

**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 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# 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.

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”

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).

AGENDA ITEM # 4

Attachment# 10.022

Request to establish a code, appropriate coverage and reimbursement for a custom neoprene wrist support.

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).

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.

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.).

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".

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.

AGENDA ITEM #10

Attachment# 10.118

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

AGENDA ITEM #11

Attachment# 10.110

Request to establish a code for wound cleanser, trade name: Microcyn Skin and Wound Care with preservatives.

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.

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.

AGENDA ITEM #14

Attachment# 10.030

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

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™.

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.

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.

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

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.

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

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

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 symphysis 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

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.

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 LAMINATION/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.

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

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

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

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 use 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.

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.

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.

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 be 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.

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.

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 CO₂, 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 CO₂ 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.

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.

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.