Centers for Medicare & Medicaid Services (CMS)
Healthcare Common Procedure Coding System (HCPCS)
Public Meeting Summary Report
Supplies & Other – Day 2
Wednesday, May 13, 2009

Introduction and Overview

Approximately 25 people attended. The agenda included 20 items.

Cindy Hake, chair, CMS' HCPCS Coding Workgroup, provided an overview of the HCPCS public meeting process as it relates to the overall HCPCS coding process.

Joel Kaiser, Director, Division of DMEPOS Policy, 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.

Prior to the Public Meetings, CMS HCPCS workgroup meets to review all HCPCS code applications and makes 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 meetings, CMS HCPCS workgroup reconvenes, and considers all the 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 world wide web site 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, May 13, 2009, 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 #09.001
Request to establish a code for whey protein powder, trade name: DecubAmine.

No Primary Speaker

AGENDA ITEM #2
Attachment #09.063
Request to establish a code for a complete organic nutrition beverage, trade name: PediaSmart.

Attachment #09.090
Request to establish a code for lactose free toddler formula, trade name: Baby's Only Organic.

No Primary Speaker

AGENDA ITEM #3
Attachment#09.058
Request to establish 2 codes for the medibottle; one for hospital and clinic use and one for home use.

Primary Speaker: Mark Burchett of The Medicine Bottle Company

AGENDA ITEM #4
Attachment #09.025
Request to establish a code for a specialty infant feeding device, trade name: Bionix Controlled Flow Baby Feeder.

No Primary Speaker

AGENDA ITEM #5
Attachment #09.093
Request to establish 2 codes: one to report evaluation and another to report re-evaluation services rendered by a Kinesiotherapist.

Attachment #09.119
Request to establish code to identify therapy services performed by Kinesiotherapists.

Primary Speaker: J.T. Magee of American Kinesiotherapy Association

AGENDA ITEM #6
Attachment #09.034
Request to establish a code for a custom made to measure Lycra tension based Elbow, Wrist, Hand Orthosis, trade name: Boston Dynamic Movement-EWHO.

Attachment#09.035
Request to establish a code for a custom made to measure Lycra tension based Thoracic, Lumbar Sacral Orthosis, trade name: Boston Dynamic Movement TLSO.

Primary Speaker: Nate Smiley of Boston Brace International

AGENDA ITEM #7
Attachment #09.057
Request to establish a code for an orthopedic brace, trade name: Exomed Spine and Scapula Stabilizer Brace, Model S3.

No Primary Speaker

AGENDA ITEM #8
Attachment #09.043
Request to establish a code for a range of motion, easy-glide therapeutic stationary chair, trade name: Exodus I.

Attachment #09.044
Request to establish a code for a range of motion easy-glide therapeutic wheelchair, trade name: Exodus II.

Primary Speaker: John Carman of Genesis Chairs

AGENDA ITEM #9
Attachment #09.004
Request to establish a code for a filtering heat moisture exchange (HME), trade name: Provox(R) Micron HME.

Primary Speaker: Jan Lewin, M.D.

AGENDA ITEM #10
Attachment #09.091
Request to establish a code for an in vitro diagnostic test, trade name: QuantiFERON-TB Gold In-tube test (QFT-GIT).

No Primary Speaker

AGENDA ITEM #11
Attachment #09.030
Request to establish a code for a chemiluminescent light source system, trade name: ViziLite Blue Oral Examination Product.

Primary Speaker: Jan Palmer of The Palomino Group

AGENDA ITEM #12
Attachment #09.015
Request to establish a code "that provides reimbursement for wireless communication between the prosthesis and a Graphical User Interface (GUI)," trade name: Motion Control Bluetooth Computer Interface Module.

No Primary Speaker

AGENDA ITEM #13
Attachment #09.026
Request to establish a code and reimbursement for an ophthalmological dark adaptometer, trade name: MDD-1 Macular Adaptometer home monitoring device.

Primary Speaker: David Newsome, M.D.

AGENDA ITEM #14
Attachment #09.003
Request to establish a new code for a nebulizer replacement generator "that would allow for annual replacement", trade name: Aeroneb GO OnQ generator.

No Primary Speaker

AGENDA ITEM #15
Attachment #09.115
Request to establish a code for an oxygen thermal fuse, trade name: FireSafe Cannula Valve.

Primary Speaker: Mark Sanda of LifeGas

AGENDA ITEM #16
Attachment #09.120
Request to establish a code for a traction device, trade name: GRAV-TRAC.

Primary Speaker: Ralph Rydell, M.D.

HCPCS Public Meeting Agenda Item #1
May 13, 2009

Attachment: #09.001

Topic/Issue:
Request to establish a code for whey protein powder, trade name: DecubAmine.

Background/Discussion:
According to the requester, DecubAmine is a nutritional supplement that aids in the wound healing process. It is typically administered by blending it with foods and/or beverages or mixing with water for G-tube administration. DecubAmine was originally designed for patients and long term care residents who have, or are at risk of developing, Decubitis Ulcers. However, it is also very helpful for those who are recovering from surgery, those who are suffering from chronic diseases that deplete their systems of essential nutrients, and diabetic patients who have poor circulation and suffer with foot ulcers. DecubAmine is a protein powder that contains whey protein, L-Arginine, L-Glutamine and the essential fatty acids necessary for complete cell development, which contribute to wound healing, sound nutritional balance and improved weight gain. The concentrated whey protein contains all the branched chain amino acids that other types of protein don't have. Without all four elements, complete cell development cannot occur. According to the requester, existing code categories are inadequate to describe this item because of the difference in its ingredients as well as the proposed use as a first line of defense for post surgical patients, patients with chronic disease, and patients at-risk of developing pressure sores.

CMS HCPCS Preliminary Decision:
Existing code B4155 ENTERAL FORMULA, NUTRITIONALLY INCOMPLETE/MODULAR NUTRIENTS, INCLUDES SPECIFIC NUTRIENTS, CARBOHYDRATES (E.G. GLUCOSE POLYMERS), PROTEINS/AMINO ACIDS (E.G. GLUTAMINE, ARGININE), FAT (E.G. MEDIUM CHAIN TRIGLYCERIDES) OR COMBINATION, ADMINISTERED THROUGH AN ENTERAL FEEDING TUBE, 100 CALORIES = 1 UNIT adequately describes the product that is the subject of this request. On Medicare claims, code B4155 should be used with modifier BO "ORALLY ADMINISTERED NUTRITION, NOT BY FEEDING TUBE", if the route of administration is oral intake only.

Medicare Payment:
The payment rules associated with the existing code apply to this product. Pricing = 39

Summary of Primary Speaker Comments at the Public Meeting:
There was no primary speaker for this item. Written comments were submitted by the applicant thanking the coding committee for the preliminary decision to assign existing B4155.

HCPCS Public Meeting Agenda Item #2
May 13, 2009

Attachment: #09.063

Topic/Issue:
Request to establish a code for a complete organic nutrition beverage, trade name: PediaSmart.

Background/Discussion:
According to the requester, PediaSmart is a good source of nutrition for children who suffer from chronic illness, growth failure, eating disorders, and injuries or recovery from surgery. In addition, children who suffer from food sensitivities may consume this product. PediaSmart can be used as a meal replacement option for children who skip meals or as a nutritional supplement to complement a healthy child's diet. PediaSmart is available in organic chocolate and vanilla flavors and is recommended for children ages 1 through 13 years. It is an enteral nutrition product that can be fed orally or by tube (under physician's direction). According to the requester, PediaSmart differs from similar products because it contains organic milk protein concentrate (as a protein source) and organic sources of carbohydrates. The proprietary carbohydrate blend provides a steady supply of energy without any artificial stimulants. PediaSmart also contains organic oils.

CMS HCPCS Preliminary Decision:
Existing code B4160 "ENTERAL FORMULA, FOR PEDIATRICS, NUTRITIONALLY COMPLETE CALORICALLY DENSE (EQUAL TO OR GREATER THAN 0.7 KCAL/ML) WITH INTACT NUTRIENTS, INCLUDES PROTEINS, FATS, CARBOHYDRATES, VITAMINS AND MINERALS, MAY INCLUDE FIBER, ADMINISTERED THROUGH AN ENTERAL FEEDING TUBE, 100 CALORIES = 1 UNIT," adequately describes the product that is the subject of this request. On Medicare claims, code B4160 should be used with modifier BO "ORALLY ADMINISTERED NUTRITION, NOT BY FEEDING TUBE", if the route of administration is oral intake only.

Medicare Payment:
The payment rules associated with the existing code apply to this product. Pricing = 46

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

HCPCS Public Meeting Agenda Item #2
May 13, 2009

Attachment: #09.090

Topic/Issue:
Request to establish a code for lactose free toddler formula, trade name: Baby's Only Organic.

Background/Discussion:
According to the requester, Baby's Only Organic lactose free toddler formula is a certified organic milk based formula that is free of lactose, corn, wheat, peanuts, MSG and gluten. Its carbohydrate source is 100% organic brown rice syrup. This formula provides complete nutrition for children ages 1 to 3 years. It can be used as an infant formula under the guidance of a physician. It is also used as a nutritional beverage and to compliment a diet that includes table foods. And it can be used to supplement breast milk. It has been used as a sole source of nutrition before solid foods are introduced or as a source of enteral nutrition in medical situations where a complete nutritional lactose free product is needed. This formula can be used for children who have sucrose intolerance, fructose and lactose intolerance, corn, gluten and chemical sensitivities. It can be used for oral feeding and tube feeding (under a physician's direction). According to the requester, this product differs from other formulas because it does not contain corn syrup, corn maltodextrin, sucrose, or cane sugars. There is no current HCPCS code to describe this product.

CMS HCPCS Preliminary Decision:
Existing code B4158 "ENTERAL FORMULA, FOR PEDIATRICS, NUTRITIONALLY COMPLETE WITH INTACT NUTRIENTS, INCLUDES PROTEINS, FATS, CARBOHYDRATES, VITAMINS AND MINERALS, MAY INCLUDE FIBER AND/OR IRON, ADMINISTERED THROUGH AN ENTERAL FEEDING TUBE, 100 CALORIES = 1 UNIT," adequately describes the product that is the subject of this request. On Medicare claims, code B4158 should be used with modifier BO "ORALLY ADMINISTERED NUTRITION, NOT BY FEEDING TUBE", if the route of administration is oral intake only.

Medicare Payment:
The payment rules associated with the existing code apply to this product. Pricing = 46

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

HCPCS Public Meeting Agenda Item #3
May 13, 2009

Attachment: #09.058

Topic/Issue:
Request to establish 2 codes for the medibottle; one for hospital and clinic use and one for home use.

Background/Discussion:
According to the requester, the Medibottle is a pediatric medication delivery system designed for infants. A care-giver measures an accurate dose of oral, liquid medication, loads an oral dispenser with the medicine, fills the medibottle like a regular baby bottle, and attaches a nipple. The caregiver inserts the loaded oral dispenser into the inner sleeve of the bottle. The sleeve's tip has a very precise tolerance that restricts the flow of medicine, creating a small and powerful jet or "little squirt" each time the dispenser plunger is pressed. These small amounts of medicine displace the liquid in the very tip of the nipple. According to the requester, it is this functionality that offers a "significant therapeutic distinction" over other means of delivering oral medication to an infant, and it is clinically proven "superior" by top-level researchers. The most recent study involved 76 hospitalized infants and a bitter-tasting medication. The medibottle was found to be 85% more likely to deliver 100% of the prescribed dosages than its closest competitor, the industry standard oral syringe. The requester comments that the difference in successful delivery of the full dose results in improved compliance and a decrease in the effects and cost of non-compliance, which makes this medication delivery system more than a matter of convenience. The requester asks for a code to identify the medibottle, which is not identified in the existing code set.

CMS HCPCS Preliminary Decision:
A national program operating need to establish a code for this product was not identified by Medicare, Medicaid or the Private Insurance Sector. 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 that there would be no Medicare payment for these items.

Summary of Primary Speaker Comments at the Public Meeting:
The primary speaker disagreed with the workgroup's preliminary decision. The speaker commented regarding the clinical utility of the Medibottle and requested "guidance" regarding what would be necessary to establish a program operating need to establish a permanent code. The speaker claimed the workgroup needs to look at published data rather than the claim activity. According to the speaker based on data available the device can reduce the cost of non-

compliance, with prescription regimes, while at the same time improving the health of America's infant population.

HCPCS Public Meeting Agenda Item #4
May 13, 2009

Attachment: #09.025

Topic/Issue:
Request to establish a code for a specialty infant feeding device, trade name: Bionix Controlled Flow Baby Feeder.

Background/Discussion:
According to the requester, the Bionix Controlled Flow Baby Feeder (CFBF) is a feeding system that slowly introduces oral feedings to premature and medically fragile babies. Medical conditions such as prematurity, congenital cardiac conditions and failure to thrive are often associated with feeding problems related to inability to coordinate sucking/swallowing/breathing functions, resulting in adverse or traumatic feeding experiences. Such events can lead to aspiration, feeding aversions, long-term feeding disorders and medical issues. The CFBF utilizes 6 flow settings that can be adjusted without removing and reintroducing the bottle to the baby. Adjusting and progressively increasing the flow rate enables the baby to develop coordination while reducing adverse events. As such the CFBF is designed to transition babies from non-oral to oral feeding. The CFBF consists of 6 components: 1) 60mL graduated bottle; 2) Yellow flow restrictor, 6 settings; 3) Purple valve and seal; 4) Green flow adjuster; 5) Silicone nipple; and 6) Blue cap ring. There are no 3rd party payers that pay for this product at this time.

CMS HCPCS Preliminary Decision:
A national program operating need to establish a code for this product was not identified by Medicare, Medicaid or the Private Insurance Sector. 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 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 #5
May 13, 2009

Attachment: #09.093

Topic/Issue:
Request to establish 2 codes: one to report evaluation and another to report re-evaluation services rendered by a Kinesiotherapist.

Background/Discussion:
According to the requester, Kinesiotherapy is a separate and distinct sub-section within physical medicine. It is the study of human movement to design and implement exercise programs to meet the rehabilitative needs of individuals with disease, injury and/or physical disorders under the direction of a physician. Kinesiotherapy seeks to maximize strength, coordination and range of motion so that an individual's functional level is enhanced. Initial evaluation determines if skilled therapy is required or if a home therapy program is more appropriate. It involves assessing the patient's previous level of function, rehabilitation potential and ability to improve function through an established plan of care. Re-evaluation measures rehabilitation progress as compared to expected achievement of goals. It determines whether goals are being met, whether adjustments to the plan of care are required, and whether discharge from skilled therapy is appropriate. According to the requester, there are CPT codes for evaluation and re-evaluation for physical therapy, occupational therapy and athletic trainers. However, there are no codes to designate specifically that these services were provided by a Kinesiotherapist.

CMS HCPCS Preliminary Decision:
A national program operating need to establish HCPCS Level II codes for Kinesiotherapy evaluations and reevaluations was not identified by Medicare, Medicaid or the Private Insurance sector. CMS suggests that the applicant contact the American Medical Association (AMA) for CPT coding guidance.

Medicare Payment:
If payment were made for these services, 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 the workgroup's preliminary decision. The speaker stated that Kinesiotherapy is a separate and distinct profession within the field of Physical Medicine and Rehabilitation. According to the speaker, the AMA has refused a request for Kinesiotherapy Evaluation CPT codes. The speaker stated that the lack of codes leads to "compliance challenges" for Kinesiotherapists, and the establishment of HCPCS Level II code will enable "compliant claims".

HCPCS Public Meeting Agenda Item #5
May 13, 2009

Attachment: #09.119

Topic/Issue:
Request to establish code to identify therapy services performed by Kinesiotherapists.

Background/Discussion:
According to the requester, Kinesiotherapy is the study of human movement to design and implement exercise programs to meet the rehabilitative needs of individuals with disease, injury and/or physical disorders under the direction of a physician. Kinesiotherapy seeks to maximize strength, coordination and range of motion so that an individual's functional level is enhanced. It is a separate and distinct sub-section within physical medicine. The HCPCS code set includes modifiers that can be appended to CPT therapy codes to identify services delivered under an outpatient Speech Language pathology plan of care (GN); and outpatient Occupational Therapy plan of care (GO); and an outpatient Physical Therapy plan of care (GP). According to the requester, Kinesiotherapists can use therapy codes, however, they do not have a mechanism to specifically report services provided under a Kinesiotherapy plan of care.

CMS HCPCS Preliminary Decision:
A national program operating need to establish a HCPCS Level II code for Kinesiotherapy services was not identified by Medicare, Medicaid or the Private Insurance Sector. CMS suggests that the applicant contact the American Medical Association (AMA) for CPT coding guidance.

Medicare Payment:
If payment were made for these services, 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 the workgroup's preliminary decision. The speaker stated that Kinesiotherapy is a separate and distinct profession within the field of Physical Medicine and Rehabilitation. According to the speaker, the AMA has refused a request for Kinesiotherapy Evaluation CPT codes. The speaker stated that the lack of codes leads to "compliance challenges" for Kinesiotherapists, and the establishment of HCPCS Level II code will enable "compliant claims".

HCPCS Public Meeting Agenda Item #6
May 13, 2009

Attachment: #09.034

Topic/Issue:
Request to establish a code for a custom made to measure Lycra tension based Elbow, Wrist, Hand Orthosis, trade name: The Boston 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 adjustment."

Background/Discussion:
According to the requester, the Boston Dynamic Movement Elbow, Wrist, Hand Orthosis (EWHO) is a custom made to measure upper limb orthosis designed using computer generated patterns with specific tension direction of pull and thickness as dictated by patient assessment and need. The tightness of fit helps reduce abnormal tone, involuntary movements and spasticity. This device is intended to treat the upper extremity needs of neurologically impaired individuals of all ages, such as those diagnosed with Cerebral Palsy, Post-Traumatic Brain Injury, and Cerebrovascular accident. The Boston 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. Existing codes do not describe a tension-based, form-fitting orthosis that provides slight compression, covers multiple joints and applies specific lines of force and tension to a neurologically impaired upper limb. Lycra-based systems require their own family of codes.

CMS HCPCS Preliminary Decision:
Establish Axxxx GARMENT, BELT, SLEEVE OR OTHER COVERING, ELASTIC OR SIMILAR STRETCHABLE MATERIAL, ANY TYPE, EACH

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 Benefit Category Determination. The speaker stated that the "Dynamic Movement Orthosis (DMO) EWHO" should be classified as an orthosis because it: 1) performs a "significantly different function" because it is tension-based; 2) restricts movement across joints; and 3) "confers significant therapeutic distinctions (reduces tone and improves special awareness). The speaker also commented that this item is sold to 4.77% of the target

population and that a precedent exists for coding “diagnosis-specific products”. The speaker recommends that a new “L” code be created for this EWHO.

HCPCS Public Meeting Agenda Item #6
May 13, 2009

Attachment: #09.035

Topic/Issue:
Request to establish a code for a custom made to measure Lycra tension based Thoracic, Lumbar Sacral Orthosis, trade name: Boston Dynamic Movement 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, Boston Dynamic Movement Thoracolumbosacral Orthosis (TLSO) is custom made to measure from computer generated patterns of Lycra material. This body forming TLSO consist of sections of Lycra reinforcements stitched to a base fabric using specific tension, 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 a 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. Its unique ability to stretch in specific planes of motion provides a function not captured in current code descriptions. Existing code L1005 "Tension Based Scoliosis Orthosis and Accessory Pads, Includes Fitting And Adjustment" is used when fitting a neuromuscular patient diagnosed with scoliosis. However, not all of our patients present with scoliosis, therefore code L1005 cannot be used in all instances.

CMS HCPCS Preliminary Decision:
Establish Axxxx GARMENT, BELT, SLEEVE OR OTHER COVERING, ELASTIC OR SIMILAR STRETCHABLE MATERIAL, ANY TYPE, EACH

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 Benefit Category Determination. The speaker suggested that the TLSO should be classified as an orthosis because it: 1) performs a "significantly different function" because it is tension-based; 2) restricts movement across joints; and 3) "confers significantly therapeutic distinctions (reduces tone and improves special awareness). The speaker also commented that precedent exists for coding "diagnosis-specific products". The speaker recommends that a new "L" code be created.

HCPCS Public Meeting Agenda Item #7
May 13, 2009

Attachment: #09.057

Topic/Issue:
Request to establish a code for an orthopedic brace, trade name: Exomed Spine and Scapula Stabilizer Brace, Model S3. Applicant's suggested language: Lxxxx "SSO (Spine and shoulder orthosis), flexible, prefabricated, extends anterior from deltoid traversing the trapezium and terminating into the length of the spinal column, provides trunk support, reduces load on the cervical/thoracic intervertebral disks, provides posterior retraction and depression of the scapula, produces a centering of the humeral head, includes tension adjustment tabs, elastic compression straps, includes fitting and adjustment"

Background/Discussion:
According to the requester, Exomed S3 is a brace that restores normal shoulder movement. It employs a velcro strapping system coupled with proprietary propioceptive fabric materials (padding and mesh vest) to signal the brain and allow biofeedback to patients. The Exomed extends anteriorly from the deltoid traversing the trapezius and terminating into the length of the spinal column. This brace is designed to help restore normal shoulder, scapula, and thoracic kinematics. Evidence shows that the Exomed S3 increases proprioception and properly aligns the spine, trunk, internal rotation and anterior tilt of the scapula; and can also improve shoulder strength in internal and external rotation in asymptomatic individuals. It simultaneously stretches tight anterior structures to correct postural alignment, unloading intervertebral disc pressure. According to the requester, braces, immobilizers and supports described in existing HCPCS codes do not have the capability to cause alignment (by changing the rotation and tilt of the scapula). They only provide support or immobilization. The Exomed S3 therefore, performs a different (static vs dynamic) function. It is a dynamic brace. The therapeutic distinction over static braces is improved strength and function. There are no existing codes to describe a brace that has the ability to retract the scapula and center the humeral head.

CMS HCPCS Preliminary Decision:
Establish Axxxx GARMENT, BELT, SLEEVE OR OTHER COVERING, ELASTIC OR SIMILAR STRETCHABLE MATERIAL, ANY TYPE, EACH

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 #8
May 13, 2009

Attachment: #09.043

Topic/Issue:
Request to establish a code for a range of motion, easy-glide therapeutic stationary chair, trade name: Exodus I. Applicants' suggested language: "Therapeutic stationary chair".

Background/Discussion:
According to the requester, the Exodus I is a range of motion easy-glide therapeutic stationary chair. The seat unit of the device may be moved in a rocking, swinging, or gliding motion. This product provides increased joint range of motion, increased muscle activity, reflexive recruitment of major muscle groups, stimulation of respiration, stimulation of vascular and lymphatic activity, improved venous return from the distal aspects of the extremities, increased metabolic rate, improved sense of well-being, increase in movement amplitude and improved performance in activities of daily living. Exodus 1 can be used for limited active therapy by creating motion of a seat relative to a support frame to promote user health through stimulation of circulation, muscles, and neurocirculation and neuromuscular systems. It can be locked to provide for a stable seating unit which provides an additional utility of being capable of functioning as a seat assist device. The linkage system between the seating unit and the primary support frame allows the seating unit to be elevated and tilted forwardly so as to provide a seat assist to aid an individual being seated or to assist an individual to rise from a seated position. Exodus 1 is not exercise equipment, but a "pre-exercise" instrument, designed to bring people to the point where they can benefit from traditional exercise or physical therapy. It is designed for people who, for whatever reason, are unable to exercise. According to the requester, this device is not described in the existing code set, and therefore a new code is warranted.

CMS HCPCS Preliminary Decision:
A national program operating need to establish a code for this product was not identified by Medicare, Medicaid or the Private Insurance Sector. 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 that there would be no Medicare payment for this item.

Summary of Primary Speaker Comments at the Public Meeting:
The primary speaker disagreed with the workgroup's preliminary decision and reiterated the original request for a new code to identify the Exodus I as a unique device, and enable patient

access. The speaker stated that the Exodus I device is “pre-exercise” equipment that helps patients who cannot exercise and that it confers clinical benefits such as improved circulation, respiration, tissue perfusion, metabolism, wound healing, and re-training neural pathways. According to the primary speaker it aids in pain management, relieves anxiety and reinforces the psychological aspects of healing. The primary speaker asks to at least code it as a wheelchair, or if not, as a wheelchair with full Range-of-Motion (ROM) benefits.

HCPCS Public Meeting Agenda Item #8
May 13, 2009

Attachment: #09.044

Topic/Issue:
Request to establish a code for a range of motion easy-glide therapeutic wheelchair, trade name: Exodus II. Applicant's suggested language: "Therapeutic Wheelchair".

Background/Discussion:
According to the requester, the Exodus II is a range of motion easy-glide therapeutic wheelchair. The seat unit of the device may be moved by an individual seated therein in a rocking, swinging, or gliding motion. Use of this product provides increased joint range of motion, increased muscle activity, reflexive recruitment of major muscle groups, stimulation of respiration, stimulation of vascular and lymphatic activity, improved venous return from the distal aspects of the extremities, increased metabolic rate, improved sense of well-being, increase in movement amplitude and improved performance in activities of daily living. Exodus II can be used for limited active therapy by creating motion of a seat relative to a support frame to promote user health through stimulation of circulation, muscles, and neurocirculation and neuromuscular systems. It can be locked to provide for a stable seating unit which provides an additional utility of being capable of functioning as a seat assist device. The linkage system between the seating unit and the primary support frame allows the seating unit to be elevated and tilted forwardly so as to provide a seat assist to aid an individual being seated or to assist an individual to rise from a seated position. Exodus II is not exercise equipment, but a "pre-exercise" instrument, designed to bring people to the point where they can benefit from traditional exercise or physical therapy. It is designed for people who, for whatever reason are unable to exercise. According to the requester, this device is not described in the existing code set, and therefore a new code is warranted.

CMS HCPCS Preliminary Decision:
A national program operating need to establish a code for this product was not identified by Medicare, Medicaid or the Private Insurance Sector. 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 that there would be no Medicare payment for this item.

Summary of Primary Speaker Comments at the Public Meeting:
The primary speaker disagreed with the workgroup's preliminary decision. The primary speaker reiterated the original request for a new code to identify the Exodus II device and enable patient

access. The speaker stated that the Exodus II device is “pre-exercise” equipment that helps patients who cannot exercise and that it confers clinical benefits such as improved circulation, respiration, tissue perfusion, metabolism,wound healing, and re-training neural pathways. According to the primary speaker it aids in pain management, relieves anxiety and reinforces the psychological aspects of healing and mental aspects. The primary speaker asks to at least code it as a wheelchair, or if not, as a wheelchair with full Range-of-Motion (ROM) benefits.

HCPCS Public Meeting Agenda Item #9
May 13, 2009

Attachment: #09.004

Topic/Issue:
Request to establish a code for a filtering heat moisture exchange (HME), trade name: Provox(R) Micron HME. Applicant's suggested language: "HME w/sub-micron filter"

Background/Discussion:
According to the requester, the Provox Micron HME is a specialized stoma cover for laryngectomized persons that acts as a heat moisture exchange, heating and moisturizing inhaled air. It also filters out gross and sub-micron air particles such as viruses, bacteria, dust and pollen. With this combination of humidification and filtration the laryngectomized person can return to and maintain a near normal pulmonary function. Provox Micron is indicated for laryngectomy patients. According to the requester, the HME portion of the Micron HME has similar properties and functions as a standard HME which is currently covered under code A7507. However, the Provox Micron HME offers the added function of an air filtration system with a filtering efficiency of greater or equal to 99.8% in the filtering of viruses, bacteria, dust and pollen. "With third party laboratory tests confirming this efficiency, the possibility exists that a laryngectomized person wearing a Micron HME could suffer fewer colds or flu from airborne viruses and bacteria while the allergy sufferer could suffer less from pollen and dust." Also according to the applicant, there is no proof that other products offer similar micro-particle filtering efficiencies, and furthermore, these "efficiencies" are not "effectively covered" in existing HCPCS codes. Provox Micron HME is intended for a single use with an effective life up to 24 hours. It cannot be reused, cleaned or soaked.

CMS HCPCS Preliminary Decision:
Existing code A7507 "FILTER HOLDER AND INTEGRATED FILTER WITHOUT ADHESIVE, FOR USE IN A TRACHEOSTOMA HEAT AND MOISTURE EXCHANGE SYSTEM, EACH" adequately describes the product that is the subject of this request.

Medicare Payment:
The payment rules associated with the existing code applies to this product. Pricing = 37

Summary of Primary Speaker Comments at the Public Meeting:
The primary speaker disagreed with the workgroup's preliminary decision. The primary speaker claimed that there is a significant therapeutic distinction between this submicron filter when compared with the use of other filters also coded at A7507 on the basis that this is the only HME for laryngectomized individuals that incorporates an electrostatic filter capable of filtering a virus molecule. According to the primary speaker the HME with sub-micron filter is indicated for high risk populations in high risk seasons or environments. The speaker also indicated that to

date, no HCPCS code addresses both features (humidification and air filtration), and for these reasons, a new HCPCS code is warranted.

HCPCS Public Meeting Agenda Item #10
May 13, 2009

Attachment: #09.091

Topic/Issue:
Request to establish a code for an in vitro diagnostic test, trade name: QuantiFERON-TB Gold In-tube test (QFT-GIT). Applicant's suggested language: Axxxx "QFT-GIT collection system, each"

Background/Discussion:
According to the requester, the QFT -GIT is a third generation blood test used to diagnose Tuberculosis (TB) infection. The QFT-GIT test measures the cell mediated immune responses of white blood cells after stimulation with the specific mycobacterial proteins contained in the specialized blood collection tubes. It allows the sample preparation, mixing and incubation to be completed at the site of collection rather than previous QFT tests which required the blood sample be transported to the laboratory in order to begin incubation. The QFT uses specialized blood collection tubes that contain antigens of TB proteins or controls. Incubation of the blood occurs in the tubes and the samples are then stable for up to three days and are then sent to the laboratory which performs the ELISA essay. According to the requester, there is only one other FDA approved blood diagnostic test for TB. However, it requires labor intensive sample preparation procedure and is based on an ELISpot measurement system rather than an ELISA methodology. According to the requester, Medicare, Medicaid and many commercial plans pay for the technical component of QFT-GIT under laboratory fee schedule (86480 TUBERCULOSIS TEST, CELL MEDIATED IMMUNITY MEASUREMENT OF GAMMA INTERFERON ANTIGEN RESPONSE), but there are no HCPCS codes available to use for payment of the QFT-GIT collection system.

CMS HCPCS Preliminary Decision:
A national program operating need was not identified by Medicare, Medicaid or the Private Insurance Sector to separately code this supply item used as part of a procedure. CMS suggests that the applicant contact the American Medical Association (AMA) for CPT guidance.

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

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

HCPCS Public Meeting Agenda Item #11
May 13, 2009

Attachment: #09.030

Topic/Issue:
Request to establish a code for a chemiluminescent light source system, trade name: ViziLite Blue Oral Examination Product. Applicant's suggested language: "Pre-diagnostic chemiluminescent light and TBlue marking system used for the detection of mucosal abnormalities including premalignant and malignant lesions, not to include cytology or biopsy procedures".

Background/Discussion:
According to the requester, ViziLite Blue is a disposable, single-use oral lesion identification and marking system, used as an adjunct to the conventional head and neck examination. It is used by trained health care providers for the identification, evaluation and monitoring or oral mucosal abnormalities in a population at increased risk for oral cancer. The patient rinses with a 1% acetic acid swab for 30 to 60 seconds to partially desiccate target lesions and promote the removal of excess salivary glycoproteins. ViziLite is then activated and used to examine the oral cavity and oropharyngeal spaces. Through light reflectance of lesions, abnormal areas are identified and swabbed with Tblue for further evaluation. The kit contains 1 ViziLite 30 mL acetic acid solution; 1 ViziLite lightstick; 1 Vizilite retractor; and 1 TBlue Oral lesion marking system kit. According to the requester, there are no existing codes that could be used in the medical setting, other than miscellaneous. It has been clinically demonstrated in peer-reviewed literature that the sensitivity of mucosal examinations for pathological changes is improved with the inclusion of chemiluminescent lighting.

CMS HCPCS Preliminary Decision:
A national program operating need to establish a code for this product was not identified by Medicare, Medicaid or the Private Insurance Sector. 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:
If payment were made for this item, 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 the workgroup's preliminary decision. The speaker claimed that there is a "significant operating need" on the part of private insurers to identify this product when used by physicians (as opposed to Dentists), because the existing CDT code (D0431) is "useable only by dentists when billing this procedure". The speaker stated the Federal Bureau of

Prisons strongly encourages every federal prison facility incorporate ViziLite Plus into their care protocols. The speaker also claimed that the U.S. House of Representatives, Committee on Veterans' Affairs "is reviewing potential use at VA facilities".

HCPCS Public Meeting Agenda Item #12
May 13, 2009

Attachment: #09.015

Topic/Issue:
Request to establish a code "that provides reimbursement for wireless communication between the prosthesis and a Graphical User Interface (GUI)," trade name: Motion Control Bluetooth Computer Interface Module.

Background/Discussion:
According to the requester, the Bluetooth Computer Interface Module provides a wireless connection between all current and future motion control microprocessor-based prosthetic controllers (current examples include the Utah Arm, ProControl 2, and the Utah Hybrid Arm) and a GUI interface (most commonly found on a personal computer or a laptop). The wireless connection is an alternative to the legacy technology, which is a direct-wired connection practically limiting the wearer to a 6-foot range from the computer. The wireless connection enables a prosthetist or therapist to view and adjust settings in the prosthesis while the patient performs activities, without the patient being tethered to a computer. For the same reason, the wireless connection is also beneficial in prosthetic training. In addition, through the use of this technology, special, "more interactive" training programs can be sent home with a patient. The MC Bluetooth Communication System significantly enhances the function of the prosthesis, by allowing optimization of the prosthesis to the wearer's actual working environment, or their activities of daily living, while performing the actual activities. The wireless connection requires uniquely engineered software and security protocol to prevent an authorized person from accessing the prosthesis and making unauthorized changes which may put the user at risk of injury and/or death. "There are no L codes that describe a wireless connection to a Graphical User Interface."

CMS HCPCS Preliminary Decision:
A national program operating need to establish a code for this product was not identified by Medicare, Medicaid or the Private Insurance Sector. 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 #13
May 13, 2009

Attachment: #09.026

Topic/Issue:
Request to establish a code and reimbursement for an ophthalmological dark adaptometer, trade name: MDD-1 Macular Adaptometer home monitoring device.

Background/Discussion:
According to the requester, the MDD-1 is a patient self-administered home testing and monitoring device for patients with age-related macular degeneration (AMD) and diabetic retinopathy. It is a handheld device shaped like a small hairdryer with a single button on the handle facing the user. It delivers a flash of light and then uses voice technology to ask the patient a series of questions about the digital number it has displayed in the viewfinder. It times how long the patient takes to correctly respond. It stores patient-specific data and makes it available for physician interpretation. Longer flash recovery times compared to baseline could indicate the presence of retinal malfunction or disease, or worsening pathology. The MDD-1 is intended for use for personal, at-home monitoring, to detect worsening pathology and to "warn" the user that a physician visit is warranted. There is an MDD-2 model for use by physicians when conducting a dark adaptation examination (see CPT 92284). According to the applicant, the MDD-1 is unique in that it was designed specifically to perform the dark adaptation test, and in that it provides reproducible measurements of macular function. It "replaces the need for the current Amsler Grid testing device." The applicant is seeking a code to identify the MDD-1 and "to reimburse for the cost of the device."

CMS HCPCS Preliminary Decision:
A national program operating need to establish a code to identify the MDD-1 Macular Adaptometer home monitoring device was not identified by Medicare, Medicaid or the Private Insurance Sector. 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:
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 the workgroup’s preliminary decision. The speaker also disagreed with the Medicare Benefit Category Determination. The speaker believes this device should be considered DME because it has a very extended shelf life. Also, supply code A9279 describes devices used for “monitoring”, this device is “more for testing”. The speaker claimed this device, when used in the home by the patient, has the potential to detect devastating eye

disease years before an opthalmology specialist can. And finally, the speaker feels that this new way to test warrants the creation of an entirely new code and payment.

HCPCS Public Meeting Agenda Item #14
May 13, 2009

Attachment: #09.003

Topic/Issue:
Request to establish a new code for a nebulizer replacement generator "that would allow for annual replacement", trade name: Aeroneb GO OnQ generator.

Background/Discussion:
According to the requester, the Aeroneb OnQ generator is a component of the Aeroneb GO Nebulizer system which uses a generator rather than compressed air. It generates consistently-sized aerosol particles with an average inhaled respirable mass of 25% of total dose, with virtually no wasted drug. The OnQ generator acts as a micropump to form droplets of medication for inhalation. The system is used to deliver aerosolized respiratory medication. The Aeroneb Go nebulizer is used by pediatric and adult patients, and is intended to aerosolize physician-prescribed solutions for inhalation that are approved for use with a general-purpose nebulizer. The generator has a life expectancy of 1 year, and is warranted for 1 year. The applicant requests a HCPCS code that would allow the annual replacement cost.

CMS HCPCS Preliminary Decision:
A national program operating need to establish a code to separately identify this product was not identified by Medicare, Medicaid or the Private Insurance Sector. 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, however written comments were submitted asking for a code that would pay double the current allowable for A7005, but only up to once per year. "In this manner, beneficiaries could be assured replacement kits for any product that was out of warranty but at no additional cost to Medicare."

HCPCS Public Meeting Agenda Item #15
May 13, 2009

Attachment: #09.115

Topic/Issue:
Request to establish a code for an oxygen thermal fuse, trade name: FireSafe Cannula Valve. Applicant's suggested language: "In-line fire arresting device for oxygen patients"

Background/Discussion:
According to the requester, the FireSafe Cannula Valve acts as a thermal fuse that limits the damage caused by in-line fires started by patients who smoke while on oxygen, or by faulty equipment. This is "a medical device designed for use in the treatment of patients on oxygen to prevent injury and death." It works by sealing off the oxygen supply and stopping fires without impeding the normal flow of oxygen to the patient. The device resembles a generic oxygen tubing connector and fits seamlessly into the oxygen tubing circuits. It is composed of a high grade plastic and is light enough to allow in-line use that will not weigh down the cannula and impede flow. The internal mechanism of the device is a plastic fuse. When fire reaches the FireSafe cannula valve, the plastic fuse melts and the spring releases its pressure, shutting down the fire. According to the requester, there is not a code that covers the large issue of fire safety for oxygen patients. The requester recommends use of two FireSafe Cannula Valves per patient, one as close to the patient as possible, and the other near the source of oxygen. This prevents the ability of a fire to "run" the length of the oxygen tubing.

CMS HCPCS Preliminary Decision:
A national program operating need to establish a code for this product was not identified by Medicare, Medicaid or the Private Insurance Sector. 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 the workgroup's preliminary decision. The speaker stated this device offers a clinical intervention tool to respiratory therapist involved in the care of patients on oxygen who do not comply with smoking restrictions. The speaker claimed an in-line fire arrester is needed in addition to patient education, smoking cessation and sprinkler technology to ensure a safe patient environment. The speaker indicated "national safety and compliance organizations (NFPA/VA/Joint Commission)" acknowledge the need for such device. And the speaker reiterated the original request for a code for an in-line fire arrestor.

HCPCS Public Meeting Agenda Item #16
May 13, 2009

Attachment: #09.120

Topic/Issue:
Request to establish a code for a traction device, trade name: GRAV-TRAC.

Background/Discussion:
According to the requester, Grav-Trac is a device that applies traction to the lumbar spine and discs through the use of the patient's own body weight. It utilizes a steel supporting structure with an aluminum hanging bar. The device clamps to the door lentel without the use of tools. The patient grasps the hanging bar with both hands and drops their legs, hanging by their hands from the bar to affect traction. This gravity traction device uses the patient's body weight to stretch the spine. Use of this device relieves many types of low back pain by decreasing the pressure within the lumbar discs and distending the spine. It opens up the discs and reduces pressure in the disc. Grav Trac helps to resolve the protruding discs, bulging discs and degenerative discs. It can support over 500 pounds. According to the requester, existing codes do not describe gravity traction for the lumbar spine, and use of this device is a more effective way of achieving spinal traction than other coded traction devices.

CMS HCPCS Preliminary Decision:
A national program operating need to establish a code to separately identify this product was not identified by Medicare, Medicaid or the Private Insurance Sector. 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:
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 the workgroup's preliminary coding decision and with the Medicare Benefit Category determination. The speaker stated the GRAV-TRAC is a medical device sold only for the treatment of lower back pain. GRAV-TRAC is less cumbersome than the traditional and common methods of spine traction that are currently coded because the patient is not in bed when using the GRAV-TRAC and therefore, reduction of pull due to friction created by the patient's body on the bed is not a factor.

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. This monthly payment includes payment for all stationary oxygen equipment, supplies, and accessories and delivery of oxygen contents (stationary and portable). A monthly add-on to this payment is made for portable oxygen equipment only for those beneficiaries who require portable oxygen. The monthly payments for oxygen equipment cap after the 36th monthly payment is made, after

which monthly payments for the ongoing delivery of contents continue for 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.