name "Lively" was omitted from the code to clarify that the code represents a category of similar products, rather than a single, individual products or brand. The language "WITH OR WITHOUT KNEE JOINT" was added to clarify that product with or without knee joints are included in this code category.

Primary Speaker – Kathy Dodson of the American Orthotic and Prosthetic Association expressed her concern that the "with or without" phrasiology in codes may lead to inaccurate reimbursement. Ms. Dodson suggested the addition of a new code that would be a companion code current L2038 and would allow the provision of this orthosis with a knee joint. Ms. Dodson also suggested that CMS not make changes to the wording of L2038.

Meeting Agenda Item #3
June 7, 2005
HCPCS Request #05.114

Background/Discussion:
Kathy Dodson of American Orthotic and Prosthetic Association submitted a request to establish a new "L" code for Polycentric Knee Joint to replace L2435 ADDITION TO KNEE JOINT, POLYCENTRIC JOINT, EACH JOINT, which was discontinued 12/31/04. According to the requester, Polycentric Knee joints are used as the knee joints of orthoses that cross the anatomical knee joint (typically Knee Orthoses (KO) or Knee Ankle Foot Orthoses (KAFO)). The joints allow flexion and extension through a normal range of motion. The joints are actually added to the device as fabrication of the device occurs. The general term for polycentric actually describes several types of joint mechanisms developed, produced and marketed by multiple manufacturers and distributors. The term "polycentric" by its very nature implies "more than one center of rotation". This general description is further described by the functional breakdown of "bi-centric" joints. This means that they have two (2) centers of rotation about which motion occurs. Polycentric joints are indicated for any patient who uses a device where closely duplicating the relationship of the anatomical knee joint enhances the stability of the knee and where sheer or excessive pressures can put the patient at risk for further injury to knee joint, or to the skin tissues on the surface of the leg itself.

CMS HCPCS Workgroup preliminary decision: To establish a new "L" code.

L???? Addition to lower extremity orthosis, polycentric knee joint, for custom fabricated orthosis, each joint.

Use new code L???? to identify a polycentric knee joint when used with a custom fabricated KAFO. It is not appropriate to bill separately for this item for a prefabricated KAFO.

Primary Speaker – Kathy Dodson of the American Orthotic and Prosthetic Association spoke about her concern that the newly established L code is limited to custom items, and that there is not a mechanism to bill for a polycentric knee joint in a prefab item, forcing all patients who need it into a more expensive custom device.

Meeting Agenda Item #4
June 7, 2005
HCPCS Request #05.110 A&B

Background/Discussion:
Kathy Dodson of American Orthotics & Prosthetics Association submitted a request to establish a code for (**A**) Upper Extremity Prosthetic Glove Silicone, Production Glove; and (**B**) Upper Extremity Prosthetic Glove Silicone, Custom. According to the requester, these items are a prosthetic covering for upper extremity terminal devices fabricated from raw silicone materials. They are utilized on approximately one half of the upper extremity amputee population who are active wearers of a prosthesis, approximately 65% are production gloves and 35% are custom fabricated.

CMS HCPCS Workgroup preliminary decision: To use existing code L6890 (addition to upper extremity prosthesis, glove for terminal device, any material, prefabricated, includes fitting and adjustment); or L6895 (addition to upper extremity prosthesis, glove for terminal device, any material, custom fabricated) as appropriate.

An existing code, L6890, adequately describes prefabricated gloves for terminal devices, a category of items which are functionally similar to the item in this coding request. There are no significant therapeutic distinctions between the category of items described in this code and the item in the coding request. The existing code, L6890, adequately describes custom gloves for terminal devices. The code does not specify the type of material. The material presented (Silicone), does not alter the functionality of the basic device and is considered to be included in the code description. No insurer identified a national program operating need to alter the existing code set to differentiate gloves for terminal devices based on material if pricing is a concern, contact the insurer in whose jurisdiction a claim would be filed. For Medicare, contact CMS' Inherent Reasonableness authority. For Medicaid systems, contact the Medicaid Agency in the state in which a claim would be filed. For private insurance systems, contact the individual private insurance.

Primary Speaker – Kathy Dodson of the American Orthotics and Prosthetics Association disagrees with the workgroup decision and thinks that there is a clinical and functional reason to distinguish silicone gloves from gloves made of other materials. She commented that codes that do not specify material do not allow for recognition of significantly higher costs involved in silicone gloves. Ms. Dodson also commented about direction from CMS in terms of the appropriate venue for raising pricing concerns.

Meeting Agenda Item #5
June 7, 2005
HCPCS Request #05.151

Background/Discussion:
William Hanson of Liberating Technologies, Inc. submitted a request to establish a code for protective silicone semi-custom outer leg cover, Trade Name: Skinergy. According to the requester, the protective outer silicone leg cover is applied to the outer covering of the trans-tibial prostheses by a prosthetic technician. Skinergy acts as a protective barrier for the interior components. With over 25% stretch qualities the product is not limited to certain interior components and can accommodate for instance feet and ankle systems that possess a range of movement. The product technology was derived from prosthetic silicone gloves for upper extremity hands. According to the applicant, the silicone outer leg cover differs from other products currently coded at L5962 ADDITION, ENDOSKELETAL SYSTEM, BELOW KNEE, FLEXIBLE PROTECTIVE OUTER SURFACE COVERING SYSTEM in the following ways: 1) the silicone product is more elastic and usable for more types of feet and ankle systems, including adjustable height ankles and high-activity prosthetic feet; 2) silicone is more stain resistant (and therefore would need to be replaced less often than PVC products); 3) the manufacturing process and raw materials are more costly for silicone than for PVC products, therefore existing reimbursement is inadequate.

CMS HCPCS Workgroup preliminary decision: To use existing code, based on level of disarticulation: L5962 (addition, endoskeletal system below knee, flexible protective outer surface covering system; L5964 (addition, endoskeletal system, above knee, flexible outer surface covering system; or L5966 (addition, endoskeletal system, HIP disarticulation, flexible protective outer surface covering system.

Existing codes L5962, L5964 and L5966 (depending on level of disarticulation), adequately describe endoskeletal protective outer surface covers. There are no significant therapeutic distinctions between the category of items described in this code and the items in the coding request. These codes do not specify the type of material used in fabrication. The material presented (silicone), does not alter the function of the device and is considered to be included in the code description. For any issues regarding pricing of this item, the applicant should contact individual insurers. For Medicare, contact CMS' Inherent Reasonableness authority. For Medicaid systems, contact the Medicaid Agency in the state which a claim would be filed. For private insurance systems, contact the individual private insurance contractor.

Primary Speaker – William Hanson of Liberating Technologies, Inc. does not agree with the preliminary decision. According to Mr. Hanson, existing codes for below-knee and above-knee leg covers are unsuitable because they do not adequately describe the present class of leg covers and important distinctions between these and traditional covers. These codes were established when leg covers were made of Polyvinyl Chloride (PVC) which has distinctly different performance characteristics than silicone. Leg covers not only protect the prosthetic leg components form contamination, corrosion and

possible physical damage, but they are essential for some users in portraying the image they desire. One of the most common reasons that people with amputation reject their prosthesis is its appearance. A stained cover is often cited as the primary reason people stop wearing their prosthesis.

Silicone has a more skin-like feel and is unaffected by temperature unlike PVC which softens in heat and stiffens in cold climates. Due to its elasticity it maintains it shape better than PVC and doesn't get baggy. Finally, silicone is cost-effective. Often leg covers are replaced because they are stained. Although silicone leg covers are more expensive than PVC, considering the cost of the service call and the longevity, it is less costly in the long-term to use silicone than PVC.

Meeting Agenda Item #6
June 7, 2005
HCPCS Request #05.62

Background/Discussion

Barbara Rohan of Smith and Nephew, Inc. has submitted a request to establish a code for Computer Assisted External Fixation Struts, Trade Name: Taylor Spatial Frame (TSF) Standard and Fast Fx Struts. The requester claims that there is no existing HCPCS code which describes the struts used with computer assisted external fixation systems, which has created problems, for physicians seeking payment for these items. Applicant requests the following language: Lxxxx "COMPUTER ASSISTED EXTERNAL FIXATION STRUT, EACH". According to the requester, the External fixation systems stabilize bone fractures, bringing them into proper alignment and correcting limb deformities. The Taylor Spatial Frame is an external fixation system that consists in part of pins that are inserted into the bone above and below a fracture, rings or plates that attach to the pins and encircle the limb, and telescoping and pivoting struts that connect the rings or plates together. It is used to stabilize fractures and correct multi-planar and transitional deformities simultaneously. It is the only system that also includes computer software that assists physicians in calculating a prescription for strut adjustment and replacement that allows gradual correction of fractures and deformities. The software transforms measurements of a patients fracture or deformity into a prescription for: 1) when and how much a patient should lengthen or shorten his or her struts; and 2) when a patient should come into a doctor's office to have one of his or her struts replaced.

CMS HCPCS Workgroup preliminary decision:
Inappropriate for HCPCS Level II coding. Do not establish a code.

This is a tensioning adjustment professional service, done as an office procedure, incident to joint replacement. The struts are not separately billable. Therefore, it is unnecessary to establish a HCPCS Level II code, and inappropriate to use miscellaneous codes. CMS recommends that the applicant approach the American Medical Association (AMA) for a ruling regarding appropriate CPT coding for the professional service.

Primary Speaker – Dr. Francis McGuigan on behalf of Smith and Nephew, Inc,:

- We disagree with the HCPCS Workgroup initial decision that a HCPCS level II code is inappropriate, and the recommendation that we seek a CPT code for the procedure.
- The RBRVS payment covers the professional service, but is inadequate to pay for the strut itself.
- As a sophisticated piece of hardware necessary for a covered, medically necessary therapy, it would be most appropriately paid as medical equipment or a supply.

Meeting Agenda Item #7
June 7, 2005
HCPCS Request #05.64

Background/Discussion:
Mitchell Dobson of Hanger Prosthetics & Orthotics submitted a request to clarify with a new code or code revision a Symes level amputation, and suggests a revision of code L5700 to read "REPLACEMENT SOCKET, BELOW KNEE/SYMES, MOLDED TO PATIENT MODEL". This code currently reads: REPLACEMENT, SOCKET, BELOW KNEE, MOLDED TO PATIENT MODEL. According to the requester, the socket portion of the prosthesis is the most critical part of a prosthesis as its function is to distribute axial load, transverse sheer and regular forces onto the residual limb during gait and other activities of daily living. There are existing codes for many other levels of lower extremity amputation, however (according to the requester) the Symes level does not currently have a replacement code. The Symes socket is used for Symes (ankle disarticulation) level amputations and benefits the patient by allowing distribution of ground reaction forces over the residual limb allowing patients to ambulate and participate in other normal activities.

CMS HCPCS Workgroup preliminary decision: To establish two new "L" codes.

L???? Ankle, symes, molded to patient model socket without solid ankle cushion heel (sach) foot, replacement only.

L???? All lower extremity prosthesis, solid ankle cushion heel (sach) foot, replacement only.

Use new code L???? to describe the item that is the subject of this request.

Primary Speaker – Mitchell Dobson of Hanger Prosthetics & Orthotics is pleased with the preliminary decision to establish the two new codes listed above. Mr. Dobson suggests that revising the L5700 "Below Knee" socket code to include Symes level of amputation would remain consistent with other replacement socket coding and would further limit expansion of the L code set. Additionally, the Workgroup's preliminary decision to add L???? All lower extremity prosthesis, solid ankle cushion heel (sach) foot, replacement only, is met with great support. This code has been needed for sometime and should reduce the number of L5999 NOS codes billed. Mr. Dobson suggested that he would make at this time relative to this code is the limitation of this code by specifically excluding the "external keel sach foot", which is coded as L5970 (All Lower Extremity Prostheses, Foot, External Keel, SACH Foot). This external keel feature requires significantly more time and materials to fabricate and should remain a separate code, not included under the proposed replacement code.

Meeting Agenda Item #8
June 7, 2005
HCPCS Request #05.65

Background/Discussion:

Larry Lange of Prosthetic Design submitted a request to establish a code for a dynamic response endoskeletal connector for prostheses, trade name: FlexCon Endoskeletal Adapter. The requester claims that there is no HCPCS code that accurately describes the functions of the FlexCon™ adapters. According to the requester, the FlexCon endoskeletal adapter is a unique, patented component that permits restricted range of motion in the hip joint on the amputated side. It also provides stance flexion in early stance and a dynamic response effect in late stance. Because the FlexCon is made from high strength, lightweight carbon fiber composite material, it can also function as a leaf spring to increase the overall flexibility of the prosthesis. FlexCon is available in multiple configurations to accommodate differing amounts of joint contracture and varying residual limb lengths; and is used primarily for individuals who have a knee disarticulation or higher level of amputation combined with a significant flexion or flexion-abduction contracture of the ipsilateral hip joint. This component can also be retrofitted into an existing endoskeletal prosthesis, to accommodate changes in the amount of contracture or to correct a mal-aligned prosthesis without replacing the entire artificial limb. When the proper Flexcon adapter is used, the hip flexion contracture can be fully accommodated and the knee center located in the optimal position, posterior to the weight bearing line.

CMS HCPCS Workgroup preliminary decision: To use existing code L5920 addition, endoskeletal system, above knee or hip disarticulation, alignable system.

Your request for a separate code has not been approved because your product is an integral part of the alignable system and included in code L5920. Your product may not be billed separately for Medicare. The use of code L5999 is inappropriate for this item. For Medicare, L5920 is the appropriate code. 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.

There was no Primary Speaker for this item.

Meeting Agenda Item #9
June 7, 2005
HCPCS Request #05.87

Background/Discussion:

Bernie Tatro of Jerome Medical has submitted a request to establish a code for non-conductive Halo Traction Ring and Skull Pins, Trade Name: Resolve Halo System. According to the requester, 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 and treatment of unstable cervical spine 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 head and spinal alignment. The patient may wear the unit for six to twelve weeks without removal. During that time the patient may require diagnostic procedures such as magnetic resonance imaging. The requester is seeking a new code "to provide reimbursement when newer non-conductive materials are required for patient safety and optimal imaging" and that "would compensate for the increased expense of high-tech insulative materials". Requester suggests the following language: "ADDITION TO HALO PROCEDURES, NON-CONDUCTIVE RING AND SKULL PINS".

CMS HCPCS Workgroup preliminary decision: To establish a new "L" code.

L???? Addition to halo procedure, magnetic resonance image compatible system, glass composite with ceramic tipped pins.

Revise L0860 which currently reads (addition to halo procedures, magnetic reasonance image compatible system), to instead read: Addition to halo procedure, magnetic resonance imaging compatible system, carbon composite ring and titanium pins.

Primary Speaker – Lisa Tweardy, Director of Research & Development, Jerome Medical, supports new "L" code with a minor edit. To have new "L" code read "Addition to halo procedure, magnetic resonance image compatible system, glass composite ring with ceramic-tipped pins". Disagrees with the wording on L0860. Suggests L0860 reads "Carbon Composite Ring and Titanium Pins" w/o MR compatibility reference.

Meeting Agenda Item #10
June 7, 2005
HCPCS Request #05.69 A-C

Background/Discussion:
Stephanie Bucklin of Hanger Prosthetics and Orthotics, Inc. submitted a request to establish 3 new codes for upper extremity prosthetic addition of carbon acrylic socket laminations for below elbow; above elbow; and shoulder disarticulation levels, and request for the following language: A) ADDITION TO UPPER EXTREMITY PROSTHESIS, CARBON ACRYLIC SOCKET LAMINATION, FOR ELBOW FRAME OR FOREARM SECTION, B) ADDITION TO UPPER EXTREMITY PROSTHESIS, CARBON ACRYLIC SOCKET LAMINATION, FOR ABOVE ELBOW FRAME OR HUMERAL SECTION, AND C) ADDITION TO UPPER EXTREMITY PROSTHESIS, CARBON ACRYLIC SOCKET LAMINATION, FOR SHOULDER DISARTICULATION OR HIGHER CAP-STYLE FRAME. According to the requester, carbon acrylic socket lamination is obtained during the fabrication of the outer frame of an upper extremity prosthesis. The carbon acrylic socket lamination for a forearm section (for elbow or wrist disarticulation), humeral section (for above elbow or elbow disarticulation), or shoulder cap-style frame (for shoulder disarticulation or higher) benefits the patient because of its lightweight; and improved material strength and durability. When used with flexible inner sockets or gel socket insert systems, openings may be cut in the carbon fiber material without compromising the strength of the frame, allowing the inner socket or liner to expand and retract with muscle contractions.

CMS HCPCS Workgroup preliminary decision: To establish six new "L" codes as add-on codes for material, billable with base code:

L???1 Addition to upper extremity prothesis, below elbow/wrist disarticulation ultralight material (titanium, carbon fiber, or equal)
L???2 Addition to upper extremity prosthesis, above elbow/wrist disarticulation ultralight material (titanium, carbon fiber, or equal)
L???3 Addition to upper extremity prosthesis, shoulder disarticulation/interscapular thoracic ultralight material (titanium, carbon fiber or equal)
L???4 Addition to upper extremity prosthesis, below elbow/wrist disarticulation, acrylic material.
L???5 Addition to upper extremity prosthesis, above elbow/elbow disarticulation, acrylic material.
L???6 Addition to upper extremity prosthesis, shoulder/disarticulation/interscapular thoracic, acrylic material.

Use new code L???4, L???5, L???6, as appropriate, based on disarticulation level.

Primary Speaker – Stephen Mandacina of Hanger Prosthetics & Orthotics, agrees with the preliminary decision to establish six new L codes.

Meeting Agenda Item #11
June 7, 2005
HCPCS Request #05.70 A-F

Background/Discussion:

Stephanie Bucklin of Hanger Prosthetics and Orthotics, Inc. submitted a request to establish 6 codes for replacement sockets; with requested language as follows: A) REPLACEMENT, SOCKET, BELOW ELBOW/WRIST DISARTICULATION, NOT FOR USE WITH EXTERNAL POWER, MOLDED TO PATIENT MODEL, B) REPLACEMENT, SOCKET, BELOW ELBOW/WRIST DISARTICULATION, FOR USE WITH EXTERNAL POWER, MOLDED TO PATIENT MODEL, C) REPLACEMENT, SOCKET, ABOVE ELBOW/ELBOW DISARTICULATION, NOT FOR USE WITH EXTERNAL POWER, MOLDED TO PATIENT MODEL, D) REPLACEMENT, SOCKET, ABOVE ELBOW/ DISARTICULATION, FOR USE WITH EXTERNAL POWER, MOLDED TO PATIENT MODEL, E) REPLACEMENT, SOCKET, SHOULDER DISARTICULATION/INTERSCAPULAR THORACIC, NOT FOR USE WITH EXTERNAL POWER, MOLDED TO PATIENT MODEL, F) REPLACEMENT, SOCKET, SHOULDER DISARTICULATION/INTERSCAPULAR THORACIC, FOR USE WITH EXTERNAL POWER, MOLDED TO PATIENT MODEL. According to the requester, an upper extremity prosthetic socket replacement is necessary when an amputee encounters poor socket fit in their existing prosthesis. Inadequate fit of a prosthetic socket results in patient discomfort as well as poor control of the prosthesis. Inherent with the design and function of an upper extremity prosthesis, the inner socket must maintain an intimate anatomical fit and the prosthetic componentry must be maintained to allow for optimum functional performance. The intimate fit of a socket will help the patient in using the prosthesis to the fullest by supporting the control of the prosthetic components. The contoured inner socket allows patients to be more active in their daily lives and may even help to reduce any pain that the patient may be experiencing due to the ill-fitting socket.

CMS HCPCS Workgroup preliminary decision: To establish three new "L" codes:

L???1 Replacement socket, below elbow/wrist disarticulation, molded to patient model, for use with or without external power.

L???2 Replacement socket, above elbow/elbow disarticulation, molded to patient model, for use with or without external power.

L???3 Replacement socket, shoulder disarticulation/interscapular thoracic, molded to patient model, for use with or without external power.

Use one of the three new "L" codes as appropriate, based on the characteristic of the socket. No payer identified a national program operating need to differentiate sockets based on whether they were made for use with vs without external power.

Primary Speaker – Stephen Mandacina of Hanger Prosthetics & Orthotics, agrees with the preliminary decision to establish three new L codes.

Meeting Agenda Item #12
June 7, 2005
HCPCS Request #05.88 A&B

Background/Discussion:
Stephanie Bucklin of Hanger Prosthetics & Orthotics, Inc., submitted a request to establish a code for (**a**) a prosthetic donning sleeve, double layer low friction material, upper limb, each and (**b**) a prosthetic donning sleeve, double layer low friction material, lower limb, each, Trade Name: Donning Slip Socks, Double layer low friction donning aid. According to the requester, Hanger's "Donning Slip Socks" are double layer prosthetic donning aids that vary in size and are used to don (put on) an upper extremity (arm) or lower extremity (leg) prosthesis. The reason these types of donning aids are superior to the traditional cotton stockinette (used for donning in the past) is because this product is made of a durable nylon sailcloth, which lasts longer and causes less friction. These donning aids are an "off-the-shelf" item that is fit to the patient by the prosthetist from measurements.

CMS HCPCS Workgroup preliminary decision: To establish a new "L" code.

L???? Prosthetic donning sleeve, any material, each.

Primary Speaker – Stephen Mandacina of Hanger Prosthetics & Orthotics, agrees with the preliminary decision to establish a new L codes.

Meeting Agenda Item #13
June 7, 2005
HCPCS Request #05.89

Background/Discussion:
Stephanie Bucklin of Hanger Prosthetics and Orthotics submitted a request for reconsideration for the establishment of a code for an addition to upper extremity prosthesis, glove for terminal device, prefabricated with durability and stain resistance features. Applicant requests the following language: "ADDITION TO UPPER EXTREMITY PROSTHESIS, GLOVE FOR TERMINAL DEVICE, PREFABRICATED, WITH DURABILITY AND STAIN RESISTANCE FEATURES". According to the requester, upper extremity prosthetic coverings are used to cover and protect the delicate internal components of an arm prosthesis. Gloves, made of polyvinyl chloride, have been used for decades to cover static and dynamic prosthetic hand components. A Polyvinyl chloride (PVC) production glove provides a natural appearance to an upper extremity prosthesis. Standard PVC production gloves provide shock absorption and water resistance to protect the prosthetic hand from dust and moisture. Micro-coated PVC production gloves provide similar benefits as standard PVC gloves. However, when a micro-coating process is performed on the Centri Micro-coated PVC production glove, it is said to make the glove "stain resistant, easier to clean, and less friction against clothing than a standard PVC production glove. The micro-coated PVC production gloves are more durable than standard PVC production gloves. Use of silicone production gloves provide significant advantages in durability, function and cosmesis. Silicone production gloves offer: inherent stain resistance, increased durability, natural appearance, improved friction characteristics, water resistance, and improved elasticity.

CMS HCPCS Workgroup preliminary decision: To use existing code L6890 (addition to upper extremity prosthesis, glove for terminal device, any material, prefabricated, includes fitting and adjustment) or L6895 (addition to upper extremity prosthesis, glove for terminal device, any material, custom fabricated) as appropriate, depending on whether the glove is prefabricated or custom fabricated.

Existing codes L6890 and L6895 adequately describe the products that are the subject of this request. Difference in material does not change the core functionality of the product. Cosmetic differences and stain resistance of material also do not change the core functionality of the product. All items coded at L6890 and L6895 are expected to be durable, quality products.

Primary Speaker – Stephen Mandacina of Hanger Prosthetics & Orthotics, disagrees with the preliminary decision to use existing code L6890. The glove covering which was submitted pertains to prefabricated glove coverings for prosthetics. The submission is to add a code in addition to L6890 for specific prefabricated gloves that provide stain resistance or durability features not found on standard prefabricated gloves. These features cost considerably more because they have an entirely different chemical makeup

providing the stain resistance. A video demonstration will show these differences. Additionally, this different chemical makeup increases the softness and friction of the glove, which prevents Ultra Violet breakdown and improves the shear forces.

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Meeting Agenda Item #14
June 7, 2005
HCPCS Request #05.93

Background/Discussion:
Pete Nohre of Otto Bock Health Care has submitted a request to A.) Combine L6675 UPPER EXTREMITY ADDITION, HARNESS, (E.G. FIGURE OF EIGHT TYPE), SINGLE CABLE DESIGN and L6676 UPPER EXTERMITY ADDITION, HARNESS, (E.G. FIGURE OF EIGHT TYPE), DUAL CABLE DESIGN into one code and B.) Establish a new code for an addition to upper extremity, harness, triple control, Trade Name: Triple Control Harness. According to the requestor, this product is a triple control harness system used for controlling an above-elbow body-powered prosthesis and/or an above-elbow hybrid (body powered and myoelectric) prosthesis. It fits the patient around their shoulders and across their back with three cables that run through the harness and are connected to various prosthetic components such as an elbow or cable activated terminal device (hand/hook). Specific movements by the user pull on the cable that causes function of the prosthesis. The triple control incorporates three separate controls for the three different functions that a user needs to perform.

CMS HCPCS Workgroup preliminary decision: To establish a new "L" code.

L???? Upper extremity addition, harness, triple control, simultaneous operation of terminal device and elbow.

There was no Primary Speaker for this item.

Meeting Agenda Item #15
June 7, 2005
HCPCS Request #05.94

Background/Discussion:
Pete Nohre of Otto Bock Health Care has submitted a request to establish a code for an electrode replacement, for an upper extremity myoelectric prosthesis. Trade Name: Electrode. According to the requestor, code L6935 covers initial use of electrodes, but not replacement electrodes. The requestor is seeking a code for replacement electrodes.

CMS HCPCS Workgroup preliminary decision: To use existing code L7510 repair of prosthetic device, repair or replace minor parts.

Existing code L7510 adequately describes a category of minor replacement parts. There are numerous types of minor parts, including electrodes made of various types of materials with no therapeutic distinction. It is not feasible to categorize electrodes by type. Individual consideration by the payer is used to distinguish between electrodes. For Medicare, they are priced as the claims are received by the DMERCs. The CMS HCPCS Workgroup advises the requestor to work with the DMERCs regarding pricing for these items for Medicare. No payer has identified a national program operating need to alter the existing code set to uniquely identify the variety of electrodes on the market.

There was no Primary Speaker for this item.

Meeting Agenda Item #16
June 7, 2005
HCPCS Request #05.99

Background/Discussion:
Jeff Ashenbrenner of Otto Bock Health Care has submitted a request to establish a code for a force plate alignment procedure, Trade Name: Otto Bock L.A.S.A.R. Posture. According to the requestor, The L.A.S.A.R. (Laser Assisted Static Alignment Reference) Posture is a microprocessor-controlled alignment instrument offering the prosthetist a method for objectivity evaluating a patient. It is able to detect misalignment problems that current methods will not detect. It is used to assist the prosthetist in the static alignment of lower limb prosthesis. It can be helpful in preparing the prosthesis for fitting as well as trouble-shooting during dynamic alignment or at follow up reviews. In addition, it offers a method in the evaluation of the patient's center of balance in relation to standing balance, spinal curves, and weight distribution.

CMS HCPCS Workgroup preliminary decision: No new code.

Your request for a code has not been approved because there is currently no national program operating need on the part of any insurer to alter the existing code set to separately describe this alignment instrument. Alignment is included in the base procedure code and should not be separately billed. For Medicare, code A9270 is appropriate. For other insurers, contact the entity in whose jurisdiction a claim would be filed. For Medicaid systems, contact the Medicaid Agency in the state in which a claim would be filed for private insurance systems, contact the individual private insurance contractor.

There was no Primary Speaker for this item.

Meeting Agenda Item #17
June 7, 2005
HCPCS Request #05.102

Background/Discussion:
Brian Gustin, C.P. of Wisconsin Prosthetics and Orthotics has submitted a request to establish a code for a transtibial/symes hydrostatic prosthetic socket. According to the requestor, the transtibial/symes hydrostatic socket is a specific transtibial socket design that differs from the patella tendon bearing (PTB) socket that is included in the base procedure codes for transtibial prosthesis. The transtibial hydrostatic socket design applies areas of weight bearing over the entire amputated residual limb in a global fashion. It is intended to be used in conjunction with the roll-on type gel liners. The even volume reduction of the transtibial hydrostatic socket vs. the specific weight bearing socket results in a socket fit that has less pressure per square inch as the amputees body weight is evenly applied over the entire surface area. The applicant raises concerns regarding additional incremental costs of this vs. other socket designs.

CMS HCPCS Workgroup preliminary decision: To use existing code L5050 ankle, symes, molded socket, sach foot.

Your request for a code has not been approved because your product is an integral part of an existing HCPCS code, L5050 "ANKLE, SYMES, MOLDED SOCKET, SACH FOOT". This code includes whatever socket design and creation is most appropriately suited to the individual patient. Therefore, it is unnecessary to create a new code for any particular design, and inappropriate to bill separately for any particular design. Inquiries regarding the fee associated with the code are outside the purview of the code set maintainers should be separately submitted to individual payers. For Medicare, this inquiry should be submitted to CMS' inherent reasonableness authority.

There was no Primary Speaker for this item.

Meeting Agenda Item #18
June 7, 2005
HCPCS Request #05.103

Background/Discussion:
R. Adam Fishman of Hypobaric Systems has submitted a request to establish a code or reinstate L8490 for a suction suspension interface for prosthesis, Trade Name: Hypobaric Interface. According to the requestor, the Hypobaric Suspension System is a popular solution for suction suspension in the trans-femoral patient, especially those who are unable to use the traditional silicone liner for suspension. It is used to facilitate suction suspension for the prostheses of amputees.

CMS HCPCS Workgroup preliminary decision: To use existing code L5679 addition to lower extremity, below knee/above knee, custom fabricated from existing mold or prefabricated, socket insert, silicone gel, elastomeric or equal, not for use with locking mechanism.

An existing code, L5679 (addition to lower extremity, below knee/above knee, custom fabricated from existing mold or prefabricated, socket insert, silicone gel, elastomeric or equal, not for use with locking mechanism), adequately describes a category of items which are functionally similar to the item in this coding request and includes the socket modification process. There are no significant therapeutic distinctions between the category of items described in this code and the item in the coding request.

There was no Primary Speaker for this item.

Meeting Agenda Item #19
June 7, 2005
HCPCS Request #05.104

Background/Discussion:
Harold Sears of Motion Control, Inc. submitted a request to create a new code to identify the Flexion Wrist feature of the Motion Control Electric Hand and the Motion Control Electric Terminal Device (ETD). According to the requester, the Flexion Wrist feature gives Motion Control's myoelectric terminal devices (MC Hand or ETD) the ability to flex and extend beyond the standard position, so that the Terminal Device may be used in more functional positions and a much more natural way by the prosthesis wearer. The device is intended only for use by persons with limb loss who are using a myoelectric prosthesis. The Flexion Wrist feature adds an additional degree of freedom to the hand. It can be positioned in a neutral position, a flexed position (30º), and locked in any one of those positions while used in any activities. The lock allows the position to be maintained for load applied up to 50 lbs at the tip of the fingers in any direction. The Flexion Wrist may also be used by individuals with an electric wrist rotator without any loss of utility.

CMS HCPCS Workgroup preliminary decision: To establish a new "L" code.

L???? Upper extremity prosthesis addition, flexion/extension wrist with or without friction, for use with external powered terminal devices.

Use newly established code L???? to identify the item that is the subject of this request.

Primary Speaker – Harold Sears, of Motion Control, Inc., strongly supports the preliminary decision.

Meeting Agenda Item #20
June 7, 2005
HCPCS Request #05.105

Background/Discussion:
Harold Sears of Motion Control, Inc. submitted a request to establish a code for the Water Resistant Protective Sleeve, for use with a myoelectric prosthesis. According to the requester, the Protective Sleeve is primarily used in conjunction with Motion Control's Water Resistant Electric Terminal Device (ETD) to aid in keeping the non-water resistant areas of the myoelectric prosthesis clean and free from dirt and moisture, though it can be used with any terminal device. It allows the amputee wearer to use a prosthesis in a much wider range of environments, thus making it suitable for use in environments that have previously been prohibitive to wearers of myoelectric prostheses.

CMS HCPCS Workgroup preliminary decision: No new code.
To use existing code A9270 (non-covered item or service), for Medicare. For coding guidance for other insurers (State Medicaid Agencies, Private Insurers), contact the entity in whose jurisdiction a claim would be filed.

This is a convenience item. No insurer identified national program operating need to alter the existing code set to describe this item. There is no existing Medicare benefit category for the item that is the subject of your request. Use existing code A9270 (non-covered item or service), for Medicare. For coding guidance for other insurers (State Medicaid Agencies, Private Insurers), contact the entity in whose jurisdiction a claim would be filed. For private insurance systems, contact the individual private insurance contractor. For Medicaid, contact the Medicaid Agency in the state in which a claim would be filed.

Primary Speaker – Harold Sears, of Motion Control, Inc., disagrees with the preliminary decision to use existing code A9270. Water-resistant feature is often essential to returning a disabled individual (with an arm amputation) to their work and/or previous activities and this is medically necessary in those cases.

Meeting Agenda Item #21
June 7, 2005
HCPCS Request #05.106

Background/Discussion:
Harold Sears of Motion Control, Inc. submitted a request to establish a code for the Water Resistant feature of an Electric Terminal Device (ETD). According to the requester, the Water Resistant feature of the Motion Control Electric Terminal Device (ETD) allows the amputee wearer to use a prosthesis in a much wider range of environments. The water resistant housings are also impervious to dust and dirt, thus making it suitable for use in environments that have previously been prohibitive to wearers of myoelectric prostheses.

CMS HCPCS Workgroup preliminary decision: No new code.

Medical necessity of the water resistant feature has not been demonstrated and this is considered a convenience item. No insurer identified national program operating need to alter the existing code set to describe this item. There is no existing Medicare benefit category for the item that is the subject of your request. Use existing code A9270 (non-covered item or service), for Medicare. For coding guidance for other insurers (State Medicaid Agencies, Private Insurers), contact the entity in whose jurisdiction a claim is filed. For private insurance systems, contact the individual private insurance contractor. For Medicaid systems, contact Medicaid Agency in the state which a claim would be filed.

Primary Speaker – Harold Sears, of Motion Control, Inc., disagrees with the workgroup's recommendation to disallow a new code for the water resistant feature of the electric hook, based on the belief that this feature is a "convenience item." In fact, the water resistant feature allows the wearer of an electric prosthesis to go into wet or dirty environments that were previously prohibitive. In light of the high number of servicemen who are returning from Iraq as amputees who wish to return to active duty, the need for a rugged, water and dirt resistant device is an absolute necessity.

The goal of the prosthetic devices is to return as much function as possible to the wearer. Our studies indicate that wearers are able to achieve a higher level of function using the water resistant TD. Given that our natural hands are "water resistant", we feel that this feature in an electric TD is one step closer to nature.

Meeting Agenda Item #22
June 7, 2005
HCPCS Request #05.107

Background/Discussion:
Susan Treiber of Ossur North America/Generation II USA submitted a request to establish 2 "L" codes for Magnetorheologic (MR) Actuator (currently used on the Rheo Knee, a microprocessor-based knee, manufactured by Ossur). The applicant requests the following language: A) L58xx "Addition to lower extremity prosthesis, endoskeletal knee-shin system, single axis, magnetorheologic swing and stance phase control"; and B) L59xx "Addition to endoskeletal knee-shin system, magnetorheologic stance extension, dampening feature, with or without adjustability". According to the requester, the actuator is the part of the prosthetic knee that physically creates resistance for swing and stance phase control. The Magnetorheologic (MR) Actuator is the actuator on the Rheo Knee, Ossur's innovative microprocessor-based knee. The Rheo Knee contains a Magnetorheologic (MR) Actuator which utilizes Magnetorheologic fluid and magnetic fields to provide swing and/or stance phase control. The MR Actuator contains small iron particles suspended in oil and is a "zero-pressure" system. It produces no force to control swing and/or stance phase control. Instead, resistance is created by magnetic fields which are generated as a result to the sensors. The magnetic field actually causes the magnetic particles to line up, thus thickening the MR fluid. The actuator has a stack of thin, steel rotary blades (discs) with fine gaps between the blades.

CMS HCPCS Workgroup preliminary decision: To use existing codes L5856 (addition to lower extremity prosthesis, endoskeletal knee-shin system, microprocessor control feature, swing and stance phase, includes electronic sensor(s), any type), for swing and stance phase; and L5845 (addition, endoskeletal, knee-shin system, stance flexion feature, adjustable), for flexion feature.

Existing codes, L5856 and L5845, adequately describe a category of items which are functionally similar to the items in this coding request. There are no significant therapeutic distinctions between the category of items described in this code and the items in the coding request. No payer (Medicare, Medicaid, Private Insurance), identified a national program operating need to differentiate magnetorheologic actuators or to alter the existing code set in order to uniquely describe them.

Primary Speaker – Scott Elliott of Ossur North America, disagrees with the preliminary decision, it did not address the topics covered in the Rheo Knee coding recommendation regarding changes in coding language for the following:
(A) L5828: Fluid swing and stance (the actuator)
(B) L5848: Hydraulic stance extension damping feature

Recommended Solutions Part A – L58XX (Actuator Code)

- Option 1:
  - Create a new code for the Rheo Knee MR Actuator, similar to L5828 that replaces the word ‘fluid’ with ‘magnetorheologic’. *or*
- Option 2:
  - Allow Rheo Knee to use existing code L5828 for the MR actuator.

Recommended Solutions Part B – L59XX (Stance Extension Damping)

- Option 1:
  - Create a new code for Stance Extension Damping, similar to L5848, replacing the word ‘hydraulic’ with ‘magnetorheologic’. *or*
- Option 2:
  - Modify existing code L5848 and remove the word ‘hydraulic’ from the description, to describe the MR stance extension damping provided by the Rheo Knee.

Meeting Agenda Item #23
June 7, 2005
HCPCS Request #05.149

Background/Discussion:
Michelle Ford of InHealth Technologies has submitted a request to modify the HCPCS code set to differentiate between low pressure and duckbill style voice prostheses. Applicant suggests revising the verbiage of L8507 TRACHEO-ESOPHAGEAL VOICE PROSTHESIS, PATIENT INSERTED, ANY TYPE, EACH to instead read: "Tracheo-esophageal voice prosthesis, patient inserted, duckbill, each", and requests a new code for low-pressure voice prosthesis, requested language: LXXXX "Tracheo-esophageal voice prosthesis, patient inserted, low-pressure, each". According to the requestor, L8507 currently does not differentiate between the low pressure and duckbill style of prosthesis. The low pressure style is indicated for patients with insufficient air pressure to open the valve of patients whose esophagus is too narrow to accommodate the 8mm duckbill tip. The duckbill style was introduced in 1979, and the low pressure style has been on the market since the early 1980's.

CMS HCPCS Workgroup preliminary decision: To use existing code L8507 (tracheo-esophageal voice prosthesis, patient inserted, any type, each)

An existing code, L8507 adequately describes both types of voice prostheses that are the subject of this coding request. Also, since duckbill is a proprietary term, it should not be included in the text of a code category. There are no significant therapeutic distinctions between the category of items described in this code and the items in the coding request. It is up to the clinician to determine which style is appropriate for an individual patient. No insurer identified a national program operating need to alter the existing code set to differentiate the items that are the subject of this request. If pricing is a concern, contact the insurer in whose jurisdiction a claim would be filed. For Medicare, contact CMS' Inherent Reasonableness authority. For Medicaid systems, contact the Medicaid Agency in the state in which a claim would be filed. For private insurance systems, contact the individual private insurance contractor.

Primary Speaker – Jennifer Hutter of MedSearch Legal Nurse Consultants

- We disagree that L8507 adequately describes standard and low-pressure voice prostheses
- There are significant therapeutic distinctions between these two prostheses.
- Clinicians will be unable to provide the low-pressure prosthesis, if suppliers will not provide them due to reimbursement under L8507.

Suggested code verbiage:

- L8507 - Tracheo-esophageal voice prosthesis, patient inserted, standard-pressure, each.
- Lxxxx - Tracheo-esophageal voice prosthesis, patient inserted, low-pressure, each.

Closing Remarks

In light of new information provided at CMS' HCPCS Public Meetings, the HCPCS workgroup will reconsider its preliminary coding recommendations, CMS staff will reconsider payment methodology recommendations, and the workgroup will formulate its final recommendation. By mid November 2005, the HCPCS workgroup will mail letters to every requestor of its final decision. The 2006 HCPCS Level II Annual Update, including any coding changes, will be effective January 1, 2006, and will be published at: www.cms.hhs.gov/providers/pufdownload/anhcpcdl.asp by mid November, 2005.

Cindy Hake of CMS thanked the participants for their very valuable input at the meeting, and for all the time and effort that was spent on the presentations.

Michael Barron also thanked the audience for their participation, and officially adjourned the meeting.