Centers for Medicare & Medicaid Services (CMS)
Summary Report
HCPCS Public Meeting
Thursday, May 4, 2006

Introduction and Overview

Michael Barron, CMS Office of Operations Management, moderated the meeting. Approximately 70 people attended. The agenda included 29 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.

HCPCS Meeting Agenda Item #1
May 4, 2006
Request #06.07 A&B

Topic/Issue:
Request to establish 2 new codes: A) Dimethicone 3%, trade name: Comfort Shield® Perineal Care Washcloths and B) Exopheryl™ Odor Eliminator (Cosmetic component of system) Dimethicone (Drug Component), trade name: Comfort Clean & Shield with Exopheryl™ Odor Eliminator and Dimethicone System.

Background/Discussion:
According to the requester, (A) the Comfort Shield with 3% Dimethicone is a Category One Skin Protectant (as defined by the FDA) for the treatment and prevention of Perineal Dermatitis. Its unique one-step delivery system ensures that affected skin receives adequate barrier protection every time the product is administered; and (B) the Comfort Clean and Shield's 3% dimethicone barrier is a category one skin protectant for the treatment and prevention of perineal dermatitis. The product's unique, pre-moistened washcloths are packaged to deliver complete incontinence cleanup and barrier protection in just two steps. First, Comfort Clean® cleanses, moisturized and eliminates odors on contact. Then Comfort Shield® treats and protects skin with a 3% dimethicone barrier. Comfort Shield Perineal Care Washcloths and Comfort Clean & Shield with Exopheryl Odor Eliminator and Dimethicone have been clinically tested for efficacy and proven to be gentle and non-irritating.

CMS HCPCS Workgroup Preliminary Decision:
These items are not primarily medical in nature. No insurer identified a national program operating need to establish codes to identify them. For Medicare, there is no benefit category and code A9270 "NON-COVERED ITEM OR SERVICE", should be used. For coding guidance for other insurers, contact the entity in whose jurisdiction a claim would be filed. For private insurance, contact the individual private insurance contractor. For Medicaid, contact the Medicaid Agency in the state in which a claim would be filed.

Medicare Payment:
This item is not covered by Medicare.
Pricing = 00

Primary Speaker:
On behalf of Sage Products, the speaker disagreed with the workgroup's preliminary decision. Comfort Shield is a 5 in 1 process which cleans, moisturizes, deodorizes, and provides barrier protection in a cloth. The speaker claimed that Comfort Shield saves steps and times when compared to cleaning the patient with soap and water, then separately applying skin barriers and moisturizers and asked that the product be reimbursed and uniquely identified.

HCPCS Meeting Agenda Item #2
May 4, 2006
Request #06.143

Topic/Issue:
Request to establish a code for adult bariatric incontinence brief, trade name: Attends® Bariatric Briefs, BREZ 1090, up to 90".

Background/Discussion:
According to the requester, Bariatric sized adult incontinence products are used by obese, primarily non-ambulatory, incontinent individuals. Adult incontinence products are designed to contain bowel and bladder leakage. Bariatric sized adult incontinence products are manufactured for extra fluid capacity giving added leakage control and extra wide expandable side tabs or added wing area to ensure proper fit for individuals larger than 63" in hips/waist. These products are commonly applied to a patient by a healthcare professional or caregiver as part of a plan of care developed by a treating physician.

CMS HCPCS Workgroup Preliminary Decision:
Establish new code TXXXX "DISPOSABLE INCONTINENCE PRODUCT, BRIEF/DIAPER, BARIATRIC, EACH". For Medicare, there is no benefit category and code A4520 "INCONTINENCE GARMENT, ANY TYPE, (E.G. BRIEF, DIAPER), EACH" should be used.

Medicare Payment:
This item is not covered by Medicare.
Pricing = 00

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

HCPCS Meeting Agenda Item #3
May 4, 2006
Request #06.08

Topic/Issue:
Request for Medicare and Medicaid coverage for the Good-Care Feeding Bottle, and associated modification to the HCPCS code set.

Background/Discussion:
According to the requester, the Good-Care Feeding Bottle is a baby feeding bottle that helps reduce gas and colic. Baby can drink from any angle, while standing, lying down or sitting. Bottle is simple to use and works like a regular bottle. Has no tubing so the baby won't choke or swallow anything. The requestor claims that this bottle can eliminate the air therefore helping reduce colic and gas; thus reducing the number of visits the baby takes to the hospital and expenses related to hospitalization. Patient population is for newborn and older. This bottle serves the following medical purposes: prevents neck strain; prevents choking if baby falls asleep; reduces liquid contact with teeth to avoid tooth decay; reduces ear infections caused by liquid escaping and flowing into the ear; and reduces hiccups caused by swallowing air.

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

Medicare Payment:
This item is not covered by Medicare.
Pricing = 00

Primary Speaker:
On behalf of Good Care Products, the speaker disagreed with the workgroup's preliminary decision and reiterated the company's request for a code. The speaker claimed that the Good-Care Feeding Bottle: 1) reduces gas and colic by reducing air ingestion; 2) is leak proof, decreasing the choking hazard; and 3) prevents ear infections from external leakage of milk into the ear.

HCPCS Meeting Agenda Item #4
May 4, 2006
Request #06.61

Topic/Issue:
Request to establish a code for a pediatric seat insert with an integrated back and seat that provides additional positioning support to patients, trade name: kidsert™

Background/Discussion:
According to the requester, due to reimbursement difficulties, many children with disabilities who require constant positioning support are forced to rely on inexpensive, off-the-shelf umbrella strollers from common retail stores as their primary mobility device. These strollers do not provide the safety and support that a disabled child needs, and many parents and caregivers compensate for this by trying to "prop up" the child into a better position with pillows, towels or other device in an attempt to give them support. The kidsert™ is a pre-contoured, water-repellant polyethylene foam and polyester pediatric integrated seat insert that can be added to a common, sling seat stroller, and offers a solution to this problem. The kidsert™ has anatomical contouring in the backrest and seat to provide extra support for disabled children with special positioning requirements, and is designed to compensate for the deficiencies of sling-back stroller seating. Currently, there are no other integrated pediatric seat inserts besides the kidsert™ that allow for increased positioning support in both the seat and the back that can be used in a standard sling seat pediatric stroller. All others are components of more expensive, custom mobility devices for the disabled. This request seeks an addition to the HCPCS seat and back cushion code series. The applicant's recommended code language is "Umbrella seating system with seat and back, pre-contoured insert, pediatric".

CMS HCPCS Workgroup Preliminary Decision:
Revise existing code T5001 which currently reads: "POSITIONING SEAT FOR PERSONS WITH SPECIAL ORTHOPEDIC NEEDS, FOR USE IN VEHICLES" to instead read: "POSITIONING SEAT FOR PERSONS WITH SPECIAL ORTHOPEDIC NEEDS".

For Medicare, existing codes E2293 "BACK, CONTOURED, FOR PEDIATRIC SIZE WHEELCHAIR INCLUDING FIXED ATTACHING HARDWARE", and E2294 "SEAT, CONTOURED, FOR PEDIATRIC SIZE WHEELCHAIR INCLUDING FIXED ATTACHING HARDWARE", are available for assignment, if appropriate. For coding guidance for Medicare, contact the Statistical Analysis Durable Medical Equipment Regional Carrier (SADMERC). For Medicaid, code T5001 is available for assignment; seek coding guidance from the Medicaid Agency in the state in which a claim would be filed. For coding guidance for private insurance, contact the individual private insurance contractor.

Medicare Payment:
This item is not covered by Medicare.
Pricing = 00
Primary Speaker:
There was no Primary Speaker for this item.

HCPCS Meeting Agenda Item #5
May 4, 2006
Request #06.71

Topic/Issue:
Request to establish 11 new codes to distinguish protective helmets and isolate straps, guards, ear covers and replacement interface; and delete code E0701 "Helmet with face guard and soft interface material, prefabricated".

Background/Discussion:
According to the requester, medical grade helmets for the use of skull protection should be identified separately from cranial reshaping helmets. Two of the existing codes are L codes that identify cranial reshaping helmets. Existing E code E0701 "HELMET WITH FACE GUARD AND SOFT INTERFACE MATERIAL, PREFABRICATED" only identifies one type of protective helmet. There are several different types of helmets used to reduce head injuries. The type of helmet is determined by a clinician based on the degree of physical activity of the client, the potential of striking surfaces and the degree of spasticity or frequency of seizures. The majority of the client's need of these types of helmets would be for post-operative use, persons with seizure disorders, gait problems, hemophilia, and behavioral problems. According to the requester, existing code L0100 "CRANIAL ORTHOSIS (HELMET), WITH OR WITHOUT SOFT INTERFACE, MOLDED TO PATIENT MODEL" is currently being used incorrectly, to identify protective helmets that do not fit the description of E0701 (for example, helmets without a face guard). The applicant is requesting the following modifications to the HCPCS code set:
Delete E0701 Helmet with face guard and soft interface material, prefabricated
Create EXXXX Helmet, protective, halo style, soft, prefabricated
EXXXX Helmet, protective, full, soft, prefabricated
EXXXX Helmet, protective, full, soft or hard, custom-fabricated
EXXXX Helmet, protective, full, hard, prefabricated
EXXXX Helmet, post-op protective, hard, prefabricated
EXXXX Helmet, newborn, hard, prefabricated
EXXXX Helmet addition, ear covers, per pair
EXXXX Helmet addition, face guard, each
EXXXX Helmet addition, chin guard, each
EXXXX Helmet addition, face bar, each
EXXXX Helmet, soft interface, replacement only

CMS HCPCS Workgroup Preliminary Decision:
1) Revise code E0701 which currently reads: "HELMET WITH FACE GUARD AND SOFT INTERFACE MATERIAL, PREFABRICATED" to instead read: "HELMET, PROTECTIVE, ANY TYPE, INCLUDES ALL COMPONENTS AND ACCESSORIES", to clarify that E0701 is intended for use to identify any type of protective helmet.
2) Revise code L0100 which currently reads: "CRANIAL ORTHOSIS (HELMET), WITH OR WITHOUT SOFT INTERFACE, MOLDED TO PATIENT MODEL" to instead read "CRANIAL REMODELING ORTHOSIS, WITH OR WITHOUT SOFT INTERFACE, MOLDED TO PATIENT"

3) Revise code L0110 which currently reads: “CRANIAL ORTHOSIS (HELMET), WITH OR WITHOUT SOFT-INTERFACE, NON-MOLDED” to instead read: “CRANIAL REMODELING ORTHOSIS, WITH OR WITHOUT SOFT-INTERFACE, NON-MOLDED”

The revisions to L0100 and L0110 are to clarify that these codes are intended for use with cranial remodeling orthoses, and are not appropriate for use to identify protective helmets.

Medicare Payment:
Fee schedule and payment rules associated with existing codes apply to these products.
Pricing = 32 (E0701)
Pricing = 38 (L0100 and L0110)

Primary Speaker:
On behalf of Danmar Products, the speaker agreed with the workgroup’s decision to revise codes L0100 and L0110. However, the speaker disagreed with the workgroup’s decision to revise E0701 to incorporate all types of protective helmets into one code. According to the speaker, protective helmets differ by clinical indication, material, and costs. The speaker requests that codes be established to differentiate hard vs. soft and prefabricated vs. custom fabricated helmets.

HCPCS Meeting Agenda Item #6
May 4, 2006
Request #06.12

Topic/Issue:
Request to establish a code for a compliance monitoring device, trade name: ResMed ResTraxx Data Center System.

Background/Discussion:
According to the requester, ResTraxx is a wireless compliance monitoring device that reports compliance data for CPAP patients. ResTraxx is a proactive system that does not require patients to take any additional steps in order to collect compliance data that that can be used to improve compliance. The requestor states that currently there are no codes that cover a wireless or other form of compliance monitoring device. ResMed requests the creation of a new code, based on a DME rental that can be used by the DME provider for CPAP therapy management.

CMS HCPCS Workgroup Preliminary Decision:
Establish new code AXXXX "MONITORING FEATURE/DEVICE, STAND-ALONE OR INTEGRATED, INCLUDES ALL ACCESSORIES, COMPONENTS AND ELECTRONICS, NOT OTHERWISE CLASSIFIED"

Medicare Payment:
This item is not covered by Medicare.
Pricing = 00

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

HCPCS Meeting Agenda Item #7
May 4, 2006
Request #06.90

Topic/Issue:
Request to establish a code Electronic Therapy Data Management Device (ETDMD) for Use with Continuous Positive Airway Pressure (CPAP) Devices or Bi-Level Respiratory Assist Devices (RADs), trade name: Respironics® SleepLink™ Modem System and Respironics® SmartCard® Technology. Requester Suggested Language**:** "Electronic Therapy Data Management Device (ETDMD) for Use with Continuous Positive Airway Pressure (CPAP) Devices or Bi-Level Respiratory Assist Devices (RADs)"

Background/Discussion:
According to the requester, the Respironics® SleepLink™ Modem System and Respironics® SmartCard® Technology are two products that fall within the proposed new code for electronic therapy data management devices. These ETDMDs are used only when CPAP or RAD therapy is medically necessary to treat severe respiratory disorders, such as obstructive sleep apnea. ETDMDs are used to collect, transmit and manage electronic data from either CPAP devices or RADs.

The Respironics® SleepLink™ Modem System is purchased, delivered, set up, monitored and repaired by the home medical equipment provider and permits remote transmission of data to the physician's office or hospital clinic via traditional telephone lines. Upon request by the treating physician, the provider also can adjust the prescribed treatment parameters (including therapy mode) on the patient's CPAP device or RAD via telephonic transmission. For instances in which telephonic transmission is not feasible or not preferred, Respironics SmartCard® Technology permits the provider or the patient to physically transport or mail the data in the same electronic format used by the SleepLink™ Modem . The SmartCard® System includes a removable credit card-sized disk that can be transported readily to the physician's office or hospital clinic. Similar to the SleepLink™ Modem, the provider can perform remote adjustment to the prescribed treatment parameters (including therapy mode) on the patient's CPAP device or RAD via the SmartCard®.

When added to a standard CPAP device or RAD, ETDMDs provide the treating physician with real-time electronic data on the clinical effectiveness of the prescribed therapy, the potential need for adjustments in prescribed treatment parameters and patient adherence to the prescribed treatment regimen. According to the requester, the existing HCPCS codes and reimbursement structure for standard CPAP devices and RADs do not recognize the added cost of equipment and associated professional support services.

CMS HCPCS Workgroup Preliminary Decision:
Establish new code AXXXX "MONITORING FEATURE/DEVICE, STAND-ALONE OR INTEGRATED, INCLUDES ALL ACCESSORIES, COMPONENTS AND ELECTRONICS, NOT OTHERWISE CLASSIFIED"

Medicare Payment:
This item is not covered by Medicare.
Pricing = 00

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

HCPCS Meeting Agenda Item #8
May 4, 2006
Request #06.109

Topic/Issue:
Request to establish a new code for an electronic positive airway pressure (PAP) monitoring device, trade name: e-Compliance.

Background/Discussion:
According to the requester, a unique code is needed for the e-Compliance to facilitate easier claims transmission and review, eliminate the need for manual pricing, and tracking of utilization in order to support outcomes data and validation of coverage. DeVilbiss requests a new code defined as "Electronic Device for Monitoring of Positive Airway Pressure (PAP) Device Compliance." The e-Compliance is used to confirm a patient's compliance during initial use of PAP devices. It provides objective data regarding usage of the device as well as other critical data which allows the health care team to assess the plan of care outlined for the patient. Studies indicated that patients are less complaint if they experience discomfort during sleep. The eCompliance alerts the home medical equipment supplier of non-compliance and allows the opportunity to contact the patient to determine what issues need to be addressed to ensure compliance. Additionally, when the monitoring device is used with bi-level or auto-adjusting devices, the physician can make further determinations regarding the clinical benefits of a PAP device and assess whether a different device or alternative treatment is indicated.

CMS HCPCS Workgroup Preliminary Decision:
Establish AXXXX "MONITORING FEATURE/DEVICE, STAND-ALONE OR INTEGRATED, INCLUDES ALL ACCESSORIES, COMPONENTS AND ELECTRONICS, NOT OTHERWISE CLASSIFIED"

Medicare Payment:
This item is not covered by Medicare.
Pricing = 00

Primary Speaker:
On behalf of Sunrise Medical, the speaker stated that Sunrise agreed with the workgroup's preliminary decision to establish a code to identify monitoring features/devices. The ability to have a specific code for the purposes of billing compliance monitoring will be useful in simplifying the billing process and tracking utilization. The speaker stated that monitoring devices eliminate self-reporting errors and enables early intervention with non-compliance, and enables "tech-savvy" patients to participate in their treatment.

HCPCS Meeting Agenda Item #9
May 4, 2006
Request #06.131

Topic/Issue:
Request to establish a code for a compliance-monitoring eye patch, trade name: Smart Eye Patch™.

Background/Discussion:
According to the requester, Smart Eye Patch is a new kind of compliance-monitoring eye patch for treatment of lazy eye. It is a single patient use, lightweight, comfortable eye cover designed to treat a child. Smart Eye incorporates a sensor and electronics for compliance monitoring, and comes with a read-out adapter and software. The read-out adapter connects to a computer to further analyze and display information related to compliance. Smart Eye protects the eye from minor impacts better than traditional eye patches. If fits under most eyeglasses. Smart eye monitors, records, analyzes and reports to parents and doctors when it is worn, and when they need to intervene to reinforce compliance. A sensor and microcontroller in the Smart Eye detect and analyze each time the patch is worn and when it is taken off. Significant data is stored in the chip's memory. When the child goes to bed, the patch is connected to a data transfer device, which sends the information about wearing to a computer for further analysis and review by parents and, through internet, by doctors. Smart eye is typically used in the treatment of children between the ages of three and six who have amblyopia.

CMS HCPCS Workgroup Preliminary Decision:
Establish AXXXX "MONITORING FEATURE/DEVICE, STAND-ALONE OR INTEGRATED, INCLUDES ALL ACCESSORIES, COMPONENTS AND ELECTRONICS, NOT OTHERWISE CLASSIFIED"

Medicare Payment:
This item is not covered by Medicare.
Pricing = 00

Primary Speaker:
On behalf of Bio-Key Engineering, the speaker thanked the workgroup for the new monitoring devices code; however, the speaker requested language that is specific to ophthalmic products. The speaker claimed that bundling conceptually related but significantly different systems (and future devices and systems) under one code may make it difficult to match appropriate reimbursement to the different contexts. Such mismatching under one code may make it difficult to match appropriate reimbursement to each need, and may lead to inefficiencies relating to payment and to delivery of services to those in need of these systems.

HCPCS Meeting Agenda Item #10
May 4, 2006
Request #06.30

Topic/Issue:
Request to establish a code for ECG Electrode, trade name: CardioQuick Patch™, a precordial overlay device for performing 12-lead electrocardiographic examinations.

Background/Discussion:
According to the requester, the CardioQuick Patch system is a precordial overlay for placement of V1-V6 electrocardiography electrodes used in 12-lead ECG examinations. The CardioQuick Patch is a single patient application device designed to stay with and on the patient for up to three days and replaces single electrode sensors for performing 12-lead ECG. The overlay or harness has electrode sensors embedded within the overlay, making sensor placement quicker and sensor handling easier. Current practice is for a health care practitioner to manually place ten (10) separate electrodes to create the traditional 12-lead ECG recording. The CardioQuick Patch allows placement of all six precordial (chest) electrodes in a manner that puts the electrodes in their proper location and orientation all at once. What further makes the CardioQuick Patch a unique product is a quick release liner, enabling patient care workers to quickly expose the adhesive and place all six precordial electrodes in under 25 seconds. The CardioQuick Patch is designed with the ability to adjust the electrodes so that is will fit 95% of the U.S. adult population.

CMS HCPCS Workgroup Preliminary Decision:
No insurer identified a national program operating need to create a new code in order to differentiate this product. Use existing codes A4556 ELECTRODES, (E.G., APNEA MONITOR), PER PAIR and A4557 LEAD WIRES, (E.G., APNEA MONITOR), PER PAIR for leads, as appropriate, to identify this product.

Medicare Payment:
Fee schedule and payment rules associated with existing codes apply to these products. Pricing = 34

Primary Speaker:
On behalf of Cardio-Quick Sys, the speaker disagreed with the workgroup's preliminary decision, and requests the establishment of a code to identify a precordial overly for placement of V1-V6 electrocardiography electrodes. According to the speaker, codes A4556 and A4557 do not describe this product because these codes identify individual electrodes and leads, where as the Cardio Quick Patch is a patch comprised of 6 chest leads in a unified device.

According to the speaker, this device assures accurate placement of leads; thereby expanding the EMS personnel who would be able to perform 12-lead ECG's. As a result, more patients will benefit by early ECG transmission and patient morbidity would decrease. The speaker claimed that the Cardio Quick Patch represents a new and totally unique vehicle for capturing ECG data from the patient. It holds the potential to improve patient outcomes and reduce related health care costs. As such, it warrants a unique code to facilitate claims and review process, eliminating the need for manual pricing.

HCPCS Meeting Agenda Item #11
May 4, 2006
Request #06.40

Topic/Issue:
Request to establish a code for Blood ketone test/reagent strips, trade name: Precision Xtra Blood B-Ketone Test Strips.

Background/Discussion:
According to the requester, Precision Xtra Blood B-Ketone Test Strips are used in connection with the Precision Xtra Advanced Diabetes Management System, a home glucose monitor that also allows people with diabetes to test their blood for ketone levels. The test strip is a supply that is necessary for the use of and for the proper functioning of the meter when testing for blood ketones. The strip is not intended for repeated use, as is the case with blood glucose strips. While there are currently HCPCS codes that can be used for urine test strips (A4250) and for blood glucose test strips (A4253), there is no HCPCS code to accurately identify and differentiate blood ketone test/reagent strips. Abbott is recommending the establishment of a new code "Blood ketone test/reagent strips, per 8 strips".

CMS HCPCS Workgroup Preliminary Decision:
No insurer identified a national program operating need to establish a code to identify this product. For Medicare, there is no benefit category, and code A9270 "NON-COVERED ITEM OR SERVICE" should be used. For coding guidance for other insurers, contact the insurer in whose jurisdiction a claim would be filed. For private insurance, contact the individual private insurance contractor. For Medicaid, contact the Medicaid Agency in the state in which a claim would be filed.

Medicare Payment:
This item is not covered by Medicare.
Pricing = 00

Primary Speaker:
On behalf of Abbott, the speaker disagreed with the workgroup's decision, specifically the statement that "there is no benefit category". The speaker claims that the Precision Ketone Test Strips meets the statutory definition of DME and, since blood ketone test strips are used in conjunction with a blood glucose monitor by individuals with diabetes, the ketone strips fall under the DME benefit. In addition, the speaker suggests that there is a national program operating need for a new code because insurance companies and state Medicaid programs are covering blood ketone test strips and the American Diabetes Association endorses their use. The speaker claims that the lack of a discrete billing code complicates the claims submission process.

HCPCS Meeting Agenda Item #12
May 4, 2006
Request #06.65

Topic/Issue:
Request to establish HCPCS codes for 1) fertility diagnostic device, trade name: Clearblue Easy Fertility Monitor; and 2) Clearblue Easy Fertility Monitor Testing Sticks.

Background/Discussion:
According to the requester, the Clearblue Easy Fertility Monitor is an over-the counter in-vitro diagnostic device which is intended to be used by women as an aid to conception by identifying those days in a woman's cycle on which intercourse is most likely to lead to conception. The device consists of an electronic monitor and works with urine test sticks sold separately. The device detects rises in two key fertility hormones: estrone-3-glucuronide (E3G), the major urinary metabolite of estrogen, and luteinizing hormone (LH). The product defines and displays three phases of fertility through early morning urine hormone measurement: low, high and peak fertility. Fertility Monitor is designed to adapt its testing strategy to the individual. The user will be required to test with ten or twenty test sticks per cycle of use. The Clearblue Easy Fertility Monitor Testing Stick is held in the urine stream for 3 seconds, the cap transferred to cover the sampling end and the test stick is placed in the reading slot of the monitor. The monitor will display the fertility status for that day 5 minutes after the test stick is inserted in the reading slot.

CMS HCPCS Workgroup Preliminary Decision:
No insurer identified a national program operating need to establish a code to identify these items. They are not primarily medical in nature. For Medicare, there is no benefit category, and code A9270 "NON-COVERED ITEM OR SERVICE" should be used. For coding guidance for other insurers, contact the entity in whose jurisdiction a claim would be filed. For Medicaid, contact the Medicaid Agency in the state in which a claim would be filed. For private insurance, contact the individual private insurance contractor.

Medicare Payment:
This item is not covered by Medicare.
Pricing = 00

Primary Speaker:
On behalf of Inverness Medical, Inc., the speaker disagreed with the workgroup's preliminary decision. According to the speaker, the Clearblue Easy is better than other methods of fertility monitoring devices because it increases conception rates, results in safer childbirths, and is less expensive than traditional infertility treatment without the monitor. The speaker also indicated that 12 states pay for infertility services.

HCPCS Meeting Agenda Item #13
May 4, 2006
Request #06.108

Topic/Issue:
Request to establish a new code for arterial stiffness/hardness monitor, trade name: Vital Vision MS-1200.

Background/Discussion:
According to the requester, this device is the only product available which measures the stiffness of the arterial wall in both a clinical and home setting. The S-value, arterial stiffness/hardness indication, is computed by the MS-1200 software by measuring non-linear pressure/volume relationship of the artery. The S-value, also referred to as H-value in some journals, is presented as a numerical value with a range of 1 through 8, with 8 representing significant impedance to the artery. In a clinical or home setting the purpose of this device is to monitor the progression or reduction of the conditions associated with atherosclerosis or the effectiveness of the prescribed treatment for atherosclerosis. Currently, only in-clinic procedures involving ultrasound and cat-scan technology are available to monitor the progression or reduction of the conditions associated with atherosclerosis. The Vital Vision performs the secondary functions of an oscillometric blood pressure measuring devices and computerized oscillometric pulse measurement. Vital Vision is intended for long-term multiple use and carries a 2-year warranty against defect. The applicant claims that existing code A4670 "Automatic Blood Pressure Monitor", as verified by the SADMERC, describes only secondary and tertiary uses of this device, and does not reflect the actual use of the device in terms of cardiovascular health and monitoring arterial stiffness.

CMS HCPCS Workgroup Preliminary Decision:
No insurer identified a national program operating need to establish a code to identify this item. Clinical information provided with the application does not demonstrate a superior clinical outcome as a result of monitoring arterial stiffness, or as a result of using this device. For Medicare, there is no benefit category for arterial stiffness monitoring. When used as a blood pressure monitor, existing code A4670 "AUTOMATIC BLOOD PRESSURE MONITOR" may be used.

Medicare Payment:
This item is not covered by Medicare.
Pricing = 00

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

HCPCS Meeting Agenda Item #14
May 4, 2006
Request #06.129

Topic/Issue:
Request to establish 2 codes for the procedure and supply of a continuous, beat-to-beat, non-invasive blood pressure monitor and sensor, trade names: TL-150 Tensymeter and TRA-150 T-Line Radial Artery Sensor with patient-specific wrist splint. Requester suggested language:
MXXXX – Non-invasive, continuous, beat-to beat, blood pressure monitor and sensor hook-up for monitoring with real-time waveform.
AXXXX – Radial artery sensor with patient-specific wrist splint for non-invasive, continuous, beat-to-beat, blood pressure monitoring with real-time waveform.

Background/Discussion:
According to the requester, the TL-150 Tensymeter (or T-Line) is a patented, unique device that allows non-invasive measurement of continuous beat-to-beat blood pressure. The TL-150 system includes the TL-150 Monitor, a durable capital medical equipment, and the TRA-150 T-Line Radial Artery Sensor, a disposable single-patient-use medical supply. The T-Line enables clinicians to continuously obtain the beat-to beat blood pressure from a patient undergoing surgery without the need for invasive catheterization of the radial artery. Continuous beat-to-beat blood pressure monitoring is preferred over intermittent means of measurement because of the frequent and often significant episodes of hemodynamic instability that occur during surgery. Such episodes are not detected very well by intermittent means, such as an automatic blood pressure cuff. Continuous measurement allows early detection and treatment of hemodynamic events. Because the T-Line is non-invasive and continuous, it provides the clinician the added safety of beat-to-beat blood pressure management without the risks generally recognized and associated with invasive arterial catheters, including thrombosis, air emboli, local hematoma, nerve damage, infection, vascular damage and ischemia resulting in potential loss of function in fingers and, in some cases, loss of limb.

CMS HCPCS Workgroup Preliminary Decision:
HCPCS Level II is not the appropriate coding jurisdiction for this item. When used during an inpatient procedure, it is included in the DRG. When used in an outpatient setting, it is included in the APC. CMS suggests that the applicant contact the American Medical Association (AMA) for CPT coding guidance.

Primary Speaker:
On behalf of Tensys Medical, the primary speaker disagreed with the workgroup's preliminary decision that (1) the HCPCS process is not the appropriate coding forum for the TL-150 set-up service and TL-150 sensor and (2) Tensys should contact the AMA instead.

The workgroup has exercised its authority and discretion in the past to establish other codes to denote categories of services that could have been but were not addressed by the AMA. Accordingly, the creation of a code to denote the set up of the TL-150 system falls within the jurisdiction of the workgroup. Even though a procedure is rendered in a hospital outpatient department and, hence, subject to APC payment, the hospital must

nevertheless use HCPCS codes to submit the UB-92 claims. Furthermore, as a professional service, a code is needed to denote the TL-150 set-up service so that certain health care professionals may bill separately to the local Part B Carrier, just as they do with CPT code 36620, which describes the invasive set-up service. The AMA CPT Editorial Panel does not code medical supplies like the TL-150 sensor. Therefore, only the workgroup has the jurisdiction to establish the A-code to denote this single-use supply. Tensys maintains that the codes requested are not only appropriate but also necessary because the current HCPCS coding system does not reflect these categories of service and supply.

HCPCS Meeting Agenda Item #15
May 4, 2006
Request #06.34A

Topic/Issue:
Request to establish a code for: Durable, CO_2 Powered Needle-Free Injection Management System, trade name: Biojector® 2000 Needle-Free Injection Management System Device.

Background/Discussion:
According to the requester, the B2000 is a high speed delivery system designed to inject medication intramuscularly or subcutaneously without a needle. The system has three components: a durable injection device, a disposable needle-free syringe, and a CO_2 cartridge. The product employs compressed carbon dioxide as a power source to eject medication through a tiny orifice in a fraction of a second, effectively penetrating the skin. The B2000 is the first of the needle-free injectors to provide safe and effective injections for both drugs and vaccines of up to 1mL in volume, allowing for the home administration of drugs previously only capable of administration in the physician's office. The product has been developed for home use by a patient or in a clinical setting by healthcare professionals as a safer and cost-effective alternative to conventional needles and infusion pumps. The requestor claims that the CO_2 power source delivers larger and deeper medication doses and can be used to deliver IM or subcutaneous injections of up to 1ml; whereas other injectors on the market deliver only subcutaneous doses of up to 0.5ml. The requestor also differentiates based on CO_2 power source vs: spring-loaded devices; durability (in terms of design and total number of doses it can be used to deliver); and metal, as opposed to plastic materials used in manufacture.

CMS HCPCS Workgroup Preliminary Decision:
Existing code A4210 "NEEDLE-FREE INJECTION DEVICE, EACH", adequately describes needle-free injection devices. No insurer identified a national program operating need to differentiate this product based on attributes discussed in this application. Use existing code A4210.

Medicare Payment:
Not a covered DMEPOS item, no separate Medicare payment for this supply.
Pricing = 00

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

HCPCS Meeting Agenda Item #16
May 4, 2006
Request #06.34 B&C

Topic/Issue:
Request to establish HCPCS "A" codes for: needle-free injection syringes and CO_2 cartridges, trade name: Biojector® 2000 Needle-Free Injection Management System Supplies: B) Disposable Syringes; and C) CO_2 Cartridges

Background/Discussion:
According to the applicant, this request is for codes to identify disposable supplies sold separately for use with the B2000 Needle-free injection management system. The syringe for the B2000 is significantly different than a standard syringe. It is manufactured specifically for the device, it is thicker than a standard syringe, or syringes used in other needleless systems (spring loaded). It is manufactured to withstand the additional pressure necessary to deliver an intramuscular versus subcutaneous injection. This capability is a significant distinguishing characteristic of the Biojector® 2000. The syringe has a patented geometry and method of forming the orifice which makes it consistently repeatable. It is a one piece syringe and does not utilize a jeweled orifice. The disposables are sold in separate boxes 1) a box of 100 syringes, and 2) a box of 10 CO_2 cartridges. These two boxes together are sufficient supplies for 100 injections. The syringe holds a variable volume of drug up to a maximum of one cubic centimeter (cc) or milliliter (mL). The syringe is filled either using a fill needle, or a plastic fluid transfer device. The CO_2 energy source is unique and specifically designed and sold separately for to the B2000, and delivers between 10 and 15 injections each. The CO_2 cartridge enables the B2000 to deliver the IM and higher volume injections. The additional pressure created by the CO_2 power source requires stronger disposable plastics built to withstand the added pressure.

CMS HCPCS Workgroup Preliminary Decision:
No insurer identified a national program operating need to separately identify these items. Use existing code A4211 "SUPPLIES FOR SELF-ADMINISTERED INJECTIONS".

Medicare Payment:
This item is not covered by Medicare.
Pricing = 00

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

HCPCS Meeting Agenda Item #17
May 4, 2006
Request #06.63

Topic/Issue:
Request to modify existing HCPCS code A4306 "Disposable drug delivery system, flow rate of 5 ml or less per hour" to reflect the full range of flow rates offered by products on the market. Requester suggested language**:** A4306 "Disposable drug delivery system, flow rate of less than 50 ml per hour". General product name: disposable drug delivery systems, trade name: PainPump and PainPump2.

Background/Discussion:
According to the requester, the PainPump1 is a vacuum driven pump that continually infuses a local anesthetic into the surgical field via a catheter placed intra-operatively. PainPump2 is an electronically driven pump that continually infuses a local anesthetic into the surgical field via a catheter placed intra-operatively. It is also intended for placement near a nerve to continue a peripheral nerve block. Both pumps are intended for the adult population undergoing orthopedic, bariatric, obstetric-gynecological, general, cardio-thoracic, podiatric, and plastic surgery, as well as anesthesia. The device is used exclusively to deliver medications and narcotics fro the management of pain associated with medical conditions. Current HCPCS codes describing disposable drug delivery systems (A4305, A4306) are inadequate to describe the range of products available and in use in the outpatient hospital and ambulatory care settings. A4305 describes systems with flow rates of 50 ml/hr or more, and A4306 describes systems with rates 5 ml/hr or less. There is no provision for pumps delivering rates for 6 to 49 ml/hr. Many pumps including Stryker Instruments' PainPump and PainPump2 provide flow rates less than 5 ml per hour but also deliver rates of flow that are in the 6-49 ml/hr range, thus it is unclear how to describe these products. We request that the descriptor for A4306 be changed to better describe the products being classified under it, and to insure that all products can be described with specific coding regardless of their flow rate. Changing A4306 to include all flow rates less than 50 ml/hr would eliminate the gap in rates under current codes. This will provide consistency in coding.

CMS HCPCS Workgroup Preliminary Decision:
Revise code A4306 which currently reads "DISPOSABLE DRUG DELIVERY SYSTEM, FLOW RATE 5 ML OR LESS PER HOUR" to instead read "DISPOSABLE DRUG DELIVERY SYSTEM, FLOW RATE OF LESS THAN 50 ML PER HOUR"

Medicare Payment:
This item is not covered by Medicare.
Pricing = 00

Primary Speaker:
On behalf of Stryker Corporation, the primary speaker agreed with the workgroup's preliminary decision to revise the descriptor of code A4306, and stated that the modification better reflects the full range of flow rates offered by products on the market and resolves confusion.

HCPCS Meeting Agenda Item #18
May 4, 2006
Request #06.67

Topic/Issue:
Request to establish a code for an external insulin pump in-warranty software upgrade, trade name: Paradigm® Pathway Program.

Background/Discussion:
According to the requester, The Paradigm® Pathway ™ is a separately purchased software program which allows current users of insulin pumps to upgrade their existing pumps and obtain clinically pioneering features, without purchasing a new pump. There are no HCPCS codes which describe this unique item. E0784 "external infusion pump, insulin" is used when an entire pump is purchased. The requester suggests the following language for the requested new code: "EXXXX Software upgrade, external ambulatory infusion pump".

CMS HCPCS Workgroup Preliminary Decision:
No insurer identified a national program operating need to establish a code to identify a software upgrade. For Medicare, there is no benefit category, and code A9270 "NON-COVERED ITEM OR SERVICE" should be used. For coding guidance for other insurers, contact the entity in whose jurisdiction a claim would be filed. For Medicaid, contact the Medicaid Agency in the state in which a claim would be filed. For private insurance, contact the individual private insurance contractor.

Medicare Payment:
This item is not covered by Medicare.
Pricing = 00

Primary Speaker:
On behalf of Medtronic, the primary speaker disagreed with the workgroup's preliminary decision and asked that a code be created to describe the software upgrade for external ambulatory infusion pump. The speaker stated that instead of purchasing new pumps as technology evolves, patients can upgrade their pump with the latest technology for a nominal fee compared to a new pump by using the Pathway Software. According to the speaker, the upgrade is considered medical, a physician's prescription is required, and it is only used in conjunction with a medical item, and a code is needed for payers who cover the software upgrade.

HCPCS Meeting Agenda Item #19
May 4, 2006
Request #06.70

Topic/Issue:
Request to establish a code for a needle destruction device, trade name: Disintegrator Plus Insulin Needle & Lancet Destruction Device. Requester suggested language**:** "FDA Approved Insulin Needle Destruction Devices for Home Use"

Background/Discussion:
According to the requester, Disintegrator Plus Insulin Needle & Lancet Destruction Device is a small teardrop shaped portable insulin needle and lancet destruction device for use at home by patients with diabetes. It uses a small 9.6 volt rechargeable battery to deliver a plasma arc that disintegrates the needles. The device is intended for lancets and insulin needles. It can be used with most insulin pens and with disposable insulin syringes form 1/3 to 1 cubic centimeter in volume. This portable, rechargeable battery operated device utilizes a plasma arc to melt the steel portion of an insulin syringe (or pen) needle to lancet into a harmless 'BB' shaped ball, eliminating the potential for injury to the patient and allowing for household disposal without endangering waste handlers, the environment for the general public. The used needle or lancet is inserted into a hole on the device and the power button is pressed for a few seconds (lights on the unit are used to indicate when the process is complete). The unit produces an arc of electricity that melts the needle into a harmless 'BB' shaped ball. The applicant mentions 2 states that identify this device using either a miscellaneous "T" code, or using "Y" codes, (which are not HIPAA compliant).

CMS HCPCS Workgroup Preliminary Decision:
No insurer identified a national program operating need to establish a code to identify a needle destruction device. This item is not primarily medical in nature. For Medicare, there is no benefit category, and code A9270 "NON-COVERED ITEM OR SERVICE" should be used. For coding guidance for other insurers, contact the entity in whose jurisdiction a claim would be filed. For Medicaid, contact the Medicaid Agency in the state in which a claim would be filed. For private insurance, contact the individual private insurance contractor.

Medicare Payment:
This item is not covered by Medicare.
Pricing = 00

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

HCPCS Meeting Agenda Item #20
May 4, 2006
Request #06.03A & B

Topic/Issue:
Request to establish 2 "L" codes: A) one for seamless diabetic socks, trade name: SmartKnit Seamless Socks; and B) one for seamless diabetic socks with X-Static silver fiber, trade name: SmartKnit Seamless Sock with X-Static.

Background/Discussion:
According to the requester, the SmartKnit Seamless Sock is made using a patented knitting process, designed specifically for the protection of diabetic feet. This sock has a seamless toe and heel design, soft conforming fit (to reduce sock wrinkles), a non-restrictive top and an antimicrobial treatment. The SmartKnit Sock is knit from a core spun coolmax fiber, which provides superior wicking properties. The SmartKnit Sock with X-Static is made using silver (polyester X-Static blend) fiber, which provides superior wicking properties and odor reduction, and is antimicrobial, antifungal, thermal dynamic and antistatic. The antimicrobial and antifungal kill fungus and bacteria. The wicking properties for both socks move moisture away the foot creating a dryer, healthier environment for the diabetic foot. The SmartKnit socks have also been shown to disperse pressure on the foot, reducing specific pressure points and possible breakdown in that area. These socks are used for the reduction of ulcers in the diabetic population. The SmartKnit Sock is used as an interface between the diabetic foot and the shoe.

CMS HCPCS Workgroup Preliminary Decision:
No insurer identified a national program operating need to establish codes to identify these items. They are not primarily medical in nature. They are not orthotic or prosthetic devices, therefore use of "L" codes is inappropriate. For Medicare, there is no benefit category, and code A9270 "NON-COVERED ITEM OR SERVICE" should be used, and use of miscellaneous codes is inappropriate. For coding guidance for other insurers, contact the insurer in whose jurisdiction a claim would be filed. For private insurance, contact the individual private insurance contractor. For Medicaid, contact the Medicaid Agency in the state in which a claim would be filed.

Medicare Payment:
This item is not covered by Medicare.
Pricing = 00

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

HCPCS Meeting Agenda Item #21
May 4, 2006
Request #06.35

Topic/Issue:
Request to either establish a new "L" code for a Static Ankle Plantar-Flexion Prevention Device, trade name: the Strassburg Sock™ Plantar Fasciitis Night Splint or modify the wording in code L1901 to replace "ankle orthosis" with "ankle foot orthosis". Requester suggested language: LXXXX "Ankle Foot Orthosis, neoprene or Lycra, adjustable with Velcro strap, prefabricated, includes fitting and adjustment"

Background/Discussion:
According to the requester, the Strassburg Sock™ is a night splint used primarily for the treatment of plantar fasciitis. It is constructed of a tubular knit nylon/Lycra blend, a plastic d-ring, 2 adjustable Velcro straps, and extensive sewing. The lightweight breathable material allows for a more effective and comfortable positioning of the foot and ankle which speeds healing, improves compliance, and provides support and counterforce on the limb by restricting or eliminating motion in the diseased or injured body part. The Strassburg Sock not only holds the ankle in the proper position, but also dorsiflexes the toes engaging the windlass mechanism providing a more efficient method to hold the plantar fascia at its maximum anatomic length.

CMS HCPCS Workgroup Preliminary Decision:
No insurer identified a national program operating need to establish a code to identify this item. It is not an orthotic; therefore use of "L" codes is inappropriate. For Medicare, there is no benefit category, and code A9270 "NON-COVERED ITEM OR SERVICE" should be used. For coding guidance for other insurers, contact the insurer in whose jurisdiction a claim would be filed. For private insurance, contact the individual private insurance contractor. For Medicaid, contact the Medicaid Agency in the state in which a claim would be filed.

Medicare Payment:
This item is not covered by Medicare.
Pricing = 00

Primary Speaker:
On behalf of Strassburg Medical, the primary speaker disagreed with the workgroup's preliminary decision and reiterated the original request for the establishment of a new code for the Strassburg Sock. According to the speaker, the Strassburg Sock meets the definition of an orthotic functionally and structurally; and is consistent with coding precedent established for currently coded products. The speaker stated that code L4396 describes this product; however, he suggests that "a new product specific code would be more appropriate with more reasonable reimbursement".

HCPCS Meeting Agenda Item #22
May 4, 2006
Request #06.50

Topic/Issue:
Request to establish a code for wrist joint ulna-hemi wrist/polymer prosthesis, trade name: Scheker Distal Radio-Ulnar Joint (DRUJ) Prosthesis.

Background/Discussion:
According to the requester, the Scheker prosthesis is a modular, semi-constraint prosthesis utilized to reconstruct the distal radioulnar joint to stabilize the joint and resolve the pain associated with the instability. There is no other device equivalent to this prosthesis. There are some devices that replace the ulnar head, but do not maintain stability. This joint replacement has been used for patients on whom one or more of the so-called "salvage procedures" have been performed to correct ulnar head instability, ulna-carpal abutment, distal radioulnar joint arthritis, and chronic, painful instability of the distal radial ulnar joint. The forces acting in the forearm include axial loading and lifting against gravity, in which the distal radioulnar joint is involved.

CMS HCPCS Workgroup Preliminary Decision:
No insurer identified a national program operating need to separately identify this item. Payment is included with the procedure, and therefore this item is not separately billable. For Medicare, when performed in an in-patient setting, the procedure is included in the DRG. In OPPS, the device is bundled into the procedure payment, although the device is separately reportable using code C1776 "JOINT DEVICE (IMPLANTABLE)". For coding guidance for other insurers, contact the insurer in whose jurisdiction a claim would be filed. For private insurance, contact the individual private insurance contractor. For Medicaid, contact the Medicaid Agency in the state in which a claim would be filed.

Primary Speaker:
On behalf of Aptis Medical, the primary speaker stated that the Scheker DRUJ is a completely new product that is not described by existing codes. The speaker requested a "separately billable" code for use in HOPPS. DRUJ is a hemi-joint implant that replaces both joint surfaces and all 3 structures.

HCPCS Meeting Agenda Item #23
May 4, 2006
Request #06.130

Topic/Issue:
Request to establish a code for a custom made orthosis for the lower leg and foot, trade name: Ulcer Healing Orthosis (UHO).

Background/Discussion:
According to the requester, the Ulcer Healing Orthosis is a custom made orthosis for the lower leg and foot that is fitted into a modified shoe. The Ulcer Healing Orthosis is indicated for diabetics with plantar ulcers, charcot joint, and or foot deformity. It offloads the plantar ulcer, allowing it to heal. The patient puts the UHO on, followed by their shoe, and then begins walking.

CMS HCPCS Workgroup Preliminary Decision:
Existing code L1940 "ANKLE FOOT ORTHOSIS, PLASTIC OR OTHER MATERIAL, CUSTOM-FABRICATED" adequately describes this item when used as an orthotic. For Medicare, there is no benefit category for off-loading, therefore the "GY" modifier must be used with code L1940 when this device is used for off-loading. For coding guidance for other insurers, contact the entity in whose jurisdiction a claim would be filed. For Medicaid, contact the Medicaid agency in the state in which a claim would be filed. For private insurance, contact the individual private insurance contractor.

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

Primary Speaker:
On behalf of DuPage Prosthetic-Orthotic Services inc., the primary speaker disagrees with the workgroups preliminary decision. According to the speaker L-code 1940 does not benefit the Patient condition category of a diabetic with chronic plantar ulceration, it does not benefit category Off-Loading, as required by the American Diabetes Association, it does not benefit adjunctive wound therapy, it does not require a modified shoe, it does not require extensive wound evaluation, it does not require a clear checks socket prior to fabrication, it does not require extensive photo file of patients wound progress, it does not require biweekly checkup appointments to monitor wound healing and orthotic effectiveness. The Ulcer Healing Orthosis is a United States Patented Method and device thereby providing specific utility method and design claims not afforded L-Code 1940. The (UHO) provides all the benefits mentioned above and will save the Medicare Trust Fund Monies by preventing the many Co morbidities associated with current failure rates in wound healing. The Speaker requested in accordance with the National Coverage Decision (70.2.1) that new condition categories, new L-Codes, and create a new quality improvement initiative concerning the use of the (UHO) for Diabetic Plantar Ulcer Patients.

HCPCS Meeting Agenda Item #24
May 4, 2006
Request #06.69

Topic/Issue:
Request to establish an "E" code for a portable shower, trade name: FAWSsit. Requester suggested language: EXXXX "Shower stall, portable, includes shower attachments, drain pan, and electric pump".

Background/Discussion:
According to the requester, FAWSsit is a portable, collapsible shower stall. The total weight of the FAWSsit is 38 pounds, and it folds to 8 inches in depth. FAWSsit does not require tools to set up. FAWSsit must be set up in an area where water resources are available, as well as a drain for removing the person's bath water (ex: kitchen). The FAWSsit is designed for patients who are wheelchair bound, or who have any debilitating conditions and are too weak or too sick to use a traditional shower/bath. According to the requester, when the patient is unable to bathe or shower in a traditional bath setting, the FAWSsit can decrease the incidence of urinary tract infections, promote circulation, promote muscle relaxation and wound care cleanliness by allowing the patient to be able to bathe.

CMS HCPCS Workgroup Preliminary Decision:
No insurer identified a national program operating need to establish a code to identify a portable shower. This item is not primarily medical in nature. For Medicare, there is no benefit category, and code A9270 "NON-COVERED ITEM OR SERVICE" should be used. For coding guidance for other insurers, contact the entity in whose jurisdiction a claim would be filed. For Medicaid, contact the Medicaid Agency in the state in which a claim would be filed. For private insurance, contact the individual private insurance contractor.

Medicare Payment:
This item is not covered by Medicare.
Pricing = 00

Primary Speaker:
On behalf of Care Giver Support Products Inc., the primary speaker disagreed with the workgroup's preliminary decision and reiterated the applicant's original request for the establishment of a new HCPCS code. The speaker stated that the FAWSsit is a new technology medical device that meets the needs of medically disabled people as it aids in maintaining good hygiene. The FAWsit eliminates the expenses of home remodeling for those who cannot afford renovations. According to the speaker, a national code is necessary for payers that cover this product.

HCPCS Meeting Agenda Item #25
May 4, 2006
Request #06.132

Topic/Issue:
Request to establish a code for an air purifier, trade name: Airsonett Airshower.

Background/Discussion:
According to the requester, the Airsonett Airshower system consists of a filter section with HEPA filter, a cooler section, a nozzle and control and regulating equipment, all in one complete mobile unit that plugs into an ordinary wall socket. Purified air is delivered about 20 inches above a patient's head. The clean, slightly cooled air moves slowly downward due to its somewhat higher density, displacing the contaminated ambient air with negligible turbulence and mixing, which guarantees a particulate level of less than 5,000 particles/ft3 in the breathing zone, preferable during night time sleep. Airsonett is clinically indicated primarily for patients with allergic asthma and atopic dermatitis. Applicant suggests that code language covers an airshower with the following specification: "Vertical laminar air displacement by controlled thermal stratification, creating a clean air zone of less than 5000 particles/ft3 (particles with aerodynamic diameter $\geq$0.5µm) measured within a 2 inch radius from patients nose lying down in a bed in a normal indoor environment".

CMS HCPCS Workgroup Preliminary Decision:
No insurer identified a national program operating need to establish a code to identify this air purifier. This device is not primarily medical in nature. For Medicare, there is no benefit category, and code A9270 "NON-COVERED ITEM OR SERVICE" should be used. For coding guidance for all other insurers, contact the entity in whose jurisdiction a claim would be filed. For Medicaid, contact the Medicaid agency in the state in which a claim would be filed. For private insurance, contact the individual private insurance contractor.

Medicare Payment:
This item is not covered by Medicare.
Pricing = 00

Primary Speaker:
On behalf of Airsonett, the primary speaker disagreed with the workgroup's preliminary decision and requested that a HCPCS code and coverage be granted. According to the speaker, the Airsonett Airshower decreases need for medication, decreases symptoms, decreases infections, eliminates allergens from the air, and improves sleep of asthma and allergy patients. The Swedish Handicap Institute for has approved the Airsonett Airshower for validated air improvement.

HCPCS Meeting Agenda Item #26
May 4, 2006
Request #06.72

Topic/Issue:
Request to establish a code for intermittent pneumatic segmented compression device, trade name: C-Boot™.

Background/Discussion:
According to the requester, the C-Boot is the first intermittent pneumatic compression device powered automatically by energy generated from the patient's body. C-Boot is lightweight, self-powered device allows patients to maintain complete mobility without the need for cumbersome external pumps. As patients step, their own kinetic energy starts C-Boot's intermittent pumping action. The pneumatic segmented device inflates and deflates to produce sequential graduated intermittent compression that reduces edema, promotes circulation and hastens the healing process in a highly effective, natural way. According to the requester, the C-Boot is different from other, similar products that require an electrical compressor limit a patients' mobility when in use. In addition, a prior code verification issued by the SADMERC to use A4465 "NON-ELASTIC BINDER FOR EXTREMITY" understates the purpose of the C-Boot and does not describe segmented, pneumatic, dynamic pressure as provided by the C-Boot.

CMS HCPCS Workgroup Preliminary Decision:
Existing code A4465 "NON-ELASTIC BINDER FOR EXTREMITY" adequately describes a category of items with the same or similar function. Clinical information provided by the applicant does not include peer-reviewed evidence that would support a claim of superior clinical outcome when using this device, as compared with other devices categorized at A4465. No insurer identified a national program operating need to differentiate this item based on patient mobility while the compression device is in use.

Medicare Payment:
This item is not covered by Medicare.
Pricing = 00

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

HCPCS Meeting Agenda Item #27
May 4, 2006
Request #06.81

Topic/Issue:
Request to establish a code for single unit anti-rotation device applied to the leg, trade name: Hug-a-leg.

Background/Discussion:
According to the requester, the Hug-A-Leg single unit device is used when the patient lies down to stabilize the leg at the hip, the knee, the ankle or the foot area. It is used in a reclining position. The doctor, the nurse or patient can adjust the device as two molded areas cushioned inside with foam can completely adjust to the patient in a customized fashion because of the foam and the movable parts to fix the leg while the patient is reclining, to prevent both external rotation and internal rotation that occurs while a patient is lying down. This can be used with a cast or without a cast on any leg fracture. This product can be used after a hip surgery, knee surgery, and ankle surgery. It prevents both internal and external rotation aligning the structures for optimal healing. According to the requester, manufacturers will not bring this product to market and hospitals will not purchase it without an "L" code and an associated reimbursement amount.

CMS HCPCS Workgroup Preliminary Decision:
No insurer identified a national program operating need to establish a code to identify this anti-rotation device. It is a convenience item. For Medicare, there is no benefit category, and code A9270 "NON-COVERED ITEM OR SERVICE" should be used. For coding guidance for other insurers, contact the entity in whose jurisdiction a claim would be filed. For Medicaid, contact the Medicaid Agency in the state in which a claim would be filed. For private insurance, contact the individual private insurance contractor. Inquiries regarding coverage are not within the purview of the HCPCS code set maintainers, and should be submitted directly to insurers.

Medicare Payment:
This item is not covered by Medicare.
Pricing = 00

Primary Speaker:
On behalf of Hug-A-Leg, the primary speaker disagreed with the workgroup's preliminary decision that Hug-A-Leg is a convenience item and reiterated the original request for a HCPCS code to describe this item. According to the speaker, Hug-A-Leg devices are classified by the FDA as a brace, and meets the legal definition of an orthotic in that it is intended for medical purposes to be worn on the upper or lower extremity to support, correct, or prevent deformities or to align body structures for functional improvement. The speaker stated that Hug-A-Leg products prevent other problems, such as malunion and pain, and thereby curtail overall cost of medical treatment.

HCPCS Meeting Agenda Item #28
May 4, 2006
Request #06.82

Topic/Issue:
Request to establish a code for double unit anti-rotation device applied to the leg, trade name: Hug-a-leg.

Background/Discussion:
According to the requester, the Hug-A-Leg double unit device is a customizable external device to fix a legs position and to support the leg and prevent deformities. It can also be used on an arm. It is a joint, ankle or external fixation limb brace. It can be used with or without a cast. Hug-A-Leg prevents external rotation or internal rotation of broken bones and torn tissues to heal. This device prevents the external rotation that is the foot flopping outward, and aligns the soft and hard tissues. There are sliding portions of the brace with soft moldable foam against the body that is completely customized to the patient. The two units can be joined with connecting bars. These act as a complete external fixation. The patient population for whom this product is clinically indicated are patients with hip fractures, patients with hip replacement, complex injuries of the knee including implants, all fractures of the lower leg including ankle, foot with or without a joint injury requiring stabilization, cases of brittle soft bones as with diabetes, all ligamentous traumatic injuries.

CMS HCPCS Workgroup Preliminary Decision:
No insurer identified a national program operating need to establish a code to identify this anti-rotation device. It is a convenience item. For Medicare, there is no benefit category, and code A9270 "NON-COVERED ITEM OR SERVICE" should be used. For coding guidance for other insurers, contact the entity in whose jurisdiction a claim would be filed. For Medicaid, contact the Medicaid Agency in the state in which a claim would be filed. For private insurance, contact the individual private insurance contractor. Inquiries regarding coverage are not within the purview of the HCPCS code set maintainers, and should be submitted directly to insurers.

Medicare Payment:
This item is not covered by Medicare.
Pricing = 00

Primary Speaker:
On behalf of Hug-A-Leg, the primary speaker disagreed with the workgroup's preliminary decision that Hug-A-Leg is a convenience item and reiterated the original request for a HCPCS code to describe this item. According to the speaker, Hug-A-Leg devices are classified by the FDA as a brace, and meets the legal definition of an orthotic in that it is intended for medical purposes to be worn on the upper or lower extremity to support, correct, or prevent deformities or to align body structures for functional improvement. The speaker stated that Hug-A-Leg products prevent other problems, such as malunion and pain, and thereby curtail overall cost of medical treatment.

HCPCS Meeting Agenda Item #29
May 4, 2006
Request #06.107

Topic/Issue:
Request to establish a code for a pressure off-loading shoe, trade name: DynaWalk™. Requester suggested language**: "**AXXXX – Pressure off-loading system, includes metatarsal bars, heat-moldable insert, and rocker sole, each".

Background/Discussion:
According to the requester, the DynaWalk™ is a pressure off-loading system that can be precisely adjusted to offload diabetic foot ulcers, fractures, and post-op conditions requiring off-loading. It is designed to enhance mobility for foot wounds, trauma, and some types of fractures. The insert consists of three layers. The top layer is plastazote, the middle layer is poron and the bottom layer is EVA. The footplate and metatarsal bars are made of ABS with an over mold constructed of polyurethane. Pressure off-loading of the foot is appropriate as part of an ulcer management program to promote healing of the ulcer and injured structures. Pressure off-loading is done through the use of metatarsal bars that can be precisely positioned to off-load either the forefoot or the rear foot. The system also comes with a triple-density heat moldable insole to help distribute pressures more evenly and off-load pressure sensitive areas, allowing a faster healing cycle. The triple-density heat moldable insert can be used for the treatment of foot biomechanics abnormalities. The support is adjusted to minimize shearing forces. The footplate is rigid so as to provide a solid platform on which motion to the foot is significantly minimized.

CMS HCPCS Workgroup Preliminary Decision:
Existing code L3260 "SURGICAL BOOT/SHOE, EACH" adequately describes the item that is the subject of this application. No insurer identified a national program operating need to differentiate the DynaWalk from other items coded at L3260 that perform the same or similar function. Medicare does not have a benefit category for off-loading. Use of L2999 or other miscellaneous codes is inappropriate.

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

Primary Speaker:
On behalf of Shimi-Shoe Walking Technologies, Ltd., the primary speaker disagreed with the workgroup's preliminary decision that existing code L3260 adequately describes the Shimi-Shoe. The speaker stated that the Shimi-Shoe is strictly designed for off-loading of the diabetic foot ulcer as a treatment modality; and is not intended for post-operative protection of a surgical site, and therefore the Shimi-Shoe is not described by code L3260.

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.