Centers for Medicare & Medicaid Services (CMS)
Healthcare Common Procedure Coding System (HCPCS)
Public Meeting Summary Report
Supply & Other – Day 2
Wednesday, April 23, 2008

Introduction and Overview

Approximately 40 people attended. The agenda included 19 items.

Joel Kaiser of CMM presented an educational overview of the 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 and is also attached to this summary. 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/feeschedulegeninfo.

Cindy Hake provided an overview of the HCPCS public meeting process as it relates to the overall HCPCS coding process.

Prior to the Public Meetings, CMS HCPCS workgroup meets to review all HCPCS code applications, and make preliminary coding recommendations CMS also makes a preliminary recommendation 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 meetings, CMS HCPCS workgroup reconvenes, and considers all input provided at the Public Meetings regarding its preliminary coding recommendations. CMS also reconsiders its Medicare payment recommendations. CMS maintains the permanent HCPCS level II codes, and reserves final decision making authority concerning requests for permanent HCPCS codes. Final decisions regarding Medicare payment are made by CMS and must comply with the Statute and Regulations. Payment determinations for non-Medicare insurers, (e.g., state Medicaid Agencies or Private Insurers) are made by the individual state or insurer.

All requestors will be notified in writing, in November, of the final decision regarding the HCPCS code request(s) they submitted. At around the same time, the HCPCS Annual Update is published at:
www.cms.hhs.gov/HCPCSReleaseCodeSets/ANHCPCS/itemdetail.asp.

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

website at: http://cms.hhs.gov/medhcpcsgeninfo/downloads/2008guidelines.pdf . 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 at: http://cms.hhs.gov/medhcpcsgeninfo/downloads/2009_alpha.pdf. A decision tree, outlining CMS' decision-making criteria is also available at: http://cms.hhs.gov/medhcpcsgeninfo/downloads/decisiontree.pdf.

Centers for Medicare & Medicaid Services (CMS) Healthcare Common Procedure Coding System (HCPCS) Public Meeting Agenda for Supplies and "Other"
Wednesday, April 23, 2008, 9:00 am – 5:00 pm
CMS Auditorium
7500 Security Boulevard
Baltimore (Woodlawn), Maryland 21244-1850

8:15 a.m. Arrival and sign-in

9:00 a.m. Welcome
Background and purpose of meeting
Meeting Format and Ground Rules

For each agenda item, a written overview of the request and CMS's preliminary coding decision is provided. An overview of Medicare pricing/payment, methodology is also attached to this agenda. Preliminary decisions are not final or binding upon any payer, and are subject to change. Meeting participants will hear presentations about the agenda item from the registered primary speaker and other speakers (if any). Presentations will be followed by an opportunity for questions regarding that particular agenda item. The public meetings provide an opportunity for the general public to provide additional input related to requests to modify the HCPCS code set. Final decisions are not made at the public meetings. Applicants will be notified of final decisions in November.

The agenda includes a summary of each HCPCS code application on the agenda. The information provided in each summary reflects claims made by the applicant and should not be construed as a statement of fact or an endorsement by the federal government.

AGENDA ITEM #1
Attachment #08.76
Request to establish new codes for a custom made ankle foot orthosis, trade name: Ulcer Healing Orthosis (U.H.O.)

Primary Speaker: John Rooney of DuPage Prosthetic-Orthotic Services, Inc.

AGENDA ITEM #2
Attachment #08.111
Request to establish a code for a portable shower for the wheelchair bound individual, Trade name: FAWSsit Fold Away Wheelchair Shower.

No Primary Speaker

AGENDA ITEM #3
Attachment #08.113
Request to establish 2 codes for pelvic shorts, trade name: Coreshorts.

Primary Speaker: Greg Bay of Coretection

AGENDA ITEM #4
Attachment #08.35
Request to establish a code for a custom made to measure Lycra tension based Thoracic Lumbar Sacral Orthosis (TLSO), trade name: Dynamic Movement orthosis TLSO.

Attachment #08.36
Request to establish a code for a custom made to measure Lycra tension based elbow, wrist, hand orthosis (EWHO), Trade Name: Dynamic movement EWHO.

No Primary Speaker

AGENDA ITEM #5
Attachment #08.11
Request to establish a code for vibrating shoes with a self contained power source, trade name: Good Vibrations Therapeutic Vibrating Shoes.

Primary Speaker: Richard Koenig, M.D.

AGENDA ITEM #6
Attachment #08.101
Request to establish a code for a dynamically molded inlay. Trade name: Dynamic Insole.

Primary Speaker: Eric Koetter of Active Ankle Systems, Inc.

AGENDA ITEM #7
Attachment #08.40
Request to establish a code for a mechanical traction device, trade name: SecureTrack™.

No Primary Speaker

AGENDA ITEM #8
Attachment #08.34
Request to establish a code for a controlled active range of motion device, trade name: Camo®ped.

Primary Speaker: Christian Marten of OPED, Inc.

AGENDA ITEM #9
Attachment #08.05
Request to establish a code for a pneumatic, height-adjustable folding chair, trade name: LaunchPad.

No Primary Speaker

AGENDA ITEM #10
Attachment #08.10
Request to establish a code for a rehab chair.

No Primary Speaker

AGENDA ITEM #11
Attachment #08.39
Request to establish a code for a Hip Flexion Assist Orthoses (HFAO).

No Primary Speaker

AGENDA ITEM #12
Attachment #08.139
Request to establish a code and "right" and "left" code modifiers to identify flex therapy devices that support and correct the head and cervical spine by reducing neurological tone.

Primary Speaker: Brian King of Restorative Medical

AGENDA ITEM #13
Attachment #08.89
Request to establish a code for a temperature differential sensor, manual. Trade name: TempTouch®.

Primary Speaker: Don Lawson of Diabetica Solutions, Inc.

AGENDA ITEM #14
Attachment #08.81
Request to establish a code for an Anatomical Model, Stereolithography (SLA) Model, Biomodel or CT-Based Anatomical Model.

Primary Speaker: Rhonda Jacob, M.D.

AGENDA ITEM #15
Attachment #08.60
Request to establish a code for a closed system drug transfer device (CTSD), trade name: PhaSeal® System.

Primary Speaker: Jim Jorgenson of University of Utah

AGENDA ITEM #16
Attachment #08.94
Request to establish a code for the multi-use disposable supply components used with the Medi-Jector VISION® Needle-Free Injection System.

Primary Speaker: Mike Kasprick of Antares Pharma, Inc.

AGENDA ITEM #17
Attachment #08.08
Request to establish a code for an air purifier, trade name: Aurora M600 Air Sterilizer.

Primary Speaker: Glenn Shimmel of Med-Tech Systems

AGENDA ITEM #18
Attachment #08.27
Request to establish a code for a tissue repair system, trade name: Xclose™ Tissue Repair System.

Primary Speaker: Jolayne Fisher of Argenta Advisors

AGENDA ITEM #19
Attachment #08.83
Request to establish a code for a Convenience Kit for Assisted Reproduction. Trade name: Conceivex Conception Kit™.

Primary Speaker: Blix Winston of ACMD Consulting, LLC

HCPCS Public Meeting Agenda Item #1
April 23, 2008

Attachment #08.76

Topic/Issue:
Request to establish new codes for a custom made ankle foot orthosis, trade name: Ulcer Healing Orthosis (U.H.O.)

Background/Discussion:
According to the requester, the Ulcer Healing Orthosis is "a custom made ankle foot orthosis, plastic or other, rigid proximal anterior support section, attached laterally, via flexible plastic hinge, with cushioned liner, posterior proximal section cushioned liner, corrugated mid section alignment guide, medial lateral ankle section cushioned lined, posterior heel cushioned pad, plantar platform cushioned insert, rigid planar platform hollow, plantar platform dynamic alignment wedges, used with a modified diabetic shoe, internally and externally modified for acceptance of orthosis, nylon sheath prior to donning, ridged clear plastic platform check fitting." The UHO is used to control the alignment and motions of the joints of the foot and ankle associated with diabetes, i.e. Calanevalgus, Equinovarus, charcot joint mid-foot collapse. Providing a custom designed plantar platform that addresses the excessive plantar forces that are symptomatic upon weight bearing due to the bullet head shape protuberance of a charcot joint collapse of the mid foot, causing the devascularization of skin, the UHO allows revascularizsation to occur while ambulating. The patient dons the UHO then puts on their shoe, and ambulates. According to the requester, no existing code describes the features, functions or therapeutic significance of the UHO.

CMS HCPCS Preliminary Decision:
Existing code A9283 FOOT PRESSURE OFF LOADING /SUPPORTIVE DEVICE, ANY TYPE, EACH adequately describes the product that is the subject of this request. The UHO is the predicate product for which code A9283 was established.

Medicare Payment:
Based on guidance contained in an informal benefit category determination, we believe there would be no Medicare payment for this item.

Summary of Primary Speaker Comments at the Public Meeting:
The primary speaker disagreed with CMS' preliminary decision. The speaker also disagreed with CMS' informal benefit category determination. He stated that the UHO meets the criteria for the orthotic benefit category, and asked that it be identified with a new "L" code for custom made lower leg ankle/foot brace (orthotic). The speaker also suggested 23 additional new "L" codes for shoe add-on features and condition-type add-on features. According to the speaker "There is no other brace available for a diabetic with a foot deformity with plantar ulceration."

HCPCS Public Meeting Agenda Item #2
April 23, 2008

Attachment #08.111

Topic/Issue:
Request to establish a code for a portable shower for the wheelchair bound individual, Trade name: FAWSsit Fold Away Wheelchair Shower. Suggested language: "shower stall, portable, includes shower attachments, drain pan and electric pump".

Background/Discussion:
According to the requestor, the FAWSsit is a portable, fold-up shower stall, which can be used anywhere there is access to warm water. This shower is lightweight and has a strong structural aluminum frame. It folds flat for easy storage, and has an opaque curtain for privacy. The shower comes with a drain pan with a pump to remove wastewater. The shower is large enough to make it easily accessible for caregivers to assist patients. The total weight of the standard size FAWSsit is 38 pounds, and it folds to 8 inches in depth. It is 48 inches high and 36 inches wide. The FAWSsit does not require tools to set up. It is completely assembled and requires less than 5 minutes to set up. It must be set up in an area where both hot and cold water resources are available, as well as a drain for removing the person's bath water (ex: kitchen). The FAWSsit is designed for wheelchair patients of all ages and types or patient any debilitating conditions who are too weak or too sick to use a traditional shower/bath. There are two additional FAWSsit models to address the health needs of the morbidly obese (bariatric model) and individuals who must stay in a reclined position for being bathed (Recliner). When a 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. Some examples of the types of patients that would use the FAWSsit after discharge from the hospital are: head/spinal cord injury, amputation, CVA, total joint replacement, Hospice patient and diabetic/renal/vascular would care complications. There are no existing codes to describe a full portable shower that is used in the home that can be moved anywhere in the home where there is water access.

CMS HCPCS Preliminary Decision:
No insurer (i.e., Medicare, Medicaid, Private Insurance Sector) identified a national program operating need to establish a code to identify this product. For coding guidance, contact the entity in whose jurisdiction a claim would be filed. For private insurers, contact the individual private insurance contractor. For Medicaid, contact the Medicaid Agency in the state in which a claim would be filed. For Medicare, contact the Medicare contractor.

Medicare Payment:
Based on guidance contained in an informal benefit category determination, we believe there would be no Medicare payment for this item.

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item #3
April 23, 2008

Attachment #08.113

Topic/Issue:
Request to establish 2 codes for pelvic shorts, trade name: Coreshorts. Applicant's suggested language:
(1) "Lumbar-sacral-hip orthosis, flexible, provides lumbo-sacral-pelvic support by compression 30-40 mm HG, produces intracavitary pressure to reduce load on the pelvis, garment design, prefabricated"
(2) "Lumbar-sacral-hip orthosis, flexible, provides lumbo-sacral-pelvic support by compression 20-30 mm HG, produces intracavitary pressure to reduce load on the pelvis, garment design, prefabricated"

Background/Discussion:
According to the requestor, the Rehab and Coreshorts are orthotic supports for the pelvis, hip, and low back joints/musculature. They provide compression similar to a sacroiliac joint belt to improve pelvic stability; however, they treat the low back, pelvis and hip as a functional complex. Coreshorts provide functional stability and motion control to the hips and legs. Coreshorts incorporate diagonal elastics that cross from the hip to the opposite mid thigh. This design imitates the normal pelvic muscle sling that provides support to the body's core. The waist area has circumferential elastic that provides intracavitary pressure. The Rehab Coreshorts have an overall compression of at least 30-40 mmHg depending on appropriate fit. The Pro Coreshorts have an overall compression of at least 20-30 mmHg. Coreshorts are used in functional rehabilitation programs to provide support during physical therapy. They reduce strains and sprains, while providing support for daily functional movement. Pelvic/hip injuries and weak ligaments can be treated and prevented with the proper support of the core muscles. Rehab Coreshorts are made of 590 polyester/dorlastin material, which is "stiffer". The liner is made of the same material as well as the diagonal ("X") support that is 75% hand stretch.

CMS HCPCS Preliminary Decision:
No insurer (i.e., Medicare, Medicaid, Private Insurance Sector) identified a national program operating need to establish a code to identify this product. For coding guidance, contact the entity in whose jurisdiction a claim would be filed. For private insurers, contact the individual private insurance contractor. For Medicaid, contact the Medicaid Agency in the state in which a claim would be filed. For Medicare, contact the Medicare contractor.

Medicare Payment:
Based on guidance contained in an informal benefit category determination, we believe there would be no Medicare payment for this item.

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with CMS' preliminary decision and suggested that the Coreshorts be considered as a flexible lumbar pelvic hip orthotic. The speaker stated that these shorts improve functional control to assist in daily living activities and "can be covered under elastic binders". He also reiterated the original request to establish a code.

HCPCS Public Meeting Agenda Item #4
April 23, 2008

Attachment #08.35

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

Background/Discussion:
According to the requester, Dynamic Movement TLSOs are custom made to measure orthoses made from computer generated patterns of Lycra material. This body forming TLSO consist of sections of Lycra reinforcements stitched to a base fabric using specific tensions, directions of pull, type of material (e.g. water absorbent for under the arms) and thickness to provide corrective forces which transfer to the body segment. The patient is able to move without discomfort therefore proving the orthosis to be truly dynamic and patient compliant. The Dynamic Movement TLSO helps to re-establish normal function and balance with the use of elasticized and non-elasticized materials by introducing force along the weakened muscle line of action. Also, the intimacy of fit and slight compression generates proprioceptive feedback which provides the patient with a sense of spatial awareness helps to reduce tone, spasticity and has been found to reduce involuntary motions. Unlike current spinal devices whose purpose is to immobilize and support the spine, this device supports while both allowing and restricting motion as an enhancement to the weakened or neurologically involved portion or segment. The orthosis is worn during waking hours by the patient and is removed for sleeping. Its unique ability to stretch in specific planes of motion provides a function not captured in current code descriptions. This orthosis is used by the pediatric and adult neuromuscular patient with the diagnoses such as Cerebral Palsy, post traumatic brain injury, and cerebrovascular accident.

CMS HCPCS Preliminary Decision:
No insurer (i.e., Medicare, Medicaid, Private Insurance Sector) identified a national program operating need to establish a code to identify this product. For coding guidance, contact the entity in whose jurisdiction a claim would be filed. For private insurers, contact the individual private insurance contractor. For Medicaid, contact the Medicaid Agency in the state in which a claim would be filed. For Medicare, contact the Medicare contractor.

Medicare Payment:
Based on guidance contained in an informal benefit category determination, we believe there would be no Medicare payment for this item.

Summary of Primary Speaker Comments at the Public Meeting:
There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item #4
April 23, 2008

Attachment #08.36

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

Background/Discussion:
According to the requester, the Dynamic Movement EWHO is a custom made to measurement orthoses (brace) made from computer generated patterns of lycra material. This skin tight fitting material provides strong proprioceptive feedback. Sections of lycra reinforcements are stitched to a base fabric using specific tensions, directions of pull and types of material (higher coefficient of friction material in the palmer section), to provide corrective forces to the body segment. In the case of soft tissue contractures, the device provides a constant stretch toward functional position. When weakened muscle exists on one side of a joint that balance is not maintained; distortion, contraction and dysfunction can develop. The Dynamic Movement EWHO assists in reestablishing normal functional position with the use of elasticized and non-elasticized materials by introducing a force along the weakened muscle line of action. The intimacy of fit and slight compression generates proprioceptive feedback that helps to reduce tone and spasticity. The requester states that this device has been found to reduce involuntary motions on some pediatric cerebral palsy patients and that the device has antispastic effects on the wrists and fingers of patients with hemiplegia and may help severely affected patients with major spasticity or painful, swollen limbs. The orthosis is worn during waking hours by the patient and removed for sleeping. Unlike current upper limb devices whose purpose is to immobilize and or support the upper limb, this device supports while both allowing and restricting motion as an enhancement to the weakened or neurologically involved portion or segment. Its unique ability to provide a controlled stretch in multiple planes of motion provides a function not captured in current code descriptions.

CMS HCPCS Preliminary Decision:
No insurer (i.e., Medicare, Medicaid, Private Insurance Sector) identified a national program operating need to establish a code to identify this product. For coding guidance, contact the entity in whose jurisdiction a claim would be filed. For private insurers, contact the individual private insurance contractor. For Medicaid, contact the Medicaid Agency in the state in which a claim would be filed. For Medicare, contact the Medicare contractor.

Medicare Payment:
Based on guidance contained in an informal benefit category determination, we believe there would be no Medicare payment for this item.

Summary of Primary Speaker Comments at the Public Meeting:
There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item #5
April 23, 2008

Attachment #08.11

Topic/Issue:
Request to establish a code for vibrating shoes with a self contained power source, trade name: Good Vibrations Therapeutic Vibrating Shoes.

Background/Discussion:
According to the requester, Good Vibrations Therapeutic Vibrating Shoes yield a non invasive vibrating waveform to the foot and, are for use by people seeking relief from cold, painful or tingling feet as a result of an underlying medical condition that may cause diminished circulation, such as Diabetes or post Cerebral Vascular Accident (stroke). Good Vibrations can also be used in non-medical conditions, but rather positional situations such as in being seated for long periods of time as a traveler by automobile or airplane. The bending of one's knee, while seated causes physical compression of the tibial artery to the lower extremity and ultimately, the foot. Resultant sluggish circulation can increase the risk of Deep Vein Thrombosis. Vibrations applied to the bottom of the foot causes temporary stimulation of the circulation and flow through stimulated small muscles in the foot. According to the requestor, this product is useful in the absence of illness or injury to provide soothing comfort for tired, achy feet. The requester also claims that "persons 65 years and older…who have circulatory challenges and/or balance impairment may derive benefit" from this product. Product literature states that "there is scientific medical evidence that high frequency vibration therapy applied to the feet improves the balance of older adults." The shoes have a built in vibrating motor in the sole in the area of the arch. An on/off switch is located on the inner side of the sole of the shoe to actuate the vibrating motor. The power source is built in to the heel of the shoe and is fully rechargeable with an included 3 volt adaptor charger. After 4 to 5 hours of use, the batteries are re-chargeable in less than an hour.

CMS HCPCS Preliminary Decision:
No insurer (i.e., Medicare, Medicaid, Private Insurance Sector) identified a national program operating need to establish a code to identify this product. For coding guidance, 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 insurance contractor. For Medicare, contact the Medicare contractor.

Medicare Payment:
Based on guidance contained in an informal benefit category determination, we believe that there would be no Medicare payment for this item.

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with CMS' preliminary decision and reiterated the original request to establish a code. The speaker stated that the vibration in the shoes increases circulation; carries away bi-products and swelling; and brings nutrition to the foot. He also stated that a clinical investigation showed that "vibration noise to the feet increases balance control." According to the speaker, this is new technology and should be coded as such.

HCPCS Public Meeting Agenda Item #6
April 23, 2008

Attachment #08.101

Topic/Issue:
Request to establish a code for a dynamically molded inlay. Trade name: Dynamic Insole.

Background/Discussion:
According to the requester, the Dynamic Insole is a dynamically molded shoe inlay for the purpose of pressure relief and protection of the foot for diabetic and arthritic patients as well as those with an insensitive foot that require protection during ambulation. Pressure points vary during each stage of weight bearing gait. This product is a multiple density insert with a base layer of 3/16 inch or greater. The base layer material is a shore A or greater with soft upper layers above this. The base insert has an arch filler, deep heel cup and metatarsal accommodations. There are also separate self molding regions, one to the arch and one to the weight bearing regions, including the heel, lateral column and fare foot. The molded gel will relieve the resulting force at the greatest point of regional pressure and set into that position. The doctor will be able to allow for even greater pressure relief by applying sized padding to severe pressure (pre-ulcerative) points prior to the dynamic molding process. After the doctor has prepared the foot, they will activate the inlay, place it in the shoe and allow the person to ambulate. The force exerted during ambulation will force the liquid form of the gel to the lower pressure region. Once the gel solidifies, within a set time limit of 3-5 minutes, it will allow for re-direction of the pedal pressure and eliminate pressure points. Rebalancing weight during ambulation will allow for more patient comfort, increased activity abilities and decreased risk of problematic developments. The dynamic molded inlays will have both total contact and force re-distribution to the foot. According to the applicant, the difference between this product and items identified under code A5513 "FOR DIABETICS ONLY, MULTIPLE DENSITY INSERT, CUSTOM MOLDED FROM MODEL OF PATIENT'S FOOT, TOTAL CONTACT WITH PATIENT'S FOOT, INCLUDING ARCH, BASE LAYER MINIMUM OF 3/16 INCH MATERIAL OF SHORE A 35 DUROMETER OR HIGHER), INCLUDES ARCH FILLER AND OTHER SHAPING MATERIAL, CUSTOM FABRICATED, EACH" is that the Dynamic Insole is a dynamically molded inlay that takes into consideration the patient's entire foot, gait, and pressure points associated with them, whereas products identified at A5513 are constructed based on static non-weight bearing soft tissue imprint. The applicant claims that "this inlay will allow for significantly improved pressure reduction verses the non-weight bearing inlay" described at A5513, and this "quantum level of improvement for diabetic foot protection and comfort" warrants a new code.

CMS HCPCS Preliminary Decision:
No insurer (i.e., Medicare, Medicaid, Private Insurance Sector) identified a national program operating need to establish a code to identify this product. For coding guidance,

contact the entity in whose jurisdiction a claim would be filed. For private insurers, contact the individual private insurance contractor. For Medicaid, contact the Medicaid Agency in the state in which a claim would be filed. For Medicare, contact the Medicare contractor.

Medicare Payment:

Payment for any covered items will be based on the carrier's individual consideration of the claim since no specific code or fee schedule has been established for this item.

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with CMS' preliminary decision. The speaker stated that this insole is "designed to eliminate pressure points and potential ulcer conditions in the foot". The speaker also cited codes A5510, A5512 and A5513 as setting precedent for coding diabetic insoles, but stated that the Dynamic insole is unique and is not described within the parameters of existing codes.

HCPCS Public Meeting Agenda Item #7
April 23, 2008

Attachment #08.40

Topic/Issue:
Request to establish a code for a mechanical traction device, trade name: SecureTrack™. Applicant's suggested language: "Ambulatory patient support system consisting of overhead track and patient support frame for patient fall prevention during rehabilitation."

Background/Discussion:
According to the requester, SecureTrack™ is a mechanical traction device that assists ambulatory patients throughout their rehabilitation period, preventing falls and increasing mobility. This innovative patient support device helps patients improve their strength, flexibility, gait, and functional movement. SecureTrack™ is used in the fall prevention and rehabilitation therapy for ambulatory patients recovering from stroke, heart attack, joint surgery, amputation, pulmonary disease or any disease requiring temporary rehabilitation. The SecureTrack™ uses an adjustable U-shaped support frame attached to a pivoting trolley that glides along an overhead track that patients use while walking. The patient is secured into the adjustable support frame, holds the handgrips, and walks along a prescribed path defined by an overhead track. The patient cannot fall while walking even if they lose consciousness. It is intended to replace or supplement rolling walkers and other mobile rehabilitation devices.

CMS HCPCS Preliminary Decision:
No insurer (i.e., Medicare, Medicaid, Private Insurance Sector) identified a national program operating need to establish a code to identify this product. For coding guidance, 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 insurance contractor. For Medicare, contact the Medicare contractor.

Medicare Payment:
Based on guidance contained in an informal benefit category determination, we believe there would be no Medicare payment for this item.

Summary of Primary Speaker Comments at the Public Meeting:
There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item #8
April 23, 2008

Attachment #08.34

Topic/Issue:
Request to establish a code for a controlled active range of motion device, trade name: Camo®ped. Applicant's suggested language: "Controlled active motion device, patient-operated"

Background/Discussion:
According to the requester, Camo®Ped is a patient-driven, controlled active motion (CAM) device used for post-surgical rehabilitation after joint replacements, ligament reconstruction, cartilage repair and other surgical procedures to the knee (and hip). It provides a continuous passive motion to the injured leg by being actively operated by the patient, (usually the contra-lateral non-affected leg). The Camo® ped is used for functional, post-operative physiotherapy. As rehabilitation progresses, both legs are actively moved up to coordinated mobility and working against minor resistance. Camo®ped encourages proprioceptive stimulus reception (movement experience). Since only the lower leg is guided in the device, the patient must stabilize the joint muscles in all directions himself.

According to the requester, the SADMERC currently assigned HCPCS code A9300 "Exercise Equipment" to Camo®ped. Code A9300 represents an exercise device that can be used by people who are not injured or post-operative. "The Camo®ped is prescribed by a physician for physical therapy, and can therefore not be considered an exercise device." Existing code E0935 "Continuous passive motion exercise device for use on knee only" represents a motor-driven passive motion device. The Camo®ped is a patient-driven active motion device. There is no appropriate existing code to identify the Camo®ped.

CMS HCPCS Preliminary Decision:
No insurer (i.e., Medicare, Medicaid, Private Insurance Sector), identified a national program operating need to uniquely code this device. Existing code A9300 "EXERCISE EQUIPMENT" is available for assignment by insurers as they deem appropriate. For coding guidance, contact the entity in whose jurisdiction a claim would be filed. For private insurers, contact the individual private insurance contractor. For Medicaid, contact the Medicaid Agency in the state in which a claim would be filed. For Medicare, contact the Medicare contractor.

Medicare Payment:
Based on guidance contained in an informal benefit category determination, we believe there would be no Medicare payment for this item.

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with CMS' preliminary decision. The speaker stated that this item is not exercise equipment nor is it a continuous passive motion device. According to the speaker, the Camoped addresses sensory-motor performance, proprioception and coordination in addition to edema, pain and range-of-motion issues. The speaker reiterated the original request to establish a unique code.

HCPCS Public Meeting Agenda Item #9
April 23, 2008

Attachment #08.05

Topic/Issue:
Request to establish a code for a pneumatic, height-adjustable folding chair, trade name: LaunchPad.

Background/Discussion:
According to the requester, LaunchPad is a pneumatic, height-adjustable folding chair designed to promote healing and wellness while sitting and rising from a seated position. LaunchPad is scientifically designed to lessen the compressive force between the lower back and hip joints; minimize knee flexion; and decrease the demand necessary for rising from a chair. This chair provides an innovative portable seating option for those recuperating from back, hip, knee, or foot injuries by allowing the users' back to relax, by relieving pressure from the hips and lower back. According to the requester, LaunchPad's technology reduces the overall range of motion and eases the transition from a seated to a standing position. Its oblique seat shape shifts the hips and pelvis into the proper position, keeps the knees open flexed, and thus provides "state-of-the-art" comfort seating. Each chair is individually height adjustable by using a small handle under the seat. In addition, LaunchPad is covered with antibacterial fabric, eliminating the potential for bodily fluids to accumulate and grow harmful bacteria. LaunchPad is made of high gauge aluminum and is powder coated to protect the finish and withstand heavy usage.

CMS HCPCS Preliminary Decision:
No insurer (i.e., Medicare, Medicaid, Private Insurance Sector) identified a national program operating need to establish a code to identify this product. For coding guidance, 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 insurance contractor. For Medicare, contact the Medicare contractor.

Medicare Payment:
Based on guidance contained in an informal benefit category determination, we believe that there would be no Medicare payment for this item.

Summary of Primary Speaker Comments at the Public Meeting:
There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item #10
April 23, 2008

Attachment #08.10

Topic/Issue:
Request to establish a code for a rehab chair.

Background/Discussion:
According to the requester, the rehab chair is for home use. It is used by patients who suffer from strokes and other muscle disorders. This is a cushioned chair that includes multiple attachments, such as: a lap tray; straps that may be used for positioning; adjustable exercise bands for independent or care-giver assisted range of motion, isometric and isotonic exercises for strengthening upper and lower extremities; and a foot pedal for that may be used for aerobic exercises of the lower extremities. According to the requestor, existing code A9300 "EXERCISE EQUIPMENT" does not adequately describe this chair as this chair is used for stroke patients that need movement of muscles and restored control. The more the muscles are used, the quicker the recovery.

CMS HCPCS Preliminary Decision:
No insurer (i.e., Medicare, Medicaid, Private Insurance Sector) identified a national program operating need to establish a code to identify this product. For coding guidance, 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 insurance contractor. For Medicare, contact the Medicare contractor.

Medicare Payment:
Payment for any covered items will be based on the carrier's individual consideration of the claim since no specific code or fee schedule has been established for this item.

Summary of Primary Speaker Comments at the Public Meeting:
There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item #11
April 23, 2008

Attachment #08.39

Topic/Issue:
Request to establish a code for a Hip Flexion Assist Orthoses (HFAO). Applicant's suggested language: "HKAFO, flexion control, flexion straps, pelvic band, prefabricated, includes fitting and adjustment."

Background/Discussion:
According to the requester, the HFAO was developed to support a weak lower extremity to provide stability for ambulation. This HFAO is an off the-shelf hip-knee-ankle-foot orthosis that supports a weak hip flexor on patients that are affected by MS, CVA, spinal cord injuries, or other diagnoses that affect safe ambulation. By providing flexion support, the applicant claims that patients that otherwise have difficulty advancing their leg in swing phase can do so by use of the new HFAO. When patients are not able to initiate a step, the HFAO provides support and help flexion to advance the affected leg. The requester states that there is no existing HCPCS code to classify the pre-fabricated HFAO. The intended population is patients with MS, CVA, SCI and other neurological disorders. It is made with neoprene, plastic and elastic.

CMS HCPCS Preliminary Decision:
No insurer (i.e., Medicare, Medicaid, Private Insurance Sector) identified a national program operating need to establish a code to identify this product. For coding guidance, contact the entity in whose jurisdiction a claim would be filed. For private insurers, contact the individual private insurance contractor. For Medicaid, contact the Medicaid Agency in the state in which a claim would be filed. For Medicare, contact the Medicare contractor.

Medicare Payment:
Based on guidance contained in an informal benefit category determination, we believe there would be no Medicare payment for this item.

Summary of Primary Speaker Comments at the Public Meeting:
There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item #12
April 23, 2008

Attachment #08.139

Topic/Issue:
Request to establish a code and "right" and "left" code modifiers to identify flex therapy devices that support and correct the head and cervical spine by reducing neurological tone. Trade names: Cervical Extension™, Safe Cerv™ and HyperExtension Stop™.

Background/Discussion:
According to the requester, these devices attach to the torso portion of a spine brace. Each device has a vertical slat designed specifically for one of the three types of head supports. The slats provide measured resistance to reduce neurological tone, then apply prolonged low load passive stretch to gradually re-lengthen shortened adaptive tissue. There is no HCPCS code that describes these products.

The Cervical Extension™ is a "T" shape of Kydex® that is molded to fit the back of the head and is attached to the Vertical Slat with bolts and knobs. The Cervical Extensions support the flaccid head, relieves tone and to prevent shortening of tissue, allow adequate respirations and other body functions, and the ability to receive stimulation from their environment. These are useful for patients with the following conditions: stroke, end stage Alzheimer's disease, ALS, Multiple Sclerosis, Traumatic Brain Injury, Spinal Cord Injury and Parkinson's disease. The devices hold the patient's head upright until tone is "kicked in".

The Safe Cerv™ is also a "T" shape at the back of the head where is securely attaches to the Vertical Slat with bolts and knobs. This headpiece has a continuation of the plastic down the side of the cheek on the flexed side to provide the support required to allow the head/neck to flex into it. This device corrects lateral leaning by providing measured resistance and memory, to return the head/neck to the preset degree.

The HyperExtension Stop™ consists of a 1/8" inch Kydex® plate that is securely mounted onto the Vertical Slat at the approximate height to brace a roll at the back of the head. This device is typically used for brain injured patients to break neurological tone and allows the patient to relax.

CMS HCPCS Preliminary Decision:
No insurer (i.e., Medicare, Medicaid, Private Insurance Sector) identified a national program operating need to establish a code to identify this product. For coding guidance, contact the entity in whose jurisdiction a claim would be filed. For private insurers, contact the individual private insurance contractor. For Medicaid, contact the Medicaid Agency in the state in which a claim would be filed. For Medicare, contact the Medicare contractor.

Medicare Payment:
Based on guidance contained in an informal benefit category determination, we believe there would be no Medicare payment for this item.

Summary of Primary Speaker Comments at the Public Meeting:
The primary speaker disagreed with CMS' preliminary decision for coding and Medicare Payment. The speaker stated that this device is an orthotic used correct cervical deformities, thus allowing patients to be more active. According to the requester, there are no other splints that perform the same function nor is there an existing code to describe this product.

HCPCS Public Meeting Agenda Item #13
April 23, 2008

Attachment #08.89

Topic/Issue:
Request to establish a code for a temperature differential sensor, manual. Trade name: TempTouch®.

Background/Discussion:
According to the requester, the TempTouch® is a device for diagnosing points of inflammation on the soles of the feet of diabetic patients with neuropathy. Skin inflammation is the first stage of foot ulcers. Foot ulcers are a costly complication of diabetic neuropathy, often leading to amputations and death. TempTouch® is a temperature sensor utilizing infrared technology. It is 16 inches long with a right angle at the tip, designed for use by diabetic persons with a variety of physical limitations related to their disease. The function of TempTouch® is to measure the difference in temperature between paired landmarks on the two feet of a neuropathic patient. A temperature difference of 4° F is the key data supporting a diagnosis of skin inflammation. The requester states that existing code A9279 is inadequate to describe a device such as TempTouch® because A9279 describes monitoring devices. TempTouch® is not a monitoring device. While the line between monitoring and diagnosis is sometimes not clear, a technology clearly falls within the diagnosis category when suitable medical evidence shows a clear and substantial improvement in outcomes in nearly all cases. The evidence shows a clear and substantial improvement utilizing TempTouch® compared to standard care in virtually all likely scenarios of patient compliance.

CMS HCPCS Preliminary Decision:
No insurer (i.e., Medicare, Medicaid, Private Insurance Sector) identified a national program operating need to establish a unique code to identify the TempTouch sensor. Existing code A9279 "MONITORING FEATURE/DEVICE, STAND-ALONE OR INTEGRATED, ANY TYPE, INCLUDES ALL ACCESSORIES, COMPONENTS AND ELECTRONICS, NOT OTHERWISE CLASSIFIED" is available for assignment by insurers as they deem appropriate.

Medicare Payment:
Based on guidance contained in an informal benefit category determination, we believe there would be no Medicare payment for this item.

Summary of Primary Speaker Comments at the Public Meeting:
The speaker disagreed with CMS' preliminary coding and Medicare payment recommendations. The speaker stated that TempTouch is not a monitoring device, it is a diagnostic product used by diabetics to detect inflammation in the foot. The speaker also disagreed with CMS' informal benefit category determination and stated that this device

is durable medical equipment (DME). The speaker suggested that the HCPCS Workgroup view this device as diagnostic, rather than a monitoring device.

HCPCS Public Meeting Agenda Item #14
April 23, 2008

Attachment #08.81

Topic/Issue:
Request to establish a code for an Anatomical Model, Stereolithography (SLA) Model, Biomodel or CT-Based Anatomical Model. Trade name: ClearView® Anatomical Model.

Background/Discussion:
According to the requester, ClearView® patient-specific, medical image-based physical anatomical models are 3D x-rays used in a tactile manner for planning and executing reconstructive surgery. Anatomical modeling is also known as biomodeling, rapid prototype modeling, stereolithography (SLA) modeling and medical modeling. Medical modeling combines rapid prototyping technology from the field of engineering with advanced medical imaging technology (CT or MRI) to make three-dimensional, life-size representations of anatomic structures. The use of this modality is dependent on patient-specific clinical considerations and physician preference. This advance in technology has made improvements in patient care, whereby three-dimensional visualization can aid in planning and execution of surgery, design of implants, and fabrication of maxillofacial prostheses. This technique allows 3-Dimensional "see through" analysis of the relationship of normal and diseased or deformed body structures within the same model. The two-color stereolithography technique of model fabrication allows for superior visualization of multiple structures (i.e. bone and tumor segregated) within a single model and provides major benefits for visualization of complex, deformed or pathologic anatomy. By fully visualizing the anatomy prior to surgery, the surgeon is able to more accurately plan each surgical step, whether removing pathologic anatomy, reducing bony structures to a more anatomic position or replacing anatomy with a custom-made prosthesis. The accuracy and improved precision of these replicas is accurate to <1.0 mm depending on the CT scan. According to the applicant, the fee to create the model is not covered or reimbursed in any current CPT or HCPCS code the physician might use for medical decision-making, or for planning or performing the surgery. The applicant raises a question regarding whether the cost of the model should be attributable to the surgeon.

CMS HCPCS Preliminary Decision:
No insurer (i.e., Medicare, Medicaid, Private Insurance Sector) identified a national program operating need to establish a code to identify this product, which is not primarily medical in nature. For coding guidance, contact the entity in whose jurisdiction a claim would be filed. For private insurers, contact the individual private insurance contractor. For Medicaid, contact the Medicaid Agency in the state in which a claim would be filed. For Medicare, contact the Medicare contractor.

Medicare Payment:
Based on guidance contained in an informal benefit category determination, we believe there would be no Medicare payment for this item.

Summary of Primary Speaker Comments at the Public Meeting:
The primary speaker disagreed with CMS' preliminary decision. The speaker stated that a code is needed in order to establish reliable coverage and reimbursement policy and allow for tracking.

HCPCS Public Meeting Agenda Item #15
April 23, 2008

Attachment #08.60

Topic/Issue:
Request to establish a code for a closed system drug transfer device (CTSD), trade name: PhaSeal® System.

Background/Discussion:
According to the requester, PhaSeal is a closed system drug transfer device used to contain hazardous drugs throughout preparation, transportation, administration, and disposal. This technology has the potential for use in a variety of sites of services where chemotherapy drugs or other potentially hazardous drugs are prepared and administered. PhaSeal consists of three components: a protector, an injector, and infusion adaptor and a connector. All components of the system have thermoplastic elastomer (TPE) membranes that meet to form a dry connection and self-seal when the components are disconnected. The protector attaches to the drug vial to form an airtight seal and has a sealed expansion chamber that captures any aerosols or vapors while simultaneously maintaining equal pressure in the vial. The injector is used both during preparation and administration of the hazardous drugs. One end of the injector is luer-locked onto a syringe while the opposite end provides for a dry connection at the cannula's access point. The infusion adaptor provides a closed access point for spiking and priming the bag as well as a dry connection to the injector. The connector or y-site connector with a standard luer-lock fitting and dry membrane is available for use when the drug is to be infused by standard IV push, once again providing a dry double membrane connection to the injector and a reduction of hazardous drug contamination at the site of patient administration. An infusion clamp is also available to secure the connection between the injector luer lock and the connector at the hub of the IV line. Together these components form a system that eliminates hazardous drug interactions with the environment. According to the requester, NIOSH recommended the use of CTSDs to prevent contamination and exposure. At this time, insurers are not directly billed but "various health benefit plans have confirmed [this applicant's] belief that without a HCPCS code in place, they are unable to appropriately revise their coverage and reimbursement policies to reflect the adoption of CTSD technology".

CMS HCPCS Preliminary Decision:
No insurer (i.e., Medicare, Medicaid, Private Insurance Sector) identified a national program operating need to establish a code to identify this product. For coding guidance, contact the entity in whose jurisdiction a claim would be filed. For private insurers, contact the individual private insurance contractor. For Medicaid, contact the Medicaid Agency in the state in which a claim would be filed. For Medicare, contact the Medicare contractor.

Medicare Payment:
Based on guidance contained in an informal benefit category determination, we believe there would be no Medicare payment for this item.

Summary of Primary Speaker Comments at the Public Meeting:
The primary speaker disagreed with CMS' preliminary decision. The speaker stated that this is new technology and there needs to be a mechanism for tracking. The speaker also stated that the National Institute for Occupational Safety and Health (NIOSH) recommends closed-system drug transfer technology for safety.

HCPCS Public Meeting Agenda Item #16
April 23, 2008

Attachment #08.94

Topic/Issue:
Request to establish a code for the multi-use disposable supply components used with the Medi-Jector VISION® Needle-Free Injection System. Applicant's suggested language: "Supplies for Needle-Free Injection of Insulin"

Background/Discussion:
According to the requester, the Medi-Jector Vision® Needle-Free Supply Kit contains multi-use sterile disposable components to deliver insulin injections using the Medi-Jector Needle-Free Insulin Injection System. These kits contain Needle-Free Syringes and/or Vial Adapters for use with the durable injector. The Needle-Free Syringe is attached to the Medi-Jector VISION device, allowing the patient to draw up and deliver doses of insulin from 2-50 Units per needle-free injection. The Medi-Jector Vial Adapter connects directly and permanently to the insulin vial and enables the drawing of the insulin into the Needle-Free Syringe on the Injector without the use of needles. Each Medi-Jector Needle-Free Syringe is attached directly to the Medi-Jector injection device and can be used for up to 21 injections of insulin or 14 days before it must be replaced. The Vial Adapter is attached to each new vial of insulin. An integral spike creates a port for transfer of insulin from the vial into the Needle-Free Syringe without the use of conventional needles. The kit when used with the injection system can provide adults and children with diabetes an easy-to-use alternative to conventional insulin syringes. According to the requester, HCPCS code A4211 "SUPPLIES FOR SELF-ADMINISTERED INJECTIONS" covers supplies for self-administration of insulin, and this code is presently being used for the Needle-Free Supply Kit, however, the code has a broad definition and is intended for single-use supplies such as conventional syringes. "Reimbursement under this code was reduced in 2006…which is unacceptable for multi-use disposable components such as our Needle-Free Supplies". The Supply Kit contains supplies specific to the use with the Needle-Free Injection System and therefore requires a separate code to adequately describe and provide for proper reimbursement for the consumer of these multi-use, differentiated needle-free supplies.

CMS HCPCS Preliminary Decision:
Existing code A4211 "SUPPLIES FOR SELF-ADMINISTERED INJECTIONS" adequately describe the product that is the subject of your request.

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

Summary of Primary Speaker Comments at the Public Meeting:
The primary speaker disagreed with CMS' preliminary decision stating that, "based on the reimbursement allowance", A4211 is intended to describe single-use products,

whereas this product is a reusable injector. The speaker also commented that reimbursement decreased in 2006.

HCPCS Public Meeting Agenda Item #17
April 23, 2008

Attachment #08.08

Topic/Issue:
Request to establish a code for an air purifier, trade name: Aurora M600 Air Sterilizer.

Background/Discussion:
According to the requester, Aurora is an air sterilizer that can help alleviate Chronic Obstructive Pulmonary Disease (COPD) and related diseases. Aurora utilizes Photo Catalytic Oxidation (PCO) technology with optimum wavelength ultraviolet light to sterilize the air by destroying living organisms such as bacteria, mold, viruses and mold spores, which can exacerbate symptoms of COPD and respiratory illness. Through this technology, volatile organic compounds (VOCs) which include a wide range of gas molecules and allergens are vaporized, reducing them to inert compounds of water and carbon dioxide. Aurora is placed in the patient's bedroom and can be operated 24 hours per day, seven days a week to present sterilized air into the patient environment several times an hour. According to the requester "because the Aurora M600 has been clinically proven to be medical in nature, it is worthy of consideration for a new code." Aurora reduces the severity of symptoms, acuity of care, medication use, and the need for doctor and hospital visits. Clinical trial results showed that patients using the device over the course of two months reported a marked reduction in symptoms.

CMS HCPCS Preliminary Decision:
No insurer (i.e., Medicare, Medicaid, Private Insurance Sector) identified a national program operating need to establish a code to identify this product. For coding guidance, 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 insurance contractor. For Medicare, contact the Medicare contractor.

Medicare Payment:
Based on guidance contained in an informal benefit category determination, we believe that there would be no Medicare payment for this item.

Summary of Primary Speaker Comments at the Public Meeting:
The primary speaker disagreed with CMS' preliminary coding and Medicare payment recommendations. The speaker believes that there is a need to distinguish the M600 Air Sterilizer from "garden variety air purifiers on the market". The speaker also discussed healthcare costs associated with COPD and suggested the need to find proven ways to decrease the cost of patient care while improving patient health and quality of life. According to the speaker, the device "improves the ability of chronically disabled persons to cope with domestic, vocational and social activities…" and this demonstrates a

need to: 1) identify this device as DME; 2) establish a specific code; and 3) to establish coverage.

HCPCS Public Meeting Agenda Item #18
April 23, 2008

Attachment #08.27

Topic/Issue:
Request to establish a code for a tissue repair system, trade name: Xclose™ Tissue Repair System. Applicant's suggested language: "Anulus fibrosus implant"

Background/Discussion:
According to the requester, Xclose consists of two sterile, disposable delivery tools containing polyester tension bands constructed of tension lines and T-anchor assemblies. The system is a suture device used to close the surgical opening made in the soft tissue of the annulus fibrosis in the course of a lumbar discectomy. According to the requester, repairing the annulus fibrosis is not always part of the lumbar discectomy procedure; however this applicant believes that the disc could be herniated through the opening if the opening is not repaired. The applicant believes the XClose device serves as a prosthetic implant. The request states that: "Under current commercial and government payer systems there is no procedure code that allows for distinct reporting and payment of the tissue repair system."

CMS HCPCS Preliminary Decision:
No insurer identified a program operating need to establish a code to identify this surgical supply item. Use of code L8699 PROSTHETIC IMPLANT, NOT OTHERWISE SPECIFIED, or any other "L" code is inappropriate because this product is not a prosthetic. Inquiries regarding inclusion of closure supplies when used in lumbar discectomy procedures should be separately submitted to the American Medical Association (AMA) practice expense advisory committee.

Medicare Payment:
If payment were made for this service, we believe it may be included in some other Medicare service or procedure.

Summary of Primary Speaker Comments at the Public Meeting:
The primary speaker disagreed with CMS' preliminary decision. The speaker stated that use of miscellaneous codes is always appropriate but without specific codes patients are denied access. The speaker also disagreed with CMS' informal benefit category determination and stated that the X-close is a prosthetic because: 1) it is implanted; 2) it restores the function of the annulus; and 3) it is not disposable. The speaker reiterated the original request for a code and suggested that the individual insurer/carrier provide individual guidance regarding how this device should be coded.

HCPCS Public Meeting Agenda Item #19
April 23, 2008

Attachment #08.83

Topic/Issue:
Request to establish a code for a Convenience Kit for Assisted Reproduction. Trade name: Conceivex Conception Kit™. Applicant's suggested language: "Conception Kit for assisted insemination"

Background/Discussion:
According to the requester, the Conception Kit is a solution for couples that have had difficulty conceiving due to low sperm motility, low sperm count or a hostile vaginal environment. The Conception Kit contains a three-month's supply of ovulation predictors, conception caps, semen collectors, pregnancy tests and informational literature to help couples increase the likelihood of becoming pregnant through assisted reproductive technology (ART). Upon prescription of the Kit, the couple is able to determine that date of the luteinizing hormone surge and then collects semen in the Semen Collector. The conception Cap included in the Kit is used to concentrate the collected semen at the cervical opening in order to improve fertility. The Conception Kit is designed for single patient use through the course of three ovulation cycles. It is used in the home and the cervical cap is discarded after no more than 6 hours of wear. The applicant requests a code that will allow for automation of claims processing, specific payer and provider contract administration and utilization data gathering.

CMS HCPCS Preliminary Decision:
No insurer (i.e., Medicare, Medicaid, Private Insurance Sector) identified a national program operating need to establish a code to identify this product. For coding guidance, contact the entity in whose jurisdiction a claim would be filed. For private insurers, contact the individual private insurance contractor. For Medicaid, contact the Medicaid Agency in the state in which a claim would be filed. For Medicare, contact the Medicare contractor.

Medicare Payment:
Based on guidance contained in an informal benefit category determination, we believe there would be no Medicare payment for this item.

Summary of Primary Speaker Comments at the Public Meeting:
The primary speaker disagreed with CMS' preliminary decision. However, the speaker agreed that there is no Medicare need to code this product. The speaker stated that this product is distributed across the U.S. and sold to couples of child bearing age. According to the speaker, some states mandate infertility coverage. The speaker also reiterated the original request to establish a code.

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 Medicare Administrative Contractors (DME MACs). 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.