Centers for Medicare & Medicaid Services (CMS)
Summary Report
HCPCS Public Meeting
Wednesday, April 26, 2006

Introduction and Overview

Denise Bailey-Jones, CMS Office of Operations Management, moderated the meeting. Approximately 50 people attended. The agenda included 20 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 26, 2006
HCPCS Request #06.38

Topic/Issue:
Request to establish a code for an Anti-fungal Voice Prosthesis, trade name: ADVANTAGE Indwelling Voice Prosthesis. **Suggested language**: LXXXX – "Tracheo-esophageal voice prosthesis, extended life, includes anti-fungal/anti-bacterial agent, inserted by a licensed health care provider, each"

Background/Discussion:
According to the requester, the ADVANTAGE Indwelling Voice Prosthesis is the newest advancement in Blom-Singer voice restoration. The prosthesis incorporates a one-way silicone valve that is impregnated with 7% silver-oxide. This allows the prosthesis to stay in place for a longer period of time. Utilizing a widely available, 100% silicone prosthesis, those with fungal colonization see device failure in 2 weeks to 4 months. Device failures caused by fungal colonization are typically leakage of the prosthesis. The ADVANTAGE decreases fungal colonization and significantly increases the device lifespan for users with persistent fungal colonization. Users of the ADVANTAGE have been shown to be able to eliminate their use of oral anti-fungal agents and decrease their clinic visits. The Indwelling Advantage is placed by a clinician. It is inserted and replaced on an as-needed basis by a speech pathologist or physician only. The clinician places the ADVANTAGE in the trachea-esophageal puncture so that routine changing of the voice prosthesis is unnecessary. This prosthesis is ideal for Laryngectomees who are unable or are resistant to changing a patient maintainable prosthesis themselves (i.e. duckbill, Low Pressure styles). Also, according to the applicant, existing code L8509 "does not account for the extended wear or the silver impregnated component of the product," and "the fee schedule is also significantly lower for L8509 than for the rest of this product."

CMS HCPCS Workgroup Preliminary Decision:
Existing code L8509 "TRACHEO-ESOPHAGEAL VOICE PROSTHESIS, INSERTED BY LICENSED HEALTHCARE PROVIDER, ANY TYPE" adequately describes the product that is the subject of your request. Clinical information included with this application does not demonstrate a superior clinical patient outcome when this device is used, when compared with other similar products coded in the L8509 category. Pricing is not within the purview of the HCPCS code set maintainers. Please submit inquiries regarding fees directly to insurers.

Medicare Payment:

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

Primary Speaker:
On behalf of InHealth Technologies, the speaker disagreed with the workgroup's preliminary decision and requested a new code to distinguish this item from other items described by existing code L8509 based on technological differences, specifically, incorporation of Silver Oxide into the silicone valve mechanism.

Meeting Agenda Item #2
April 26, 2006
HCPCS Request #06.09

Topic/Issue:
Request to establish a code for a palatal implant, trade name: Pillar Palatal Implant.

Background/Discussion:
According to the requester, the Pillar Palatal Implants are used in treating mild-to-moderate obstructive sleep apnea (OSA) by addressing one of the anatomical components of OSA: the soft palate. These implants add structural support to the soft palate and trigger a patient's natural tissue response that further increases the structural integrity of the soft palate. Pillar implants are inserted via a specialized delivery tool. The delivery tool is a single use device, and is comprised of a handle and a 14-gauge needle. Each implant is 18mm long and approximately 2mm in diameter. They are made of woven polyethylene terphthalate (PET) material. Typically, three implants are placed in the soft palate via three delivery tools to complete the procedure. The implant procedure is minimally invasive, and can be performed in a single visit. According to the applicant, there are no existing codes that adequately describe palatal implants. Recommended code language: Palatal implant, each.

CMS HCPCS Workgroup Preliminary Decision:
This item does not fall within the HCPCS Level II coding jurisdiction. Use existing CPT codes as directed by the insurer in whose jurisdiction a claim would be filed. Inquiries regarding inclusion of implants and delivery tools in the CPT code should be submitted to the AMA CPT coding committee.

Primary Speaker:
On behalf of Restore Medical, the primary speaker disagreed with the workgroup's preliminary decision because:

- CPT coding guidelines do not support the use of CPT codes for supplies or implants.
- No CPT code currently exists for palatal implants.
- Pillar implants fall within the definition of a prosthetic as they replace the lost functionality of the soft palate that causes it to collapse and close the airway.
- HCPCS codes currently exist for other prosthetics that replace lost functionality.
- The place of service for the insertion of palatal implants includes the ASC setting, and requires a means of identifying the implants.

The speaker reiterated the original request to establish a new code and suggested the following language: "Palatal implant, each".

Meeting Agenda Item #3
April 26, 2006
HCPCS Request #06.66

Topic/Issue:
Request to establish a code for an osseointegrated auditory implant, trade name: Baha® System.

Background/Discussion:
According to the requester, the Baha System is an implantable prosthetic device designed to provide stimulation of the cochlea through osseointegration (bonding with living bone tissue) with the cranium. The device is comprised of 3 components: fixture, abutment and external sound processor. The applicant requests a single code to describe the complete system, including internal and external components. This medical device restores hearing for a limited group of individuals with a mixed/conductive hearing loss or unilateral (single-sided) deafness. It consists of a titanium fixture that is surgically implanted into the temporal bone just behind the ear, and which becomes osseointegrated into the bone, a percutaneous or skin-penetrating abutment that extends above the surface of the skin, and a sound processor that connects to the abutment to complete the system. The Baha system transmits vibratory energy to stimulate the cochlea utilizing bone conduction. It is "a particularly important and uniquely effective means of restoring hearing in patients with craniofacial disorders such as individuals affected by the Treacher-Collins Syndrome.

CMS HCPCS Workgroup Preliminary Decision:
Establish codes:
Lxxxx BONE-ANCHORED AUDITORY DEVICE, INCLUDES ALL INTERNAL AND EXTERNAL COMPONENTS

Lxxxx BONE-ANCHORED AUDITORY DEVICE, EXTERNAL SOUND PROCESSOR, REPLACEMENT

Revise code L8614 which currently reads COCHLEAR DEVICE/SYSTEM, to instead read: COCHLEAR DEVICE, INCLUDES ALL INTERNAL AND EXTERNAL COMPONENTS

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

Primary Speaker:
On behalf of Cochlear Americas, the speaker agreed with the workgroup's decision to establish a code, but disagreed with the proposed language. The speaker stated that the Baha system is osseo-integrated and distinct from bone-anchored technologies, and

therefore requested that the language of the proposed codes be revised to omit “bone-anchored” and replace it with “osseo-integrated”.

Meeting Agenda Item #4
April 26, 2006
HCPCS Request #06.19

Topic/Issue:
Request to establish a code for a diaphragmatic/phrenic nerve stimulator, trade name: Breathing Pacemaker System.

Background/Discussion:
According to the requester, The Avery System is a diaphragmatic, or phrenic nerve stimulator. It consists of surgically implanted receivers and electrodes mated to an external transmitter by antennas worn over the implanted receivers. A transtelephonic monitor is also provided to allow for evaluation of device function over a telephone. Phrenic nerve pacing provides ventilatory support for patients with chronic respiratory insufficiency whose diaphragm, lungs, and phrenic nerves have residual function. The external transmitter and antennas send radiofrequency (RF) energy to the implanted receivers just under the skin. The receivers then covert the radio waves into stimulating pulses. These pulses are then sent down the electrodes to the phrenic nerves, causing the diaphragms to contract. This contraction causes inhalation of air. When the pulses stop, the diaphragms relax and exhalation occurs. Repetition of this series of pulses produces a normal breathing pattern. Typically, these patients have high spinal cord injuries, central sleep apnea or other central neurological disorders, or paralyzed diaphragm(s). According to the requester, the DRG payment "is generally inadequate to cover the procedure, let alone the cost of the device;" and "existing codes only address the procedural costs and not the cost of the equipment."

CMS HCPCS Workgroup Preliminary Decision:
For Medicare, this item is included in the DRG payment when performed in an inpatient setting. Contact CMS HAPG with inquiries regarding Medicare payment under the DRG system and regarding prosthetic components when the procedure is performed in an ASC. It is not in the purview of the HCPCS workgroup to assign pricing to codes. Please submit inquiries regarding pricing directly to the insurer. For Medicaid coding guidance, contact the Medicaid Agency in the state in which the claim would be filed. Coding inquiries for private insurers, should be submitted to the individual private insurance contractor.

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

Meeting Agenda Item #5
April 26, 2006
HCPCS Request #06.05

Topic/Issue:
Request to establish a code for ostomy pouch lubricator and deodorizer, trade name: Adapt Lubricating Deodorant.

Background/Discussion:
According to the requester, Adapt Lubricating Deodorant is used to assist the ostomate in the emptying of their drainable ostomy pouch as well as neutralize the odor associated with an ostomy pouch. Some ostomates experience blockage in the pouch along with malodor. The fecal matter sticks to the inner walls of the pouch and does not advance. Adapt is specially designed to provide lubrication to the inner walls of the ostomy pouch to help prevent pouch static and sticking without weakening the heat seals at the edge of the pouch. It also contains an odor neutralizer, which eliminates the odor inherent in the used pouch. Through the prevention of sticking fecal matter, the ostomate may experience longer wear times with their drainable pouches. Adapt is supplied in either an 8 oz bottle for multiple use, or in box of 50 single use packets of 8ml each (the extra 3ml is to ensure that a full 5mls is emptied into the pouch – it allows for some product to be left in the single use packet). Applicant suggested establishment of a new A code and recommends the following language: Ostomy lubricant and deodorant, for use in ostomy pouch, liquid, per fluid ounce.

CMS HCPCS Workgroup Preliminary Decision:
Existing code A4394 "OSTOMY DEODORANT FOR USE IN OSTOMY POUCH, PER FLUID OUNCE" adequately describes the product that is the subject of this request. Lubricant is for the bag and not the patient and is not primarily medical in nature. Medicare, Medicaid and private insurers have not identified a national program operating need to separately identify ostomy bag lubricant.

Medicare Payment:
Fee schedule and payment rules associated with existing code apply to this product.
Pricing = 37

Primary Speaker:
On behalf of Hollister, the primary speaker reiterated the request for lubricant and deodorant to be identified separately as a "quality of life" issue for persons with "sticky stool". The speaker claimed that lubricant allows the stool to drop to the bottom of the pouch more readily, creating faster and effective drain time.

Meeting Agenda Item #6
April 26, 2006
HCPCS Request #06.04A+B

Topic/Issue:
Request to establish a code for (A) a dextranomer/hyaluronic acid copolymer implant material, trade name: Deflux Injectable Gel and (B) a Pediatric implantation needle, endoscopic, trade name: Deflux® Needle.

Background/Discussion:
According to the requester, Deflux is a dextranomer/hyaluronic acid copolymer implant material. It is a sterile viscous gel of dextranomer microspheres (50mg/ml) in a carrier gel of non-animal, stabilized Hyaluronic Acid which provides a biocompatible implant. The Hyaluronic Acid is produced by bacteria fermentation, thus eliminating the risk of animal-related allergic reactions and disease transfer from animals. Deflux is intended for the treatment of children with vesicoureteral reflux (VUR) grades II-IV. It is injected submucosally into the bladder wall near or beneath the ureter, or into the lower distal portion of the ureter where it intersects with the bladder wall. The injected implant material corrects the angulation of the ureter thereby allowing correct functioning of the ureter and improving urine flow. This prevents reflux of urine from the bladder up the ureters back to the kidneys (vesicoureteral reflux). Deflux is supplied in a 1ml sterile syringe with a Luer lock at the end to facilitate attachment to the Deflux needle.

CMS HCPCS Workgroup Preliminary Decision:
No insurer identified a national program operating need to establish codes to separately identify these products. For Medicare, these products are not separately billable. Payment is included in DRG when performed in an inpatient setting. In HOPPS, payment is included in the APC. For Medicaid coding guidance, submit inquiries to the Medicaid agency in the state in which the claim would be filed. For private insurers, contact the insurer in whose jurisdiction a claim is filed. Refer to AMA for CPT coding guidance.

Primary Speaker:
On behalf of Q-Med Scandinavia, Inc., the primary speaker disagreed with the workgroup's preliminary decision. The speaker stated that a HCPCS code should be granted because:

- existing codes do not describe dextranomer/hyaluronic acid and do not enable tracking
- use of dextranomer/hyaluronic acid is an established treatment for VUR as demonstrated by clinical support, presence of other codes, and established coverage policies by public and private payers
- creation of a code is supported by physicians and specialty societies
- the workgroup has an obligation to establish codes that meet the needs of all code users, including providers.

In conclusion, the speaker requested that an L-code be granted for dextranomer/hyaluronic acid.

Meeting Agenda Item #7
April 26, 2006
HCPCS Request #06.114

Topic/Issue:
Request to establish a code for a mechanical specialty terminal device, trade name: TAD N-Abler II Terminal Device.

Background/Discussion:
According to the requester, the TAD N-Abler II Terminal Device is a specialty terminal device designed to allow individuals with hand dysfunction (due to amputation, congenital deficiency, illness, or injury) to safely and independently expand the variety of normal daily living activities which they are able to perform. The device is compact and lightweight and has a quick disconnect adapter which permits 360 degrees rotation of a tool with multiple locking positions. It features a positive-locking quick connect/release tool holder which accommodates any of the many available adapted tools. It also allows 60 degrees adjustable flexion. TAD N-Abler fits standard wrist units, and easily instead of, but not to the exclusion of, the standard prosthetic hook or hand. It readily holds any of the 100+ tools adapted to fits the device and connects to standard prosthetic wrist units and easily exchanges to a body powered hook, passive or myoelectric hand.

CMS HCPCS Workgroup Preliminary Decision:
No insurer identified a national program operating need to establish a code to identify this product. It is a convenience item. For Medicare, there is no benefit category, and code A9270 "NON-COVERED ITEM OR SERVICE" should be used. Use of miscellaneous codes is inappropriate. For coding guidance from 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.

Medicare Payment:
This product is not covered.

Primary Speaker:
On behalf of Texas Assistive Devices, the speaker disagreed with the workgroup preliminary decision and objects to the classification as a convenience item. The speaker stated that the TAD N-Abler II is medically necessary and that it increases an amputee's ability to function in their everyday lives in that it allows for functionally that is similar to a natural wrist.

Meeting Agenda Item #8
April 26, 2006
HCPCS Request #06.115

Topic/Issue:
Request to establish a code for a mechanical five function prosthetic wrist, trade name: TAD N-Abler V Body Powered Five Function Wrist.

Background/Discussion:
According to the requester, the TAD N-Abler V Body Powered Five Function Wrist functions as a prosthetic wrist unit, and it is unique in how it works. It is a multifunctional unit that is operated completely unlike any other prosthetic wrists currently available. The N-Abler V's large center cylinder conduit contains a cable that controls flexion and extension. These cables are easily operated by the amputee's muscular control either in the neck, upper back, or shoulders. With a quick disconnect wrist component, the N-Abler V permits twelve angle position change for either a body powered hook, prosthetic hand, or for various specialty terminal devices (such as tools with adaptive handles to aid with specific activities, i.e., spoons, knives, hammers, and personal grooming aids including toothbrushes and combs).

CMS HCPCS Workgroup Preliminary Decision:
No insurer identified a national program operating need to establish a code to separately identify this product. Use existing code L6620 "UPPER EXTREMITY ADDITION, FLEXION/EXTENSION WRIST UNIT, WITH OR WITHOUT FRICTION" and L6625 "UPPER EXTREMITY ADDITION, ROTATION WRIST UNIT WITH CABLE LOCK" together, for a unit that provides flexion extension and rotation. Use of miscellaneous codes is not appropriate.

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

Primary Speaker:
On behalf of Texas Assistive Devices, the primary speaker strongly disagreed with the workgroup's preliminary decision because it provides inadequate reimbursement for the product. The speaker stated that the TAD N-Abler V is the only wrist unit that performs five functions in one; and that all of the features are not covered by the 2 suggested codes.

Meeting Agenda Item #9
April 26, 2006
HCPCS Request #06.51

Topic/Issue:
Request to establish a code for an addition to all upper extremity prosthetic base codes for titanium hook type terminal device, trade name: Titanium Prosthetic Hook 5XTi.

Background/Discussion:
According to the requester, terminal devices for upper extremity prostheses have been made of aluminum or stainless steal in the past. The prosthetist and patient had to choose the lightweight of the aluminum or the better durability of stainless steel. Titanium is a material that is roughly 40% lighter than stainless steel, but has slightly higher strength. The titanium hook is the same geometry and configuration as adult hooks, but is made with a titanium metal, not an alloy. There is no current L-code that provides for the use of titanium or other high strength material for upper extremity terminal devices.

CMS HCPCS Workgroup Preliminary Decision:
Use existing code L7400 ADDITION TO UPPER EXTREMITY PROSTHESIS, BELOW ELBOW/WRIST DISARTICULATION, ULTRALIGHT MATERIAL (TITANIUM, CARBON FIBER OR EQUAL), L7401 ADDITION TO UPPER EXTREMITY PROSTHESIS, ABOVE ELBOW DISARTICULATION, ULTRALIGHT MATERIAL (TITANIUM, CARBON FIBER OR EQUAL) or L7402 ADDITION TO UPPER EXTREMITY PROSTHESIS, SHOULDER DISARTICULATION/INTERSCAPULAR THORACIC, ULTRALIGHT MATERIAL (TITANIUM, CARBON FIBER OR EQUAL), as appropriate. While some codes include material in the descriptor, these codes were created to address materials such as titanium, carbon fiber or equal fro upper extremity prostheses, and therefore, new codes for titanium terminal devices would be duplicative and unnecessary. The assignment of fees is not within the purview of HCPCS code set maintainers, Inquiries regarding pricing of individual codes should be submitted directly to insurers. Use of other L 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 #10
April 26, 2006
HCPCS Request #06.77

Topic/Issue:
Request to establish a code for a Switch (pull switch, nudge switch, rocker switch), trade name: Otto Bock Switch. Suggested language: "Addition to upper extremity prosthetic, switch for myoelectric system, used for changing between two or more myoelectric prosthetic devices"

Background/Discussion:
According to the requester, the proposed code is not for a switch controlled myoelectric system, but for the use of a switch within a myoelectric system for the purpose of changing between two or more prosthetic devices (such as between a hand and wrist rotator or between a hand and an elbow). Changing between devices is a common activity of daily living for an upper extremity prosthetic user because there is only one set of electrodes in a myoelectric system that can only control one device at a time. Because of this, a switch is commonly used by the prosthetic user to change from one device to another. There are different types of switches that can be used (pull switch, nudge switch, rocker switch, etc), but these are just different ways of accomplishing the same thing – to change control from one device to another.

According to the applicant, no code currently exists for a switch used in a myoelectric system to change between two or more devices. There are currently base codes for a switch controlled myoelectric system (L6930, L6940, and L5950) that are used when a myoelectric system is controlled by a switch. For this purpose, using a switch takes the place of electrodes for controlling a prosthetic device, such as a myoelectric hand.

CMS HCPCS Workgroup Preliminary Decision:
Establish a code:
Lxxxx ADDITION TO UPPER EXTREMITY PROSTHESIS, EXTERNAL POWERED, ADDITIONAL SWITCH, ANY TYPE

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 #11
April 26, 2006
HCPCS Request #06.78

Topic/Issue:
Request to establish a code for an "Infinite locking position" prosthetic elbow joint, trade names: ErgoArm and DynamicArm Elbows. Suggested language: "Addition to upper extremity, locking elbow, infinite locking positions"

Background/Discussion:
According to the requester, an infinite lock is used in a prosthetic elbow joint to allow range of motion for the user and to allow them to position the elbow in specific positions to do a wide variety of daily activities. An infinite lock is a locking device that allows a component to be positioned, stopped and locked in any place within its full range of motion. For example, if a prosthetic elbow has a flexion range from 15° to 145°, an infinite lock allows the elbow to be locked in any position (or degree) between 15° to 145°. The infinite lock is used in prosthetic elbows to stop and lock the elbow (and therefore the terminal device such as a hand) in any position. This is used by above elbow amputees to assist with various activities of daily living such as, grasping objects in space, holding objects at the desired level (such as a cup of coffee), setting objects down on various surface levels, etc. The patient population is amputees with above elbow or higher amputation levels.

The biggest difference is product design. An infinite lock is not based on a "toothed" or "geared" system that only allows for locking positions in a determined amount of pre-set positions. An infinite lock has the capability to lock the elbow in any degree of flexion within its full range of motion. This design difference leads to greater functionality for the user as they can virtually eliminate unnatural, compensatory movements caused by not being able to position the elbow in the precise desired degree of flexion. In addition, an infinite lock design lets the user unlock the elbow joint when it is under load (weight bearing). This also adds functionality as a "toothed" lock often requires the user to set an object down, unlock and reposition the elbow, then re-grasp the object because it cannot be unlocked under load. An infinite lock will allow the user to simply reposition the elbow without having to set the object down and then pick it up again. This is obviously a much more functional approach.

CMS HCPCS Workgroup Preliminary Decision:
Use existing code L6693 UPPER EXTREMITY ADDITION, LOCKING ELBOW, FOREARM COUNTERBALANCE which was established using this product as the predicate device. Use of code L7499 or other miscellaneous codes is inappropriate. The code text does not specify pre-set or multipositional and therefore encompasses the products on the market today, including the product that is the subject of this application.

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 #12
April 26, 2006
HCPCS Request #06.86

Topic/Issue:
Request to establish a code for a switch for secondary control as an addition to upper extremity electric prosthesis.

Background/Discussion:
According to the requester, secondary input switches are used to provide function to the wearer that the primary inputs allowed by the base code cannot perform. The input devices provided by the upper extremity electric base codes control the main operation of the prosthesis. However, with advancing technology to allow better control of the prosthesis, devices are being designed that have multiple operations and require multiple inputs. Additional secondary inputs are needed for higher levels or multiple limb involvement to appropriately route the signal not provided by the base system, facilitate powering on/off, locking/unlocking the elbow, or controlling operations. These secondary inputs provide the wearer greater degrees of freed and allow an improved control of the prosthesis leading to a greater functional success with the device.
Recommended language: Addition to upper extremity electric prosthesis, switch for secondary control.

CMS HCPCS Workgroup Preliminary Decision:
Establish a code:

LXXXX ADDITION TO UPPER EXTREMITY PROSTHESIS, EXTERNAL POWERED, ADDITIONAL SWITCH, ANY TYPE

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

Primary Speaker:
On behalf of Hanger Prosthetics and Orthotics, the primary speaker supported the workgroup's preliminary decision to establish a code.

Meeting Agenda Item #13
April 26, 2006
HCPCS Request #06.85

Topic/Issue:
Request to establish a code for a heavy duty prosthetic elbow as an addition for all external upper extremity prosthetic base codes, trade names: Power-Bow, E0400HD, and E0400XHD.

Background/Discussion:
According to the requester, the heavy duty prosthetic elbow increases strength by including two locking cams instead of one. Additionally the two cams can be made of stainless steel instead of aluminum for increased strength. This is necessary for heavy duty prosthetic users lifting a large amount of load that often break usual locking cam construction. There is an existing heavy duty stainless steel wrists, but no code for heavy duty prosthetic elbow or replacement elbow. Heavy duty prosthetic elbows are used repeatedly for their lifetimes as long as functional to the user. It can withstand normal and heavy duty use within established parameters. Heavy duty prosthetic elbows can be constructed of two aluminum gear sectors, a stainless steel gear sector, or two stainless steel gear sectors with a stainless steel frame for maximum durability. The disadvantage is that this increases weight of the elbow, but durability is more desirable for heavy duty users.

CMS HCPCS Workgroup Preliminary Decision:
Establish a code:
LXXXX UPPER EXTREMITY ADDITION, HEAVY DUTY FEATURE, ANY ELBOW

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 #14
April 26, 2006
HCPCS Request #06.141

Topic/Issue:
Request to revise codes L6883, L6884, and L6885 to be designated for use with non-external power control type upper extremity prostheses and establish 3 new codes for replacement sockets for use with external power.

Background/Discussion:
According to the requester, there are many services covered under an upper extremity external power base code that do not have to be accounted for when using a non-external powered system. Among them are: testing to determine the appropriate control scheme and placement for input devices, optimizing control electronics, precise fitting, additional time for fabrication and assembly, and lengthy patient education and training. Because these differences in service and product are more labor intensive to ensure a successful fitting and these services are not done with the cable operated device, it is necessary to have socket replacement codes specifically for external powered control and each level of deficiency. Troy is requesting that codes L6883, L6884 and L6885 be designated for use with non-external power control type upper extremity prostheses at their respective levels, and requesting 3 new codes for external powered replacement sockets, recommended language: a) Replacement, socket, below elbow/wrist disarticulation, for use with external power, molded to patient model, b) Replacement, socket, above elbow/elbow disarticulation, for use with external power, molded to patient model and c) Replacement, socket, shoulder disarticulation/interscapular thoracic, for use with external power, molded to patient model.

CMS HCPCS Workgroup Preliminary Decision:
Use existing code L6883 REPLACEMENT SOCKET, BELOW ELBOW/WRIST DISARTICULATION, MOLDED TO PATIENT MODEL, FOR USE WITH OR WITHOUT EXTENAL POWER, L6884 REPLACEMENT SOCKET, ABOVE ELBOW DISARTICULATION, MOLDED TO PATIENT MODEL, FOR USE WITH OR WITHOUT EXTERNAL POWER, or L6885 REPLACEMENT SOCKET, SHOULDER DISARTICULATION/INTERSCAPULAR THORACIC, MOLDED TO PATIENT MODEL, FOR USE WITH OR WITHOUT EXTENAL POWER, as appropriate. In 2006, CMS implemented 3 new codes based on these sockets as predicate products which identify function as a category, and are intended to include external powered and mechanical prosthesis. It is inappropriate to bill any additional HCPCS Level II codes to differentiate the socket, or to bill for services.

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

Pricing = 38

Primary Speaker:

The primary speaker, on behalf of Hanger Prosthetics and Orthotics, disagreed with the workgroup's preliminary decision. According to the speaker, using one code to describe socket replacements for non-external powered and external powered is an error. The speaker states that there are functional differences in the two types of sockets; and that there is considerable time by the practitioner and patient in evaluating, testing, fabricating, fitting and training in the external powered that is not done in non-external powered. The speaker reiterated the original request for 3 new codes to distinguish non-external from external power control.

Meeting Agenda Item #15
April 26, 2006
HCPCS Request #06.74

Topic/Issue:
Request to revise code L5814 which currently reads: "Addition endoskeletal knee-shin system, polycentric, hydraulic swing phase control, mechanical stance phase lock".
Suggested language: replace "lock" with "control".

Background/Discussion:
According to the requester, the 3R60 EBS is a polycentric hydraulic prosthetic knee joint with a unique design that incorporates mechanical stance phase control. Mechanical stance phase control (with or without a lock) is designed to provide increased stability of the knee joint during loading of the limb to prevent collapse of the prosthetic knee joint and the possible fall by the amputee. Mechanical stance phase control provides a marked increase in the stability of the knee joint during loading response when the amputee is in a vulnerable position due to the ground reaction forces on the knee. This increased stability then decreases during late stance phase when the amputee is ready to initiate flexion of the knee joint. The 3R60 EBS prosthetic knee joint offers stance phase stability but because of a difference in design (there is no mechanical lock) cannot be coded under L5814 (though L5814 is the L-code that most appropriately describes the remaining functions in the 3R60 EBS). Mechanical stance phase control can be equally as effective without having a "mechanical lock."

CMS HCPCS Workgroup Preliminary Decision:
Establish a code:
Lxxxx ADDITION TO LOWER EXTREMITY PROSTHESIS, ENDOSKELETAL, KNEE-SHIN SYSTEM, POLYCENTRIC, FLUID SWING PHASE CONTROL, MECHANICAL STANCE PHASE CONTROL

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

Primary Speaker:
On behalf of Otto Bock, the primary speaker requested that, rather than creating a new code that describes stance phase control, that instead existing code L5814 should be revised to replace the word "hydraulic" with "fluid" and replace the word "lock" with "control", so that this product can fit in the existing code. This is in keeping with the original request to revise code L5814. This Otto Bock knee joint has control which, according to the speaker, is equivalent to a lock.

Meeting Agenda Item #16
April 26, 2006
HCPCS Request #06.76

Topic/Issue:

Request to establish a code for a Joint Angle Sensor, trade name: C-Leg® and Compact™ Microprocessor Knees. Suggested language: "Addition to Lower Extremity, Joint Angle Sensor"

Background/Discussion:

According to the requester, the Joint Angle Sensor is a discreet mechanical component that can be replaced, and is connected to a microprocessor within a prosthetic component. It is part of a prosthesis that provides the microprocessor with crucial data regarding the angular position of a prosthetic joint during the gait cycle. It is used to determine the flexion angle of a joint. The Joint Angle Sensor is a part within a prosthesis that gathers positional information, similar to a joystick used within a computer. The Joint Angle Sensor functions in a microprocessor-controlled knee in the following way: The knee has a small magnet within the axis of the knee. As the knee flexes and extends, the magnet rotates to a different position within the axis. There is a sensor embedded in the knee that is able to read the position of the magnet on the knee axis. The position of the magnet within the knee axis is being constantly sent to the microprocessor through a wire connection. The microprocessor then calculates the knee angle at a rate of fifty times per second from this information. The Joint Angle Sensor offers several key benefits to patients. These include: stumble recovery, helping to prevent falls while walking on uneven terrain; the reliability of accurate change from stance phase to swing phase; and stability of movement as needed. Additionally, since the Joint Angle Sensor automatically determines the correct moment in the gait cycle to switch from stance phase to swing phase, it allows the knee to anticipate the appropriate leg movement.

CMS HCPCS Workgroup Preliminary Decision:

Use existing code L5856 ADDITION TO LOWER EXTREMITY PROSTHESIS, ENDOSKELETAL KNEE-SHIN SYSTEM, MICROPROCESSOR CONTROL FEATURE, SWING AND STANCE PHASE, INCLUDES ELECTRONIC SENSOR(S), ANY TYPE, L5857 ADDITION TO LOWER EXTREMITY PROSTHESIS, ENDOSKELETAL KNEE-SHIN SYSTEM, MICROPROCESSOR CONTROL FEATURE, SWING PHASE ONLY, INCLUDES ELECTRONIC SENSOR(S), ANY TYPE, or L5858 ADDITION TO LOWER EXTREMITY PROSTHESIS, ENDOSKELETAL KNEE SHIN SYSTEM, MICROPROCESSOR CONTROL FEATURE, STANCE PHASE ONLY, INCLUDES ELECTRONIC SENSOR(S), ANY TYPE, as appropriate. These codes include microprocessors and sensors. The joint ankle sensors are therefore not separately billable. Use of miscellaneous or add-on codes is inappropriate. This item is an enhancement of functionality already described by codes L5856, L5857, and L5858.

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 #17
April 26, 2006
HCPCS Request #06.89

Topic/Issue:
Request to establish a code for a magnetorheologic actuator, trade name: Rheo Knee's magnetorheologic actuator.

Background/Discussion:
According to the requester, the magnetorheologic actuator of the Rheo Knee™ warrants a new code because the existing HCPCS codes for actuators do not fully describe its primary structural and functional characteristics. The magnetorheologic actuator contains iron particles suspended in oil. When subjected to a magnetic field, the suspended magnetic particles enable the prosthetic knee to create variable resistance to control motion during the swing and stance phases of ambulation. All prosthetic knees require an actuator to create swing and/or stance phase control for ambulation. Recommended language: Addition, single axis, magnetorheologic swing and stance phase control. As an alternative, Ms. Treiber recommends refining the existing actuator code for fluid actuators (L5828) as follows: Addition, single axis, fluid or magnetorheologic swing and stance phase control.

CMS HCPCS Workgroup Preliminary Decision:
Existing code L5828 "ADDITION, ENDOSKELETAL KNEE-SHIN SYSTEM, SINGLE AXIS, FLUID SWING AND STANCE PHASE CONTROL" adequately describes the actuator. No insurer identified a national program operating need to revise the text to include magnetorheologic. All items included in the L5828 category are fluid actuators and serve the same function.

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 #18
April 26, 2006
HCPCS Request #06.96

Topic/Issue:
Request to establish a code for the stance extension damping feature of the Rheo Knee, trade name: Rheo Knee's stance extension damping feature.

Background/Discussion:
According to the requester, the magnetorheologic actuator of the Rheo Knee™ warrants a separate code to ensure patient access to this important feature, similar to the separate code that exists for prosthetic knees with fluid actuators (L5848). Without stance extension damping, the knee moves abruptly back into an extended position, jarring the limb and producing a jerky, somewhat uncomfortable motion. The stance extension damping feature permits a smoother and safer forward progression that increases user safety. Recommended language: Addition, magnetorheologic stance extension, damping feature, with or without adjustability. As an alternative, Ms. Treiber recommends removing the "hydraulic" from the existing code for Fluid actuators (L5848) to make it more clearly applicable to other types of prosthetic knees performing the same function.

CMS HCPCS Workgroup Preliminary Decision:
Revise code L5848 which currently reads ADDITION TO ENDOSKELETAL, KNEE-SHIN SYSTEM, HYDRAULIC STANCE EXTENSION, DAMPENING FEATURE, WITH OR WITHOUT ADJUSTABILITY to instead read: ADDITION TO ENDOSKELETAL KNEE-SHIN SYSTE, FLUID STANCE EXTENSION, DAMPENING FEATURE, WITH OR WITHOUT ADJUSTABILITY. Use revised code L5848 to identify the item that is the subject of this request.

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 #19
April 26, 2006
HCPCS Request #06.28A-C

Topic/Issue:
Request to discontinue code L5995 "Addition to lower extremity prosthesis, heavy duty feature for patient weight >300 lbs", and replace with 3 separate codes (1 for feet, 1 for knees and 1 for all other heavy duty components). **Recommended language**:

1) "Addition to lower extremity prosthesis, heavy duty feature (foot only), for patient weight >300 lbs",
2) "Addition to lower extremity prosthesis, heavy duty feature (knee only), for patient weight >300 lbs", and
3) "Addition to lower extremity prosthesis, heavy duty feature (component other than foot or knee), for patient weight >300 lbs".

Background/Discussion:
According to the requester, instead of having a single code (L5995) that represents all possible heavy duty components, he suggests the establishment of three separate codes. One code for heavy duty feet; one code for heavy duty knees; and one code to encompass all other heavy duty components.

CMS HCPCS Workgroup Preliminary Decision:

A) Establish a new code:
Lxxxx ADDITION TO LOWER EXTREMITY PROSTHESIS, HEAVY DUTY FEATURE, FOOT ONLY, (FOR PATIENT WEIGHT >300LBS)

B) Establish a new code:
Lxxxx ADDITION TO LOWER EXTREMITY PROSTHESIS, HEAVY DUTY FEATURE, KNEE ONLY, (FOR PATIENT WEIGHT >300LBS)

C) Revise code L5995 which currently reads: ADDITION TO LOWER EXTREMITY PROSTHESIS, HEAVY DUTY FEATURE (FOR PATIENT WEIGHT > 300 LBS) to instead read: ADDITION TO LOWER EXTREMITY PROSTHESIS, HEAVY DUTY FEATURE, OTHER THAN FOOT OR KNEE (FOR PATIENT WEIGHT >300 LBS)

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 #20
April 26, 2006
HCPCS Request #06.83

Topic/Issue:
Request to establish a code for a prosthetic foot, ankle, and shank with posterior calf range of motion limiting device, trade name: PerfectStride.

Background/Discussion:
According to the requester, PerfectStride is a prosthetic foot that incorporates four major manufactured components and six minor manufactured components: 1) a longitudinal extending foot keel made of expoxy-laminated carbon composite, 2) an ankle coupler made of alloy, 3) a monolithically formed parabolic coiled resilient ankle joint area and shank that is anterior facing convexly curved and is made of aeronautical grade six titanium that has been solution treated, over aged and shot peened into a spring, 4) a posterior calf dorsiflexion range of motion limiting device. The ankle coupler functions to separate the parabolic coiled resilient ankle and shank from the foot keel creating a resilient ankle joint area that accurately replicates the biomechanical function of a human weight bearing tibia and ankle joint with muscular support. The mechanical design and orientation of the resilient ankle joint area and shank are key elements in providing the K3, K4 lower extremity amputee with near "normal" ankle joint kinematics and kinetic values. A new HCPCS code is justified because the PerfectStride uses grade six titanium in a new innovative spring design, utilizes more manufactured components, has a new mechanical mode of operation, and provides significant and measurable biomechanical improvements to lower extremity amputees. Recommended language: All lower extremity prosthesis foot, ankle, and shank with monolithically formed resilient anterior facing, convexly curved, and coiled ankle joint area and shank.

CMS HCPCS Workgroup Preliminary Decision:
The item has not yet been marketed in the United States. No insurer identified a national program operating need to identify it or to distinguish the item based on material used in manufacture. If and when the item is marketed in the U.S., existing code L5981 ALL LOWER EXTREMITY PROSTHESIS, FLEX-WALK SYSTEM OR EQUAL adequately identifies it. Use of L5999 or other miscellaneous codes is inappropriate.

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

Primary Speaker:
On behalf of BioQuest Prosthetics, the primary speaker disagreed with the workgroup's preliminary decision and reiterated a request for a unique code. According to the speaker, code L5981 identifies only low profile feet and is therefore not applicable to the Perfect Stride product. The speaker further claimed that the Perfect Stride offers a similar range of shock absorbing movement to products coded at L5987 and that, if L5987 were assigned, then use of code L5999 would be necessary, along with code

L5987, “ to describe the additional cost and complexity required to provide the additional biomechanical function.

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.