Centers for Medicare & Medicaid Services (CMS)
Healthcare Common Procedure Coding System (HCPCS)
Public Meeting Summary Report

Supplies & Other – Day 1

Tuesday, May 25, 2010

Introduction and Overview

Approximately 25 people attended. The agenda included 16 items.

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

Joel Kaiser, Director of the Division of Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Policy, presented an overview of the methods used for setting the payment amount for DME, prosthetics, orthotics and supplies and when the different payment categories are used. The overview was also provided as a written document to the agenda and is 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.gov/DMEPOSFeeSched/.

Prior to the Public Meetings, over the course of several months, the CMS HCPCS Coding Workgroup convene, discuss, and establish preliminary coding recommendations, on all HCPCS code applications. CMS also assigns 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 CMS HCPCS web site at http://www.cms.gov/MedHCPCSGenInfo/08_HCPCSPublicMeetings.asp#TopOfPage, as part of the HCPCS public meeting agendas.

Information provided at the CMS HCPCS Public Meetings is considered by the CMS HCPCS Coding Workgroup at a subsequent workgroup meeting. The Workgroup reconvenes after the public meetings and reconsiders its preliminary coding recommendation in light of any new information provided, and formulates its final coding decisions. 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.

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

The latest information on the process for developing agendas and speaker lists for the public meetings, as well as Guidelines for Proceedings at CMS' Public Meetings can be found on the CMS HCPCS web site specifically at: http://www.cms.gov/MedHCPCSGenInfo/08_HCPCSPublicMeetings.asp#TopOfPage. In addition, the standard application format for requesting a modification to the HCPCS Level II Code Set, along with instructions for completing the application, and background information regarding the HCPCS Level II coding process is available at: http://www.cms.gov/MedHCPCSGenInfo/01_Overview.asp#TopOfPage . The application form is updated annually and posted on the CMS HCPCS web site sometime in the summer. A decision tree, outlining CMS' decision-making criteria is also available at: http://www.cms.gov/MedHCPCSGenInfo/Downloads/decisiontree/pdf .

Centers for Medicare & Medicaid Services (CMS) Healthcare Common Procedure Coding System (HCPCS) Public Meeting Agenda for Supplies and "Other"
Tuesday, May 25, 2010, 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 made 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 complete HCPCS code application received by CMS. 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# 10.121
Request to establish 3 codes to describe the Electronic Medication Management Assistant (EMMA): 1 for the basis unit, 1 for the expansion unit and 1 for the disposable medication administration cartridge.

Primary Speaker: Christopher Bossi of INRange Systems, Inc.

AGENDA ITEM #2
Attachment#10.002
Request to establish a Level II HCPCS code for the Senticare PillStation, a "Smart, Medication Compliance System" and "Medication Error Prevention Device."

No Primary Speaker

AGENDA ITEM #3
Attachment# 10.120
Request to establish 2 codes to describe balance-based torso-weighting (BBTW) vest and belt, trade names: BW1000™ (vest), Bw1100™ (vest) and BW2000™ (belt).

Primary Speaker: Cynthia Gibson-Horn of BalanceWear / Motion Therapeutics

AGENDA ITEM # 4
Attachment# 10.022
Request to establish a code, appropriate coverage and reimbursement for a custom neoprene wrist support.

No Primary Speaker

AGENDA ITEM #5
Attachment# 10.114
Request to establish a code for a custom made to measure upper limb orthosis, trade name: Boston Dynamic Movement Orthosis EWHO (Elbow Wrist Hand Orthosis).

Attachment# 10.115
Request to establish a code for a custom made to measure spinal orthosis, trade name: Boston Dynamic Movement Thoracolumbosacral orthosis (TLSO).

Primary Speaker: James Wynne of Boston Brace

AGENDA ITEM #6
Attachment# 10.035
Request to establish an L code for Test Ankle Foot Orthoses, trade name: Check AFO Orthoses.

Attachment# 10.096
Request to establish a code to describe "test" orthosis that is used in the fabrication of a custom knee ankle foot orthosis.

Primary Speaker: Thomas DiBello as a member of AOPA

AGENDA ITEM #7
Attachment# 10.032
Request to establish a code for a custom made ankle foot orthosis, trade name: Ulcer Healing Orthosis (U.H.O.).

Primary Speaker: John Rooney

AGENDA ITEM #8
Attachment# 10.116
Request that insoles for diabetics, trade name: TMI Insoles, be reassigned from code A5510 "FOR DIABETICS ONLY, DIRECT FORMED, COMPRESSION MOLDED TO PATIENT'S FOOT WITHOUT EXTERNAL HEAT SOURCE, MULTIPLE-DENSITY INSERT(S) PREFABRICATED, PER SHOE" which is not a “covered” code, to a code that is "covered".

Primary Speaker: Robert Mager of TMI

AGENDA ITEM #9
Attachment# 10.001
Request to establish a Level II HCPCS code for the Vasyli-Armstrong (VA) / GlideSoft preconfigured, multi layer shear (friction) and pressure reducing diabetic insole.

Primary Speaker: Brandon Noble of VASYLI

AGENDA ITEM #10
Attachment# 10.118
Request to establish a code for end-diastolic pneumatic compression therapy (EDPC) using a Circulator Boot system.

Primary Speaker: Jack May of Circular Boot, Corporation

AGENDA ITEM #11
Attachment# 10.110
Request to establish a code for wound cleanser, trade name: Microcyn Skin and Wound Care with preservatives.

Primary Speaker: Dr. Adam Landsman of Oculus Innovative Sciences, Inc.

AGENDA ITEM #12
Attachment# 10.060
Request for a new HCPCS code to identify equipment for Therapeutic Low Frequency, non-contact, non-thermal ultrasound, trade name: Celleration MIST Therapy™ System 5.1.

Primary Speaker: Pamela Unger of Celleration, Inc.

AGENDA ITEM #13
Attachment# 10.087
Request to establish 3 codes to identify the components of a non-powered suction apparatus device intended for negative pressure wound therapy, trade name: SNaP™ (Simplified Negative Pressure) Wound Care System.

No Primary Speaker

AGENDA ITEM #14
Attachment# 10.030
Request to establish a code for Closed System Drug Transfer Device (CSTD) technology, trade name: PhaSeal System.

No Primary Speaker

AGENDA ITEM #15
Attachment# 10.046
Request to establish a code to describe a disposable gas-scavenging apparatus that removes inhaled anesthetics at the end of a procedure, trade name: Anecare QED-100™.

No Primary Speaker

AGENDA ITEM #16
Attachment# 10.112
Request to establish a code for a server-based software program designed to assist medical and nursing staff in calculating insulin dosages, trade name: G+ System.

Primary Speaker: Sue Grady of Glytec

HCPCS Public Meeting Agenda Item #1
May 25, 2010

Attachment# 10.121

Topic/Issue:

Request to establish 3 codes to describe the Electronic Medication Management Assistant (EMMA): 1 for the basis unit, 1 for the expansion unit and 1 for the disposable medication administration cartridge. Applicant's suggested language:

Exxx1 "Basis Unit, electronic medication management unit (each)
Exxx2 "Expansion unit, electronic medication management (each)"
Axxxx "Disposable medication administration cartridge (per prescription)"

Background/Discussion:

According to the requester, EMMA is a patient-owned, single-use, in-home medication management tool for high risk patients with complex disease states requiring multiple medications and frequent medication adjustments. The EMMA system is a unique combination of hardware and software that provides hospital style medication management in a patient's residence. It consists of a Medication Delivery Unit (MDU), wireless two-way communication software and a disposable medication package (blister card). The system allows a physician or pharmacist to remotely manage prescriptions stored and released by the patient-operated MDU. When it is time for the patient to take their medications, the MDU emits an audible and visual alert to the patient. When activated by the patient, the medications are selected from the blister cards and are released into the deliver tray. EMMA can store a month's supply of up to 10 medications per unit; and additional units may be linked together for a patient who has been prescribed more than 10 medications. The system allows for compliance monitoring and real-time dose adjustments through its wireless software capabilities. It maintains the patient's complete medication history, continuous medication reconciliation and provides clinicians and physicians with vital information about medication dosing, adjustments/interventions, refills, missed doses and treatment responses. Additionally, vital information may be transferred to the patient's electronic medical record with reliable data security. According to the requester, EMMA is expected to reduce the associated costs of medication management at home and prevent medication errors. Unlike other compliance aids, EMMA is a durable dispensing unit which provides a patient medication administration comparable to that delivered by a Pyxis or similar acute care system. There are no existing HCPCS codes to describe this product.

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 our preliminary benefit category analysis, 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 believed there is a national program operating need to identify the EMMA product. The speaker stated that CMS has received four letters from payers requesting specific HCPCS codes. The speaker identified several medication control and accountability benefits of the EMMA System, including restricting the abuse of narcotics, providing automatic alerts if medication are missed, securely discontinuing medications for removal, accounting for every dose that is dispensed, and providing hospital-style controlled access in an outpatient setting. The EMMA System consists of three separate units, and the speaker believed that a unique HCPCS code should be created for each unit. Specifically, the speaker requested the establishment of three separate HCPCS code to identify the basis unit, expansion unit, and the disposable medication administration cartridge.

HCPCS Public Meeting Agenda Item #2
May 25, 2010

Attachment#10.002

Topic/Issue:
Request to establish a Level II HCPCS code for the Senticare PillStation, a "Smart, Medication Compliance System" and "Medication Error Prevention Device"

Background/Discussion:

According to the requester, the PillStation is a smart medication compliance system that provides feedback to educate and motivate patients on the proper use of prescription drugs. Unlike medication organization or dispensing tools, the PillStation applies concepts of working memory, personalized messaging and intermittent positive reinforcement, to teach and reinforce behavior that supports medication compliance. The PillStation combines the familiar day/week medication organization bins with patented direct visualization technology and a telephonic communication system linked to advisors at a monitoring center. The Advisors have access to a complete and current database about the patient's individual prescription regime. They can visualize images transmitted from the device to confirm whether a patient has taken the right medication and the right dose at the right time. They can communicate directly with patients and notify health care providers. The faster a physician, disease manager or care giver knows about a non-compliance incident, the better the chance of averting hospitalization or additional health problems. PillStation is the only Medication Compliance System that has the capability to read dosages and differentiate between brand versus generic medications and that is an integral tool in reducing medication errors. According to the applicant, the PillStation should be considered DME because it can withstand repeated use, can normally be rented, and is primarily and customarily used to serve a medical purpose.

CMS HCPCS Preliminary Decision:

A national program operating need to establish a code was not identified by Medicare, Medicaid or the Private Insurance Sector. This item is not primarily medical in nature. 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 all insurers if 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:

There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item #3
May 25, 2010

Attachment# 10.120

Topic/Issue:

Request to establish 2 codes for the balance-based torso-weighting (BBTW) garments: one code to describe vest devices and one to describe belt devices, trade names: BW1000™ (vest), Bw1100™ (vest) and BW2000™ (belt). Applicant's suggested language:

Exxx1 "Balanced-based proprioceptive neuromuscular sensory weighting vest device, ability to weight anywhere for asymmetrical and strategic weighting and placement indicators"

Exxx2 "Balance-based proprioceptive neuromuscular sensory weighting belt device, ability to weight anywhere for asymmetrical and strategic weighting and placement indicators."

Background/Discussion:

According to the requester, Balanced-Based Torso-Weighting (BBTW) is an assessment and intervention that determines the directional loss of static and reactive balance control by systematically determining the directional impairment in the postural control system affecting balance and mobility. The treatment involves placing small amounts of weight in a garment on a person's torso, in strategic locations, to address directional impairment(s). BTTW is helpful in providing sensory or proprioceptive, biomechanical information to the neuromuscular system. BTTW used as a treatment for balance and mobility deficit that can occur with impairment of somatosensory, vestibular, visual or central nervous systems, for example, in patients with conditions such as MS, CVA, Ataxia, head injury, etc. With BBTW the patient's center of gravity can immediately move closer to center under the base of support. Once this occurs, individuals have demonstrated improvement in stability, walking speed, and ability to perform daily activities. BBTW improves postural control (balance and alignment) and reduces leaning and the possibility of falls without restricting body movement or ability. Balance wear garments include balanced-based proprioceptive neuromuscular supplemental sensory weighting device, two pounds of flexible rubberized weight in 1/4 and 1/2 pound increments, instructions for use, body chart, and indicators on the device for documentation of position and relocation of weight. The garment device allows application of the weights anywhere within the device enabling strategic placement of weights. It is made from laminated material that contains Lycra Spandex on one side, thin foam in the middle, and unbroken loop nylon on the other side. Model BW1100 vest is similar to model BW1000, but the BW1100 model allows adjustment at the shoulders for "custom-fitting". It also has a zipper. Model BW2000 is a belt garment, for use when a full vest is not necessary. The clinician will determine where times based on the patient's

responsiveness to initial application and carry over ability. In general, clients can start using the garment for 1 to 2 hours per day during upright activities, however, some can benefit from all day wear. According to the requester, BBTW garments are not described within HCPCS Level II. Existing code E0700 "SAFETY EQUIPMENT, DEVICE OR ACCESSORY, ANY TYPE" has been previously assigned by the PDAC, however code E0700 does not describe this product because the code is for prevention, not treatment.

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 our preliminary benefit category analysis, 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 believed that the BalanceWear garments qualify under the Medicare prothetic benefit category, and as such, should be evaluated as prosthetic devices. Specifically, the speaker believed that the Balance Wear garments should be considered under the prosthetic benefit category because of the relationship of the balance control system to the sensory eyes, ears, and skin organs. According to the speaker, the Balance-Based Torso-Weighting (BBTW) stabilizing garments addresses loss of balance and improves gait and mobility. In addition, the speaker stated that BalanceWear is designed for strategic weight placement, and that weight can be placed anywhere within the garment to change center gravity control and add supplementary sensory information for balance control. The speaker claimed that the BalanceWear garments are cost effective and the treatment provided by BBTW benefit patients with Parkinson's Disease, Post Brain Stem Surgery, and Multiple Sclerosis (MS).

HCPCS Public Meeting Agenda Item #4
May 25, 2010

Attachment# 10.022

Topic/Issue:

Request to establish a code, appropriate coverage and reimbursement for a custom neoprene wrist support. Applicant's suggested language: "Wrist orthosis, neoprene, may include straps, custom fabricated".

Background/Discussion:

According to the requester, neoprene wrist supports provide support, warmth and compression to treat and aid in the prevention of a variety of injuries and ailments including, but not limited to strains, sprains, arthritis, carpal tunnel syndrome, repetitive movement injuries and paralysis and contractions attributed to strokes, cerebral palsy and other neurological disorders. The supports are cut-to-order from a neoprene sheet, based on a pattern and measurements provided. Seams are glued, sewn and taped to ensure strength and durability. This product is designed for easy application and removal; and has a variety of features including thumb and finger support, Velcro closures, compression straps and extended proximal and distal lengths. According to the requester, the need exists for custom medical supports that are less restrictive, cumbersome and obtrusive than rigid and static supports. "There is currently not an "L" code that allows for coverage of a custom-fabricated neoprene support".

CMS HCPCS Preliminary Decision:

A national program operating need to establish a code to was not identified by Medicare, Medicaid or the Private Insurance Sector. Existing code A4466 GARMENT, BELT, SLEEVE OR OTHER COVERING, ELASTIC OR SIMILAR STRETCHABLE MATERIAL, ANY TYPE, EACH is available for assignment by insurers if they deem appropriate.

Medicare Payment:

The payment rules associated with the existing code apply to these products. Pricing = 00

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item. The applicant submitted written comments disagreeing with the preliminary decision and believed that custom neoprene wrist supports should be considered and given a new "L" code.

HCPCS Public Meeting Agenda Item #5
May 25, 2010

Attachment# 10.114

Topic/Issue:

Request to establish a code for a custom made to measure upper limb orthosis, trade name: Boston Dynamic Movement Orthosis EWHO (Elbow Wrist Hand Orthosis). Applicant's suggested language: "Tension based dynamic neuromuscular EWHO, consists of a custom made from measure cotton/nylon form fitting total contact base to which one or more custom reinforced polyamide or similar nylon panel(s) with lines of pull specific to patient's needs are permanently attached. Extending from proximal to the elbow/distal to the shoulder includes the wrist, hand, and thumb, may include one or more additional digits. Custom made from measurement, includes evaluation, fitting and adjustments."

Background/Discussion:

According to the requester, the Boston Dynamic EWHO is a custom made to measure upper limb orthosis consisting of a custom cotton/nylon base to which custom polyamide (nylon) reinforcements are permanently attached. It is used to restrict unwanted movement; and supports the weakened elbow, wrist and hand of patients with neuromuscular disorders. The intimacy of fit generates proprioceptive feedback which provides the patient with a sense of spatial awareness that helps to reduce tone and spasticity. Tension is determined by the thickness of the reinforcement. The reinforcements are custom made from the patient measurements and are permanently attached to the base in such a way that their tension and direction of pull are specific to that patient's needs at a specific place on their body. The orthosis is worn during waking hours and is removed for sleeping. According to the requester, existing codes do not describe an orthosis providing specific lines of force and tension to a neurologically impaired upper limb. Unlike current static upper limb devices, the EWHO's unique ability to provide a controlled movement in multiple planes of motion provides a function not captured in current code descriptions. The requester also comments that since a prior application was made, sales volume has increased.

CMS HCPCS Preliminary Decision:

Existing code A4466 GARMENT, BELT, SLEEVE OR OTHER COVERING, ELASTIC OR SIMILAR STRETCHABLE MATERIAL, ANY TYPE, EACH is available for assignment by all insurers if 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 stated their product is custom-fabricated and has a greater medical indication for treatment other than compression and warmth that are associated with the products listed under existing HCPCS code A4466. The speaker indicated that the Boston Dynamic Movement Orthosis EWHO is medically intended to reduce spasticity, normalize tone and reduce unwanted movement in the neuromuscular patient. The speaker further added that the product is intended for the treatment of those patients that would primarily fall under Medicaid and third party insurance. The speaker requested that CMS recognize the difference in function, purpose, and patient population associated with the Boston Dynamic Movement Orthosis EWHO and establish a separate HCPCS code for it.

HCPCS Public Meeting Agenda Item #5
May 25, 2010

Attachment# 10.115

Topic/Issue:

Request to establish a code for a custom made to measure spinal orthosis, trade name: Boston Dynamic Movement Thoracolumbosacral orthosis (TLSO). Applicant's suggested language: "Tension based dynamic neuromuscular TLSO, consists of a custom made from measure cotton/nylon body forming total contact base to which one or more custom reinforced polyamide or similar nylon panel(s) with lines of pull specific to patient's needs are permanently attached. Extending anteriorly from sternal notch to symphyus pubis, posteriorly from T3 or higher, to sacrococcygeal junction, may include shoulders, upper extremities, pelvis, hips and lower limbs. Custom made from measurements, includes evaluation, fitting and adjustments."

Background/Discussion:
According to the requester, the Boston TLSO is a custom made to measure, spinal orthosis consisting of a custom cotton/nylon base to which custom polyamide (nylon) reinforcements are permanently attached. The TLSO restricts unwanted movement and supports the weakened trunk, shoulder girdle, pelvis and hips of patients with neuromuscular disorders. The intimacy of fit generates proprioceptive feedback which provides the patient with a sense of spatial awareness which helps to reduce tone and spasticity. Tension is determined by the thickness of the reinforcement and the reinforcements are attached to the base in such a way that their tension and direction of pull are specific to that patient's needs at a specific place on their body. The TLSO is worn during waking hours and is removed for sleeping. According to the requester, existing codes currently billed to insurers do not adequately describe this product. Specifically, code L1005 "TENSION BASED SCOLIOSIS ORTHOSIS AND ACCESSORY PADS, INCLUDES FITTING AND ADJUSTMENT" is "a tension based scoliosis code". And code L1499 "SPINAL ORTHOSIS, NOT OTHERWISE SPECIFIED" is a non-specific code. Unlike currently coded static spinal devices, the TLSO's unique ability to limit motion in specific planes provides a function not captured in current code descriptions.

CMS HCPCS Preliminary Decision:

Existing code A4466 GARMENT, BELT, SLEEVE OR OTHER COVERING, ELASTIC OR SIMILAR STRETCHABLE MATERIAL, ANY TYPE, EACH is available for assignment by all insurers if 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 stated their product is custom-fabricated and has a greater medical indication for treatment other than compression and warmth that are associated with the products listed under existing HCPCS code A4466. The speaker indicated that the Boston Dynamic Movement Thoracolumbosacral orthosis (TLSO) is medically intended to reduce spasticity, normalize tone, and reduce unwanted movement in the neuromuscular patient. The speaker further added that the product is intended for the treatment of those patients that would primarily fall under Medicaid and third party insurance. The speaker requested that CMS recognize the difference in function, purpose, and patient population associated with the Boston Dynamic Movement TLSO, and establish a unique HCPCS code for it.

HCPCS Public Meeting Agenda Item #6
May 25, 2010

Attachment# 10.035

Topic/Issue:

Request to establish an L code for Test Ankle Foot Orthoses, trade name: Check AFO Orthoses. Requester's Suggested Lanuage: "Addition to lower extremity orthosis, test ankle foot orthosis (AFO) to be used only in conjunction addition code L2755 "ADDITION TO LOWER EXTREMITY ORTHOSIS, HIGH STRENGTH, LIGHTWEIGHT MATERIAL, ALL HYBRID LAMINATION/PREPREG COMPOSITE, PER SEGMENT, FOR CUSTOM FABRICATED ORTHOSIS ONLY".

Background/Discussion:

According to the Requester, the test ankle foot orthoses is used to check or test for problems in the fit or function of an orthosis (brace) before the final "definitive" device is constructed. The test AFO is a clear plastic device that is a supply used in the provision of a definitive (final or finished) brace. It is "only needed when the definitive brace is made from thermosetting plastic, as such, only in conjunction with use of addition code L2755. The clear test brace is made of plastic that is brittle and unsafe to use as a definitive device. These supplies are fitted to the patient's limb and the fit is evaluated for pressure, pain, irritation or abrasions. Thermosetting plastic can't be adjusted once set without damaging the plastic. The check orthosis is therapeutically beneficial in a similar manner as test sockets for prosthetic patients (L5618, L5620, L5622, L5624, L5626 and L5628), but are for use in the orthotic benefit category. This device should be considered a supply specifically related to the provision of an AFO that utilizes the L2755 addition code. According to the requester, there are no existing HCPCS codes that "provide for the additional cost" associated with fabricating and utilizing a test orthosis.

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 our preliminary benefit category analysis, 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 indicated that as technology has advanced, many orthotists have seen improved patient comfort and compliance when orthotic devices have been fabricated from thermo-setting plastics. The speaker claimed that orthoses made from these materials are often more durable and significantly lighter than orthoses made from traditional materials (e.g. plastic, polyethylene). The primary speaker believed that the additional time and material that is required to ensure the proper fit of orthoses made from thermo-setting materials warrants a new HCPCS code for both the Ankle Foot (AFO) and Knee Ankle Foot (KAFO) test orthoses.

HCPCS Public Meeting Agenda Item #6
May 25, 2010

Attachment# 10.096

Topic/Issue:

Request to establish a code to describe "test" orthosis that is used in the fabrication of a custom knee ankle foot orthosis.
Requester's suggested language: L20XX "Test Knee Ankle Foot Orthosis KAFO".

Background/Discussion:

According to the requester there is a need for a HCPCS code to describe a "test" orthosis that is used in the fabrication of a custom knee ankle foot orthosis. The test orthosis allows the Orthotist to confirm that the KAFO will fit the patient properly. It is only used to test or check for problems in the fit or function of an orthosis (brace) before the final "definitive" device is constructed using thermosetting plastic that cannot be modified once fabricated. The "test orthosis" is a single-use clear plastic brace made in a KAFO design, fabricated to a custom model of the patient's leg. According to the requester, high-tech materials that are rigid and resistant to torque (and are not adjustable once fabricated) were not contemplated or used for final products at the time the existing codes were developed. The test KAFO "should be considered a supply specifically related to the provision of a KAFO that utilizes the L2755 "ADDITION TO LOWER EXTREMITY ORTHOSIS, HIGH STRENGTH, LIGHTWEIGHT MATERIAL, ALL HYBRID LAMINIATION/PREPREG COMPOSITE, PER SEGMENT, FOR CUSTOM FABRICATED ORTHOSIS ONLY" addition code."

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 our preliminary benefit category analysis, 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 indicated that as technology has advanced, many orthotists have seen improved patient comfort and compliance when orthotic devices have been fabricated from thermo-setting plastics. The

speaker claimed that orthoses made from these materials are often more durable and significantly lighter than orthoses made from traditional materials (e.g. plastic, polyethylene). The speaker also added that although thermo-setting materials often lead to orthoses that are more efficient than orthosis made with existing thermoplastic devices, proper fit and design of the orthosis must be confirmed prior to fabrication of the finished orthosis because there is little or no ability to re-mold the base material once it has set. As a result, a test orthosis is necessary to ensure an appropriate clinical outcome. The primary speaker believed that the additional time and material that is required to ensure the proper fit of orthoses made from thermo-setting materials warrants a new HCPCS code for both Ankle Foot (AFO) and Knee Ankle Foot (KAFO) test orthoses.

HCPCS Public Meeting Agenda Item #7
May 25, 2010

Attachment# 10.032

Topic/Issue:

Request to establish a code for a custom made ankle foot orthosis, trade name: Ulcer Healing Orthosis (U.H.O.).

Background/Discussion:

According to the Requester, 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 cutinized 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 Ulcer Healing Orthosis 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. Additionally, it provides 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 revascularization to occur while ambulating. The patient does the UHO then puts on their shoe, and ambulates. The requester comments that there are no HCPCS codes in the orthotic category or elsewhere that describe a functional and therapeutic equivalent of the UHO and all its features or that describe additional items used in dispensing the UHO, such as digital photo records, bandage dress, temporary UHO, internal shoe adjustments, surgical gloves and face mask.

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:

The payment rules associated with the existing codes 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, stating that the existing code describes a secondary use, but does not describe the primary functions or objectively list all the features of the Ulcer Healing Orthosis (UHO), thereby precluding payment because the code text does not identify "features that would be paid". The speaker stated the UHO is a custom made ankle foot orthosis designed for patients with severe foot and ankle deformities due to sensory neuropathic arthropathic-diseases most commonly caused by diabetes, adding that for patients that have plantar ulcer or wound on the bottom of the foot, the UHO protects the wound area allowing the patient to walk without further damage. The speaker reiterated his request for the UHO and voiced a new request to also code check socket. The speaker stated that he "is submitting and getting paid using [code] L1960 to identify the UHO.

HCPCS Public Meeting Agenda Item #8
May 25, 2010

Attachment# 10.116

Topic/Issue:

Request that insoles for diabetics, trade name: TMI Insoles, be reassigned from code A5510 "FOR DIABETICS ONLY, DIRECT FORMED, COMPRESSION MOLDED TO PATIENT'S FOOT WITHOUT EXTERNAL HEAT SOURCE, MULTIPLE-DENSITY INSERT(S) PREFABRICATED, PER SHOE" which is not a "covered" code, to a code that is "covered".

Background/Discussion:

According to the requester, TMI insoles allow for increased blood flow, prevent poor blood circulation, and prevent swelling of the feet and ankles. This product was designed for people with poor blood circulation including patients with diabetes and pregnant women diagnosed with gestational diabetes. TMI insoles stimulate the nerve endings in the foot that correspond to every part of the body, thereby allowing foot reflexology with every step. The insoles are fitted to the patient by adjusting the amount of glycerin used, providing full contact with the patient's foot. The motion of the glycerin beneath the foot promotes increased blood flow. TMI insoles are washable and can be removed and inserted into any shoe, thereby turning any shoe into a diabetic shoe. According to the requester, TMI insoles have been assigned to HCPCS code A5510, a non-covered code. Existing codes that are "payable" are for "products of less medical value," therefore the applicant is requesting a separate, payable code for TMI insoles, as well as clarification as to product classification, billing procedures and dollar amount reimbursable to doctors.

CMS HCPCS Preliminary Decision:

Existing code A5510 FOR DIABETICS ONLY, DIRECT FORMED, COMPRESSION MOLDED TO PATIENT'S FOOT WITHOUT EXTERNAL HEAT SOURCE, MULTIPLE-DENSITY INSERT(S) PREFABRICATED, PER SHOE adequately describes the product that is the subject of this request.

Medicare Payment:

The payment rules associated with the existing code apply to this product. Pricing = 38

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with the Workgroup's preliminary decision. The speaker claimed that the TMI Insoles are significantly better than existing insoles that are currently marketed and used for diabetics. Specifically, the speaker stated that the TMI Insoles are filled with glycerin, have no animal products or water, made with hypo-allergenic materials, machine washable, self-

conforming to the patient's feet, and promote proper blood flow through food reflexology. The speaker further added that the use of glycerin in the TMI Insoles creates a massaging action that provides full contact to all of the nerve ending and help to increase blood flow, thereby increasing comfort level for the patient to do everyday activities. The speaker reiterated the request to either establish a new HCPCS code for the TMI Insoles, or to reassign the TMI Insoles to a HCPCS code that is billable and payable under the Medicare and Medicaid program.

HCPCS Public Meeting Agenda Item #9
May 25, 2010

Attachment# 10.001

Topic/Issue:

Request to establish a Level II HCPCS code for the Vasyli-Armstrong (VA) / GlideSoft preconfigured, multi layer shear (friction) and pressure reducing diabetic insole.

Background/Discussion:

According to the requester, the Vasyli-Armstrong / GlideSoft orthotic insole is a vertical-pressure and shear reducing device specifically designed for the Diabetic foot. The insole can withstand repeated use and has a life expectancy of 4 - 6 months. It is constructed using multi layer materials combined by utilizing a unique elastic interlace technology. It has a minimum 40 shore - 3/16" heat moldable, ethyl vinyl acetate (EVA) base incorporating a 4 degree intrinsic rear foot medical posting. This is covered by a nylon layer as an interface to a layer of silicon coated Teflon® material. This interface aids motion of the Teflon insert. Above the Teflon® is a layer of cellular urethane foam which acts as a shock absorber. This is covered with a layer of LD45- low density; 45 Kg / m3 Plastazote® closed cell conforming foam. The top layer is a constant temperature microencapsulated material from Outlast®. According to the requester, existing code A5512 (FOR DIABETICS ONLY, MULTIPLE DENSITY INSERT, DIRECT FORMED, MOLDED TO FOOT AFTER EXTERNAL HEAT SOURCE OF 230 DEGREES FAHRENHEIT OR HIGHER, TOTAL CONTACT WITH PATIENT'S FOOT, INCLUDING ARCH, BASE LAYER MINIMUM OF ¼ INCH MATERIAL OF SHORE A 35 DUROMETER OR 3/16 INCH MATERIAL OF SHORE A 40 DUROMETER (OR HIGHER), PREFABRICATED, EACH) does not adequately describe the shear reducing technology of the GlideSoft insole, or enable differentiation between insoles that reduce shear forces and those that do not. Shear (frictional) force on the plantar surfaces of the foot is a major contributing factor in the incidence of plantar foot ulceration. GlideSoft foot orthoses are designed for use by high risk category diabetics as both a preventive and healing aid. Most Diabetic insoles reduce vertical forces but do little if anything to reduce shear (frictional) forces. The GlideSoft insole does both. The applicant claims that reduction of both vertical pressure and shear significantly reduces the risk of ulceration.

CMS HCPCS Preliminary Decision:

Existing code A5512 FOR DIABETICS ONLY, MULTIPLE DENSITY INSERT, DIRECT FORMED, MOLDED TO FOOT AFTER EXTERNAL HEAT SOURCE OF 230 DEGREES FAHRENHEIT OR HIGHER, TOTAL CONTACT WITH PATIENT'S FOOT, INCLUDING ARCH, BASE LAYER MINIMUM OF 1/4 INCH MATERIAL OF SHORE A 35 DUROMETER OR 3/16 INCH MATERIAL OF SHORE A 40 DUROMETER (OR HIGHER), PREFABRICATED, EACH adequately describes the product that is the subject of your request.

Medicare Payment:

The payment rules associated with the existing code apply to this product. Pricing = 38

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with the Workgroup's preliminary decision. The speaker indicated that although the current HCPCS code A5512 describes the pressure relieving material and heat moldability combinations of diabetic inserts, it does not describe the Glidesoft sheer reducing technology associated with the Vasyli Armstrong device. The speaker reported that the Vasyli Armstrong device has a unique sheer reducing property that is clinically proven to reduce diabetic plantar ulcers by 75% in conjunction with pressure relief. In addition, the speaker asserted that using the Vasyli Armstrong device for prevention of diabetic ulcers will potentially save the US healthcare system millions of dollars annually. For these reasons, the speaker believed that a new HCPCS code is warranted to uniquely identify the Vasyli Armstrong device.

HCPCS Public Meeting Agenda Item #10
May 25, 2010

Attachment# 10.118

Topic/Issue:

Request to establish a code for end-diastolic pneumatic compression therapy (EDPC) using a Circulator Boot system.

Background/Discussion:

According to the requester, EDPC is a compression therapy indicated for arterial, venous and lymphatic circulatory systems. It is used to treat patients with peripheral vascular disease who fail standard therapies. EDPC therapy is accomplished by used of the Circulator Boot System. The Circulator Boot System is a counter-pulsating, external device consisting of an external heart monitor that triggers leg compressions in the end-diastolic period; thick plastic boots with movable walls that move closely against the leg to minimize dead space; and a solid metal valve assembly that introduces compressed air supplied by a compressor into the boot at the command of the heart monitor. There are two types of boots that can be used: the long boot and the miniboot. The long boot is used in patients with arterial disease above the knee, in patients with venous stasis disease/ulcers or lymphedema, and patients benefiting from cardiac assist. The miniboot is used in treating patients with arterial disease below the knee, and in those with foot ulcers potentially benefitting from the local injection of antibiotics or the debriding effects of treatments with the foot immersed in special solutions. In addition, disposable supplies include electrodes to stick to the chest and individual plastic bags to encase the leg and receive the compressed air within the boot.

CMS HCPCS Preliminary Decision:

HCPCS Level II is not the appropriate coding jurisdiction for this professional service. 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 the End Diastolic Pneumatic Compression (EDPC) Therapy remains the only option for preventing amputation for patients with chronic arterial wound, complications/co-morbidities

due to diabetes, and patients not suitable for angioplasty or bypass procedures. The speaker further added that EDPC Therapy is significantly different from other chronic wound and limb salvage therapies because of its 90% success rate with no safety issues and broad FDA indications. Currently, there are a variety of CPT codes used to report EDPC Therapy, however, lack of consistent coding present significant administrative burden to the healthcare system and providers. The speaker urged the Workgroup to establish a HCPCS code that appropriately describes an EDPC Therapy to enable appropriate tracking of the procedure before obtaining a CPT code for this therapy. The speaker believed that standardized coding via a Level II HCPCS code is necessary to relieve MAC's of current administrative burden of processing claims with unlisted CPT codes.

HCPCS Public Meeting Agenda Item #11
May 25, 2010

Attachment# 10.110

Topic/Issue:

Request to establish a code for wound cleanser, trade name: Microcyn Skin and Wound Care with preservatives. Applicant's suggested language: "Shelf stable, pH neutral oxychlorine compound in solution for treatment of chronic and acute wounds, per ounce."

Background/Discussion:

According to the requester, Microcyn (formerly marketed as Dermacyn wound cleanser) is a solution used for the treatment of acute and chronic wounds. It is applied topically, including through various mechanical debridement devices (as a replacement for sterile saline). Microcyn is intended for moistening and debriding acute and chronic dermal lesions, such as stage I-IV pressure ulcers, stasis ulcers, diabetic ulcers, post surgical wounds, first- and second-degree burns, abrasions and skin irritations. Microcyn's chemical composition includes purified water, Hypochlorous Acid, sodium Hypochlorite and Sodium Chloride. According to the requester, Microcyn meets an unmet need for use for patients who have allergies or intolerance to topical and/or systemic antibiotics, and also demonstrates promise in treating and preventing wound infections in general populations. Microcyn is supplied as 8 oz. spray, 8.5 oz. dosing and 500 mL dosing bottles. According to the requester, existing codes do not describe this product because the Microcyn technology is unique in that it has demonstrated effectiveness in eradicating a variety of microbes, including antibiotic- and bleach-resistant organisms, yet is safe enough to use around eyes, ears, nose, and mouth. The requester also comments that, while "payment is often appropriately bundled into the payment for wound care as its acquisition cost does not exceed the threshold for separate payment", separate coding would enable tracking of use, outcomes and cost.

CMS HCPCS Preliminary Decision:

A national program operating need was not identified by Medicare, Medicaid or the Private Insurance Sector to establish a code for non-sterile wound cleanser. 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.
Because this code is not marked sterile, use of existing code A6260 is inappropriate.

Medicare Payment:

Based on our preliminary benefit category analysis, 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 that although Microcyn™ is not properly classified as either an antibiotic or a wound cleanser, it delivers the benefits of both without compromising wound healing processes. The speaker further added that the Microcyn™ solution has demonstrated patient benefits in the form of quicker healing times that are not encountered with traditional cleanser-plus-antibiotic protocols. In addition, the speaker stated that unlike most "sterile" topical products, Microcyn™ is contaminant-free throughout its 24-month shelf-life, whether opened or not, and maintains its kill-rates on bacteria, viruses and fungi throughout the product life. The primary speaker believed that the utility and safety profile of Microcyn™ provide significant patient benefits and urged the Workgroup to reconsider its decision and establish a unique HCPCS code for this solution.

HCPCS Public Meeting Agenda Item #12
May 25, 2010

Attachment# 10.060

Topic/Issue:

Request for a new HCPCS code to identify equipment for Therapeutic Low Frequency, non-contact, non-thermal ultrasound, trade name: Celleration MIST Therapy™ System 5.1.

Background/Discussion:

According to the Requester, the Therapeutic Low Frequency Wound Ultrasound provides continuous ultrasonic energy to a wound. This treatment is intended to accelerate wound healing via: 1) cellular stimulation (stimulation of fibroblast activity, protein synthesis, blood flow and tissue regeneration; 2) decreased bioburden (destruction of bacteria); 3) increased blood flow (due to vasodilation effect of ultrasound); and 4) gentle debridement (ultrasound-induced tissue sloughing loosens and clears debris). It is indicated for wounds that have been determined to be non-healing after 2-4 weeks, and provides an adjunct to other wound healing modalities. Patients with non-healing wounds receive treatment three times weekly until the wound has healed. If there is no evidence of improvement after 4 weeks of treatment, noncontact low frequency ultrasound should be discontinued. MIST Therapy is provided by qualified healthcare practitioners. Equipment for therapeutic low frequency wound ultrasound includes a single-use, disposable ultrasound applicator and an ultrasound generator. In addition, a saline drip in front of the ultrasound-generating tip directs the ultrasound energy to the wound. The atomized saline carries the ultrasound energy to the wound. This method achieves "non-contact" between a mechanical vibrating device with heat (typical ultrasound) and the wound. The mist that is generated promotes healing via wound cleansing and maintenance debridement by removal of yellow slough, fibrin, tissue exudates and bacteria. According to the requester, code A6260 "WOUND CLEANSERS, STERILE, ANY TYPE, ANY SIZE" is inadequate to describe this system because it is considered a bundled supply under the Medicare DMEPOS Fee Schedule with a $0 allowable. A CPT code alone is also inadequate to describe this product. The usage of Celleration ultrasound equipment in the Home Health Care setting has expanded to 6.5%. Medicare coverage of the treatment is available in 23 states. Payers are reimbursing for the equipment when miscellaneous HCPCS codes A4649, A9999 and E1399 are reported.

CMS HCPCS Preliminary Decision:

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 therapeutic low frequency ultrasound is provided in multiple sites of care including home health, skilled nursing facilities, and acute care facilities. Currently, the service associated with therapeutic low frequency ultrasound therapy is reported using miscellaneous HCPCS codes. The speaker stated that while a CPT procedure code may be acceptable for the healthcare provider in the hospital outpatient and/or physician's office, it is not appropriate for use in the home health, skilled nursing facility, and acute care hospital settings. The speaker stated there are multiple other wound treatments with both a HCPCS and CPT code, and the request for a unique HCPCS code for the equipment associated with the Celleration MIST Therapy System is consistent with dual CPT/HCPCS coding methodology. The speaker requested a unique HCPCS code for the equipment used with therapeutic low frequency ultrasound.

HCPCS Public Meeting Agenda Item #13
May 25, 2010

Attachment# 10.087

Topic/Issue:

Request to establish 3 codes to identify the components of a non-powered suction apparatus device intended for negative pressure wound therapy, trade name: SNaP™ (Simplified Negative Pressure) Wound Care System. Applicant's suggested language:
Axxx1 Non-powered negative pressure wound therapy suction apparatus, each
Axxx2 Hydrocolloid specialty dressing, multi-layer, sterile, for non-powered negative pressure wound therapy, each dressing set
Axxx3 Holster with strap for use with non-powered negative pressure wound therapy, each.

Background/Discussion:

According to the requester, the SNaP™ Wound Care System is a non-electrically powered device for negative pressure wound therapy (NPWT) for the treatment of acute and chronic wounds. It delivers controlled levels of negative pressure to wounds and collects exudate produced by the wound to promote healing. The negative pressure is achieved by a reduction in the density of air molecules within an enclosure, which includes a wound sealed by a dressing. With the SNaP system this enclosure is created by sealing a wound with a specialized hydrocolloid dressing which is then connected to the SNaP Cartridge to apply the negative pressure. The SNaP system is indicated for patients who would benefit from a suction device particularly as the device may promote wound healing and for removal of small amounts of exudate from chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic or pressure), surgically closed incisions and flaps. The system consists of a cartridge; a hydrocolloid dressing layer with integrated nozzle and tubing; a cartridge holster with strap; and an antimicrobial gauze wound interface layer. All components of the system work as an integrated system and are applied for a single use. After the wound is cleaned and debrided, moistened antimicrobial gauze is gently packed into the wound bed and the hydrocolloid dressing with integrated nozzle and tubing are placed over the moistened gauze. Next, the tubing is cut and connected to the cartridge nozzle. The disposable cartridge is currently produced with three different pre-set pressure levels (-75mmHg, -100mmHg, and -125mmHG) and is strapped to the patient's leg, arm, or belt under clothing. It is left in place for 3-4 days and typically changed on a bi-weekly basis. The cartridge may be applied by the patient and sometimes may need to changed more frequently than the other materials in highly exudative wounds. The therapy is continued until the treating clinician determines that NPWT is

no longer necessary for wound healing. The requester claims that existing HCPCS codes for NPWT systems are for devices that are DME. The SNaP device is not DME, rather it falls within Medicare's Surgical Dressing benefit category. In addition, the requester claims that the hydrocolloid dressing differs from "the standard polyurethane dressings used by every other NPWT device or the market today." As such, the requester believes that existing HCPCS codes do not adequately describe the components of the SNaP system.

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 our preliminary benefit category analysis, we believe that there would be no separate Medicare payment for these items.

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item #14
May 25, 2010

Attachment# 10.030

Topic/Issue:

Request to establish a code for Closed System Drug Transfer Device (CSTD) technology, trade name: PhaSeal System.

Background/Discussion:

According to the Requester, the PhaSeal System is a true-closed system drug transfer device (CSTD) that is used in the preparation and handling of hazardous drugs, most often chemotherapy drugs. The system is used in (1) the institutional pharmacy or physician's office for preparation, (2) at the patient level for administration, and (3) for safe waste disposal. The PhaSeal System contains the hazardous drug throughout the process. The requester states that "Based on peer-reviewed published scientific data, we do not believe that at this time there are any other products marketed in the U.S. that possess all of the characteristics of a true closed-system drug transfer device (CSTD) as described in both the NIOSH Alert and by the International Society of Oncology Pharmacy Practitioners. The PhaSeal System is significantly distinct in its features, function, benefit and cost compared with other existing products and techniques including traditional needle and syringe methods or use of a chemotherapy dispensing pin currently used in the handling of hazardous drugs. It is because of the significant clinical benefits of the PhaSeal and the functional characteristics that differentiate it from other products and techniques that a distinct HCPCS code should be established."

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 our preliminary benefit category analysis, 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 #15
May 25, 2010

Attachment# 10.046

Topic/Issue:

Request to establish a code to describe a disposable gas-scavenging apparatus that removes inhaled anesthetics at the end of a procedure, trade name: Anecare QED-100™.

Background/Discussion:

According to the requester, QED-100 is a single use disposable device used by the anesthesia provider which actively removes inhaled (volatile) anesthetics at the end of surgery. This device helps reverse the anesthetics' effects and thereby promotes rapid emergence from anesthesia. The device is placed between the endotracheal tube and the breathing circuit and is activated at the end of surgery. The QED-100 works by allowing patients to partially rebreathe their own $C0^2$, which in turn increases cerebral blood flow thereby accelerating brain washout of the volatile anesthetics. This also increases the patient's own drive to breathe. Simultaneously, the clinician increases the patient's ventilation to help more rapidly clear the volatile anesthetics from the blood through the lungs - without lowering the $C0^2$ level. Lastly, the device contains an anesthetic absorber which captures any exhaled or residual anesthetic to prevent re-inhaling the anesthetic. The QED-100 is indicated for use on patients for whom a mechanically delivered tidal volume of greater than 500 ml during emergence is acceptable. According to the requester, no existing code adequately describes this device.

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.

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 #16
May 25, 2010

Attachment# 10.112

Topic/Issue:

Request to establish a code for a server-based software program designed to assist medical and nursing staff in calculating insulin dosages, trade name: G+ System.

Background/Discussion:

According to the requester, the G+ system is a server-based software program that incorporates an advanced algorithm that automatically adjusts to learn each patient's individual response (sensitivity) to insulin, regardless of blood sugar abnormality. It is intended for use in hospital in-patient settings to evaluate the current and cumulative patient blood sugar levels and calculate and recommend a dose of saline, glucose, and insulin to drive the blood sugar either up or down towards a predetermined target range. Once that target blood sugar range has been reached, the G+ System function recommends dosing of insulin, glucose, and saline for the purpose of maintaining the patient's blood sugar in that target range. The G+ System is not intended for use with patients with known insulin allergies or under the age of 18. The programmed logic is not a substitute for, but rather an assist to clinical reasoning. Measurements and calculations generated are intended to be used by qualified and trained medical personnel in evaluating patient conditions in conjunction with clinical history, symptoms, and other diagnostic measurements, as well as the medical professional's clinical judgment. No medical decision should be based solely on the recommended guidance provided by this software program. According to the requester, similar products differ in cost, material, product design, use and mechanism of use. The requester claims a significant therapeutic distinction from other products based on the efficacy, safety, simplicity, and cost savings of the G+ System. There are no existing codes to describe server-based software programs for disease management.

CMS HCPCS Preliminary Decision:

HCPCS Level II is not the appropriate coding jurisdiction for this product used by health care professionals in an in-patient setting.

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 the G+ System is a computer-directed intravenous insulin system that has shown to be safe.

According to the speaker, the use of the G+ System in hospital inpatient settings provide various advantages, including normalized blood glucose levels within 6-12hrs, decreased errors caused by manual calculations, reduced calls to physicians, increased outpatient education referral, decreased sliding-scale insulin injections, increased nursing satisfaction, and improved patient outcomes. The speaker also stated that the G+ System is HIPAA compliant which result in no lost patient records, easy to setup, and because of its error alerts and warning features, reduces errors. The speaker believed that the use of the G+ System will enhance hospital revenues and provide savings to the U.S. healthcare system. Based on its benefits, the speaker believed that a unique HCPCS code should be established to appropriately identify the G+ System.

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, fiscal intermediaries and A/B MACs(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) and A/B MACs.

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 payment for the ongoing 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 other than power wheelchairs 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. Effective for items furnished on or after January 1, 2011, the rental fee for power wheelchairs for each of the first 3 months of rental is equal to 15 percent of the purchase fee for the item. The rental fee for power wheelchairs for months 4 through 13 is equal to 6 percent of the purchase fee for the item. Effective for items furnished on or after January 1, 2011, only complex rehabilitative 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 blood products, transfusion medicine, splints, casts, and other devices used to reduce a fracture or dislocation, and intraocular lenses (IOLs) inserted in physician's offices.