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

Supplies and Other

Wednesday, May 9, 2012

Introduction and Overview

Approximately 80 people attended. The agenda included 28 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.

Karen Jacobs 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"
Wednesday, May 9, 2012, 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#12.066
Request to establish a code for a collagen wound dressing, trade name: Endoform Dermal Template and place it in the surgical dressing category.

No Primary Speaker

AGENDA ITEM #2
Attachment#12.016
Request to either expand existing code A6154 for use in the ostomy policy; OR establish a new HCPCS code to describe a one piece drainable ostomy pouch, trade name: Premier High Output Drainable Pouch. Applicant's suggested language: Axxxx "Ostomy pouch drainable, high output, with extended wear barrier attached."

No Primary Speaker

AGENDA ITEM #3
Attachment#12.062
Request to reinstate 12 L-codes in the L8100 series and to make changes to the verbiage of these codes, to describe gradient compression stockings, Trade Names: Mediven-95, Mondi Esprit, Forte, 550; to assign these devices to the prosthetic benefit category; and establish Medicare coverage.

Primary Speaker: Robert Weiss of National Lymphedema Network

AGENDA ITEM #4
Attachment#12.071
Request to establish a code for a heel post that is used as an addition to lower extremity orthosis. Applicant's suggested language: "Addition to lower extremity, rigid plastic modification, varus/valgus correction, stance/gait stabilizer, heel post".

Primary Speaker: Tim Costello of Midwest Orthotic Services, LLC

AGENDA ITEM #5
Attachment#12.088
Request to establish a code for the KX2 Devices Flexible Foot Lift (FFL).

Primary Speaker: Dell Klotz of KX2 Devices, LLC

AGENDA ITEM #6
Attachment#12.073
Request to establish a code for a patient-controlled passive motion (PCPM) rehabilitation device, trade name: KneeEase.

Primary Speaker: J. Allen of Rapid Knee Rehab, LLC

AGENDA ITEM #7
Attachment#12.076
Request to establish 4 codes for walk-in bath tubs, trade name: Safety Tubs Acrylic Walk-In Bath. Applicant's suggested language:
Exxxx "Walk-in bath"

Exxxx "Walk-in bath with whirlpool"

Exxxx "Walk-in bath with air spa"

Exxxx "Walk-in bath with whirlpool and air spa".

No Primary Speaker

AGENDA ITEM #8
Attachment#12.077
Request to establish two codes for components of a crashed-tested transportation securement system, trade name: WC-19 Transit Option. Applicant's suggested language: "Wheelchair accessory, WC19 compliant and tested transportation securement hardware, includes front and rear securement brackets and crash-tested pelvic restraint mounting/anchor hardware;" and "Wheelchair accessory, integrated WC19 compliant pelvic belt restraint for use only on wheelchairs with WC19-compliant transportation securement hardware".

Primary Speaker: Rita Hostak of Sunrise Medical

AGENDA ITEM #9
Attachment#12.078
Request to establish a code for a padded surface attachment for an existing wheelchair footplate, trade name: Wheel Comfort A Padded Footplate.

Primary Speaker: Ethan Ruby of WheelComfort

AGENDA ITEM #10
Attachment#12.080
Request to establish a code to identify a set of wheels that provide a new option to improve the safety of 3 wheel POVs, trade name: Active Stabilizer™. Applicant's suggested language: "Sudden turn tip prevention wheels for 3 wheel power operated vehicles".

Primary Speaker: William Ammer of Ammer Consulting

AGENDA ITEM #11
Attachment#12.086
Request to establish a code for nasal expiratory positive airway pressure (EPAP) therapy for Obstructive Sleep Apnea, (OSA), trade name: Provent Sleep Apnea Therapy. Applicant's suggested language: "Nasal expiratory positive airway pressure (EPAP) device, per box of 30 pairs".

Primary Speaker: Dr. David Gross

AGENDA ITEM #12
Attachment#12.019
Request to establish HCPCS code(s) to describe a medication labeling and identification system, trade name: Codonics Safe Labeling System that includes "Perioperative medication preparation and labeling" and a "Safe medication (anesthesia or analgesia) labeling system accessory".

Primary Speaker: Gary Enos of Codonics

AGENDA ITEM #13
Attachment#12.059
Request to have a description change for "T1505" which identifies the Electronic Medication Management Assistant system and a separate T-code for the EMMA® disposable cartridge. Trade Name: EMMA®. Applicant's suggested language: Revise existing code T1505 which currently reads ELECTRONIC MEDICATION COMPLIANCE MANAGEMENT DEVICE, INCLUDES ALL COMPONENTS AND ACCESSORIES, NOT OTHERWISE CLASSIFIED to instead read ELECTRONIC MEDICATON COMPLIANCE MANAGEMENT DEVICE, BASE UNIT (EACH); and establish code Txxxx DISPOSABLE CARTRIDGE FOR THE ELECTRONIC MEDICATION MANAGEMENT UNIT (PER CARTRIDGE).

Primary Speaker: Christopher Bossi of INRange Systems, Inc.

AGENDA ITEM #14
Attachment#12.064
Request to establish a code for a web-based patient monitoring and care coordination device, Trade Name: Health Buddy appliance. Applicant's suggested language: "Technology enabled chronic care coordination with clinical content, behavior assessment, education, remote monitoring, equipment rental, software, connections, maintenance, per month".

Primary Speaker: Karen Gilberg of Robert Bosch Healthcare, Inc.

AGENDA ITEM #15
Attachment#12.075
Request to establish a code for a dynamic jaw splint, trade name: Jaw Dynasplint® System. Applicant's suggested language: Exxxx "Dynamic adjustable jaw stretching device."

Primary Speaker: Frederick Beu of Dynasplint Systems, Inc.

AGENDA ITEM #16
Attachment#12.056
Request to establish 2 HCPCS codes to identify the Madison Oral Strengthening Therapeutic (MOST) Device. The applicant requests one code to describe the custom molded mouthpiece that incorporates bulb sensors to measure tongue pressure, and a second code to describe the device that provides manometric/pressure readings from the bulbs imbedded in the mouthpiece.

No Primary Speaker

AGENDA ITEM #17
Attachment#12.002
Request to establish a code for an oral/nasal suction catheter tips, trade names: Bebeonkers I (16-1) and Bebonkers II (16-2).

No Primary Speaker

AGENDA ITEM #18
Attachment#12.049
Request to establish a code for an ear pressure relief device, trade name: EarPopper Home Version Ep-2100. Applicant's suggested code language: "EarPopper Home Version EP-2100 is covered when prescribed by a healthcare provider for recipients with otitis media with effusion or Eustachian tube dysfunction."

Primary Speaker: Kevin Connelly of Summit Medical, Inc.

AGENDA ITEM #19
Attachment#12.050
Request to establish 11 new codes to describe a category of personal FM/DM auditory devices, trade names: MyLink+, MLxi, ML15i, ML14i, ML13i, ML12i, ML11i, ML10i, ML9i, MLxi BAHA, MLxi, Micro Link Freedom, iSense micro, iSense classic, iCOM, ZoomLInk+, EasyLink+, SmartLink+, Inspiro, AS9, AS10, AS11, AS12, AS13, AS15, DynaMic, iLapel, and Easy Boom. Applicant's suggested language:

xxxx1 "Assistive listening device, personal fm/dm system, monaural, (1 receiver, transmitter, microphone), any type"

xxxx2 "Assistive listening device, personal fm/dm system, binaural, (2 receivers, transmitters, microphones), any type"

xxxx3 "Assistive listening device, personal fm/dm neck, loop induction receiver"

xxxx4 "Assistive listening device, personal fm/dm, ear level receiver"

xxxx5 "Assistive listening device, personal fm/dm, direct audio input receiver"

xxxx6 "Assistive listening device, personal blue tooth fm/dm receiver"

xxxx7 "Assistive listening device, personal fm/dm receiver, unspecified"

xxxx8 "Assistive listening device, personal fm/dm transmitter assistive listening device"

xxxx9 "Assistive listening device, personal fm/dm adapter/boot coupling device for receiver, any type"

xxx10 "Assistive listening device transmitter microphone, any type"

xxx11 "Assistive listening device, fm/dm accessory any type".

Primary Speaker: Sharmila Sandhu of American Academy of Audiology

AGENDA ITEM #20
Attachment#12.052
Request to establish a new HCPCS code for the Shower Shirt, and to classify it as DME. The Shower Shirt is a water resistant garment intended to prevent surgical drain sites from becoming wet in the shower.

Primary Speaker: Lisa Crites of The Shower Shirt Company, LLC

AGENDA ITEM #21
Attachment#12.055
Request to establish a code for a cast and skin protector, trade name: WaterGuard® Cast & Skin Protectors.

No Primary Speaker

AGENDA ITEM #22
Attachment#12.058
Request to establish three codes for uniquely numbered, bar-coded surgical sponges, trade names: SM-1818 Safety-Sponge® (18 “x18”); SM-4416 Safety-Sponge® (4 “x4”); and SM-6005 Safety-Sponge® (towel).

Primary Speaker: Nicolas Soichet of Patient Safety Technologies, Inc.

AGENDA ITEM #23
Attachment#12.060
Request to: 1) revise existing code A4215 which currently reads: "NEEDLE, STERILE, ANY SIZE, EACH" to instead read "Needle for use with standard single use or reusable syringe, sterile, any size, each"; 2) establish Axxxx "Needle for use with pen injector, any size, sterile, each"; and 3) establish Axxxx "Needle system for use with pen injector, with automated safety cover, any size, sterile, each" to identify the pen needle, trade name: BD Nano Ultra-Fine Pen Needle & BD AutoShield Duo.

Primary Speaker: Dr. Laurence Hirsh of BD Diabetes Care

AGENDA ITEM #24
Attachment#12.010
Request to establish 3 codes for high compression inelastic, non-knitted/non-woven bandages with sub-bandage pressure 30 - 50 mmHg. Applicant's suggested language:

Axxx1 "High compression bandage, inelastic, non-knitted/non-woven, sub-bandage pressure 30 - 50 mmHg, width less than three inches, per yard"

Axxx2 "High compression bandage, inelastic, non-knitted/non-woven, sub-bandage pressure 30 - 50 mmHg, width greater than three inches and less than five inches, per yard"

Axxx3 "High compression bandage, inelastic, non-knitted/non-woven, sub-bandage pressure 30 - 50 mmHg, width greater than or equal to five inches, per yard".

Attachment #12.012

Request to establish 3 new HCPCS codes for specialty foam with self-adherent fiber bandage, trade name: 3M™ Coban™ 2 Layer Compression System. Applicant's suggested language:

Axxx1 "Specialty foam with self adherent fiber bandage, non-woven/non-knitted, inelastic, width less than three inches, per yard"

Axxx2 "Specialty foam with self adherent fiber bandage, non-woven/non-knitted, inelastic, width greater than or equal to three inches and less than five inches, per yard"

Axxx3 "Specialty foam with self adherent fiber bandage, non-woven/non-knitted, inelastic, width greater than or equal to five inches, per yard".

Attachment# 12.057

Request to establish a code for silicone-based adhesive tape, trade name: 3M™ Kind Removal Silicone Tape. Applicant's suggested language: "Axxxx Tape, silicone-based adhesive, per 18 square inches".

Primary Speaker: Cheryl Loegering of 3M

AGENDA ITEM #25
Attachment#12.061
Request to establish a code for a liquid medication dispenser, trade names: MediBottle and Medibottle +acc21000.

No Primary Speaker

AGENDA ITEM #26
Attachment#12.053
Request to establish for toddler formula, trade name: Baby's Only Organic® Dairy with DHA & ARA Toddler Formula.

No Primary Speaker

AGENDA ITEM #27
Attachment #12.054
Request to establish a code to describe “nutritionally incomplete” enteral formulae for the special needs of those with inherited metabolic disorders, trade name: PhenylAde 60 Drink Mix. Applicant's suggested language: "Enteral formula, nutritionally incomplete amino acid formulas, for special metabolic needs for inherited disease of metabolism with intentionally reduced caloric

content. May or may not include fats, carbohydrates, fiber, vitamins and minerals, administered orally or through an enteral feeding tube. 100 calories - 1 unit".

Primary Speaker: Martin Silverman of Applied Nutrition Corp.

AGENDA ITEM #28
Attachment #12.051
Request to assign a nutritional shake, trade name: Orgain, to existing code B4150.

No Primary Speaker

HCPCS Public Meeting Agenda Item #1
May 9, 2012

Attachment# 12.066

Topic/Issue:

Request to establish a code for a collagen wound dressing, trade name: Endoform Dermal Template and place it in the surgical dressing category.

Background/Discussion:

According to the requester, Endoform Dermal Template is a non-reconstituted, ovine acellular, collagen, single-use wound dressing indicated for in the treatment of partial and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds, trauma wounds, and draining wounds. Endoform is cut to fit the shape of the wound, placed on the wound bed, rehydrated with sterile saline and covered. When rehydrated, Endoform transforms into a soft conforming sheet which is naturally incorporates into the wound over time. The dressing can be left in place for 5 - 7 days. Endoform is sold in boxes of 10 dressings each and has a 2 year shelf-life. Endoform does not require physician fixation. It is simple to use and even the patient at home can perform a dressing change once a treatment plan has been established. According to the requester, Endoform was assigned code C9367 "SKIN SUBSTITUTE, ENDOFORM DERMAL TEMPLATE, PER SQUARE CENTIMETER". According to the requester, existing code C9367 is inadequate to describe this product because this product is acellular and therefore not a biologic. It should be classified as a surgical dressing and identified using existing collagen dressing code(s).

Preliminary Decision:

1) Revise codes A6021, A6022 and A6023 which currently read: A6021 “COLLAGEN DRESSING, STERILE, PAD SIZE 16 SQ. IN. OR LESS, EACH”; A6022 “COLLAGEN DRESSING, STERILE, PAD SIZE MORE THAN 16 SQ. IN. BUT LESS THAN OR EQUAL TO 48 SQ. IN., EACH”; A6023 “COLLAGEN DRESSING, STERILE, PAD SIZE MORE THAN 48 SQ. IN., EACH” to instead read: A6021 “COLLAGEN DRESSING, STERILE, SIZE 16 SQ. IN. OR LESS, EACH”; A6022 “COLLAGEN DRESSING, STERILE, SIZE MORE THAN 16 SQ. IN. BUT LESS THAN OR EQUAL TO 48 SQ. IN., EACH”; A6023 “COLLAGEN DRESSING, STERILE, SIZE MORE THAN 48 SQ. IN., EACH”.

2) Use revised A6021 “COLLAGEN DRESSING, STERILE, SIZE 16 SQ. IN. OR LESS, EACH”; A6022 “COLLAGEN DRESSING, STERILE, SIZE MORE THAN 16 SQ. IN. BUT LESS THAN OR EQUAL TO 48 SQ. IN., EACH” or A6023 “COLLAGEN DRESSING, STERILE, SIZE MORE THAN 48 SQ. IN., EACH” depending on size, to identify Endoform Dermal Template.

Medicare Payment:

The payment rules associated with the existing codes apply to this product if covered.
For A6021 - A6023, Pricing = 35

Summary of Primary Speaker Comments at the Public Meeting:

The applicant offered a brief comment at the public meeting agreeing with CMS' preliminary decision.

HCPCS Public Meeting Agenda Item #2
May 9, 2012

Attachment# 12.016

Topic/Issue:

Request to either expand existing code A6154 for use in the ostomy policy; OR establish a new HCPCS code to describe a one piece drainable ostomy pouch, trade name: Premier High Output Drainable Pouch. Applicant's suggested language: Axxxx "Ostomy pouch drainable, high output, with extended wear barrier attached."

Background/Discussion:

According to the requester, the Premier High Output Drainable Pouch can be used for drainage collection from a stoma, wound or fistula. The pouch has a soft tap spout for drainage removal and an open access window which allows for easy visualization of the draining entity. It also has an odor-barrier film and a cut-to-fit barrier that is made of extended wear barrier material. The Premier pouch holds more than 0.75 liters of drainage and comes in either a sterile or non-sterile version. This can be worn longer than a day but must be discarded after single-use. According to the requester, existing code A6154 "WOUND POUCH, EACH" can be used to describe the product but the code is not a part of the ostomy policy. Therefore, people who need the product to manage significant output from a stoma are being denied. The code is only in the Surgical Dressings policy which requires description, size, location, etc. of the "wound" in order to be covered. This is not appropriate for the product when used as an ostomy. Codes for regular drainage ostomy pouches are not appropriate since these products hold more than 0.75 liters and have a large bore spout. Existing codes for high output do not describe these products because they are for two piece products.

Preliminary Decision:

Establish Axxxx OSTOMY POUCH, DRAINABLE, HIGH OUTPUT, WITH EXTENDED WEAR BARRIER (ONE-PIECE SYSTEM), WITH OR WITHOUT FILTER, EACH

Medicare Payment:

Based on our preliminary benefit category analysis, we believe that the items would be paid in accordance with the payment rules that apply to Ostomy, Tracheostomy and Urological Supplies if covered.

Summary of Primary Speaker Comments at the Public Meeting:

The applicant offered a brief comment at the public meeting agreeing with CMS' preliminary decision.

HCPCS Public Meeting Agenda Item #3
May 9, 2012

Attachment# 12.062

Topic/Issue:

Request to reinstate 12 L-codes in the L8100 series and to make changes to the verbiage of these codes, to describe gradient compression stockings, Trade Names: Mediven-95, Mondi Esprit, Forte, 550; to assign these devices to the prosthetic benefit category; and establish Medicare coverage.

Background/Discussion:

The requester is seeking to reinstate codes in the L8100 series that previously identified compression garments. These codes were discontinued and replaced with codes in the A6500 series, effective January 1, 2006. According to the requester, the A-codes identify garments and dressings used in the treatment of burns, venous stasis ulcers, and surgical prevention. They do not properly identify compression garments used in the treatment of Lymphedema. Lymphedema results when a "malfunctioning internal body organ" (Lymphatics system) results in blockage, partial removal or fibrosing of lymphatics. Compression replaces part of the function of the lymphatic system. As such, compression bandage systems, compression garments and compression devices used in the treatment of lymphedema should be classified as "prosthetic devices"; assigned L-Codes; and covered by Medicare under§1861(s) (8).

Preliminary Decision:

Existing HCPCS Level II codes for Gradient Compression Stockings, A6530 through A6549 adequately describe the products that are the subject of this request, based on compression range. Inquiries regarding benefit category should be referred to the individual insurers.

Medicare Payment:

The payment rules associated with the existing codes apply to these products if covered.

For codes A6530, A6533 - A6541, A6544 and A6549
Pricing = 00

For codes A6531, A6532 and A6545
Pricing =35

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with CMS' preliminary decision. The speaker urged CMS to categorize these products as prosthetic devices, “not surgical dressings,” because these garments

"replace the lymph system, nodes and organs." According to the speaker, current coding of the gradient compression stockings used in the compression therapy of lymphedema is not adequate because: 1) Compression level is not sufficient descriptor to group similar products; 2) manufacturing method, materials, and stiffness distinguish similar groups; and 3) Insurers use these codes only because no more appropriate codes exist that distinguish burn garments and secondary dressings from lymphedema garments. The speaker reiterated the original request to reinstate previously discontinued "L" codes. The applicant also offered a brief comment disagreeing with CMS' preliminary decision, stating that placement of these products under "A" codes "blocks coverage," and these products "should be covered as prostheses."

HCPCS Public Meeting Agenda Item #4
May 9, 2012

Attachment# 12.071

Topic/Issue:

Request to establish a code for a heel post that is used as an addition to lower extremity orthosis. Applicant's suggested language: "Addition to lower extremity, rigid plastic modification, varus/valgus correction, stance/gait stabilizer, heel post".

Background/Discussion:

According to the requester, a Heel Post is a shaped piece of plastic that is used as an addition to a custom molded fitted orthosis. A Heel Post is indicated when a patient exhibits excessive supination or pronation and requires additional stability during standing or walking. It is appropriately used for patients with varus valgus heel deformities and instabilities as well as other associated conditions, including pronation, supination, stroke, developmental delay, hemiplegia, cerebral palsy, Down's syndrome, acquired ankle foot deformities and clubfoot. The Heel Post is designed to provide two important functions: 1) to provide varus or valgus correction to the hindfoot, and 2) to provide stabilization for the hindfoot. Heel Post is semi-circular in shape and varies in width, depending upon the size of the device to which it is applied. It is generally between 3/16" and 3/8" thick. Heel Post is heated and then affixed to the plantar aspect of a lower extremity orthosis under the heel during the vacuum forming process. According to the requester, the existing code L2755 "ADDITION TO LOWER EXTREMITY, VARUS/VALGUS CORRECTION, PLASTIC MODIFICATION, PADDED/LINED" comes the closest to describing this product. However, code L2755 is inadequate in its description of the function of a heel post, which provides both correction and stability for the patient.

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. Correction and stability are inherently a part of the product provided, therefore separate coding would be redundant. 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:

No separate payment. Payment for this addition is included in the payment for the ankle foot orthosis

Summary of Primary Speaker Comments at the Public Meeting:

The applicant disagreed with CMS' preliminary decision. The applicant stated that a new code is warranted because: 1) Only 2 of more than 75 lower extremity base codes include varus/valgus in their descriptor; 2) Additions of varus/valgus corrections to lower extremity orthotic devices were anticipated by HCPCS Workgroup as far back as the 1990s; 3) A heel post is a hindfoot varus/valgus correction; and 4) A heel post cannot be adequately described by existing codes for varus/valgus corrections. The applicant recommended that the workgroup either: modify an existing code to provide for all other types of varus/valgus correction that do not fit into the 2 existing codes or reduce existing addition codes to one code, all inclusive.

HCPCS Public Meeting Agenda Item #5
May 9, 2012

Attachment# 12.088

Topic/Issue:

Request to establish a code for the KX2 Devices Flexible Foot Lift (FFL).

Background/Discussion:

According to the requester, the Flexible Foot Lift (FFL) is a lightweight dorsiflexion assistance device for persons with foot drop; eversion of the foot and extension of the toes; and plantar fasciitis. The FFL consists of an ankle cuff made of heavy material with a "stiffener to prevent collapse;" two triangle buckles and springs attached to the outside of the cuff; and 2 straps that connect between the springs and the person's shoe, sandal or bare foot. According to the requester, the FFL has the ability to straighten the angle of the foot by applying different tensions on the spring straps. The requester claims that the product replaces expensive special made (formed) orthotic braces, yet is different from those devices because the FFL allows ankle mobility, and can be used during walking, running and biking. According to the requester, existing code L1930 "ANKLE FOOT ORTHOSIS, PLASTIC OR OTHER MATERIAL, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT" is for a non-ambulatory patient and therefore does not describe this device, and a new code is needed to identify the FFL.

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 applicant stated "we're requesting a code for a device that is not currently covered," specifically, requesting an "L" code "so there will be reimbursement." There is no existing "L" code that accurately describes the functionality or benefits of the KX2 Flexible Foot Lift. Therefore, the applicant reiterated the original request to establish a new code to describe the KX2 Flexible Foot Lift.

HCPCS Public Meeting Agenda Item #6
May 9, 2012

Attachment# 12.073

Topic/Issue:

Request to establish a code for a patient-controlled passive motion (PCPM) rehabilitation device, trade name: KneeEase.

Background/Discussion:

According to the requester, KneeEase is a patient-controlled passive motion rehabilitation device for rehabilitation following knee-replacement. KneeEase is also indicated for patients with joint distortions and contusions, arthrotomy and arthroscopy procedures, mobilizations of joints in narcosis, cruciated ligament replacement surgery (ACL/PCL), and endoprosthetic implants. The device consists of a steel frame, seat, adjustable back rest, movable parallel rod apparatus, various straps, pads, display, joystick, motor, gear box, power cord, power supply, and on/off/kill switch. It accommodates patients up to 350 pounds. The patient sits up on a seat with their lower leg secured between two moving rods which are controlled by the patient using a hand-held joystick as they dynamically flex and extend the knee joint to exactly the degree the patient chooses. According to the requester, the closest existing code to describe this product is E0935 "CONTINUOUS PASSIVE MOTION EXERCISE DEVICE FOR USE ON KNEE ONLY". However, KneeEase differs from products coded at E0935 in the following ways: 1) it uses passive motion and is patient controlled; 2) it provides significantly greater range-of-motion, extension of -2 degrees and flexion of 130 degrees, with greater precision; and 3) it does not require patients to lie in bed for up to 6 hours a day for therapy, but allows them to get out of bed and make progress in three 30-minute sessions each day.

Preliminary Decision:
Existing code A9300 "EXERICISE EQUIPMENT" 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 = 00

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item, however; the applicant submitted written comments disagreeing with the workgroup's preliminary decision. The applicant stated that the KneeEase device is not exercise equipment because "it already meets the standards to qualify as a CPM device (E0935) and can be billed as such." The applicant also claimed that there is a need for a new HCPCS code to differentiate patient-controlled technology from older continuous passive motion devices.

HCPCS Public Meeting Agenda Item #7
May 9, 2012

Attachment# 12.076

Topic/Issue:

Request to establish 4 codes for walk-in bath tubs, trade name: Safety Tubs Acrylic Walk-In Bath. Applicant's suggested language:

Exxxx "Walk-in bath"

Exxxx "Walk-in bath with whirlpool"

Exxxx "Walk-in bath with air spa"

Exxxx "Walk-in bath with whirlpool and air spa".

Background/Discussion:

According to the requester, Safety Tub Walk-in baths are bath fixtures with inward opening doors to allow ease of entry and exit. Safety Tub utilizes a patented, watertight door system with a self-sealing gasket and is supported by a freestanding metal support frame with leveling feet. These walk-in bath fixtures include an integrated 17" high seat, integrated grab bars, and cable driven drains. Safety Tub is available as a soaker unit without hydromassage or with a variety of hydromassage systems including whirlpool, heated air injection, or combination system. All products are available in either a left or right handed drain version. According to the requester, there are no existing codes to describe accessible bathing fixtures.

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:

There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item #8
May 9, 2012

Attachment# 12.077

Topic/Issue:

Request to establish two codes for components of a crashed-tested transportation securement system, trade name: WC-19 Transit Option. Applicant's suggested language: "Wheelchair accessory, WC19 compliant and tested transportation securement hardware, includes front and rear securement brackets and crash-tested pelvic restraint mounting/anchor hardware;" and "Wheelchair accessory, integrated WC19 compliant pelvic belt restraint for use only on wheelchairs with WC19-compliant transportation securement hardware".

Background/Discussion:

According to the requester, they are requesting two codes for components of a crashed-tested transportation securement system that is compliant with ANSI/RESNA WC19 for use with manual (dependent and independent) and power wheelchairs. The first code is for a crash-tested transportation securement hardware package that consists of four securement brackets, two front and two rear, that are installed on the wheelchair frame and comply with WC 19, and the mounting or anchor hardware for an integrated WC19-compliant pelvic belt restraint. The second one is for the WC19-compliant pelvic restraint. This belt restraint is specifically designed for transportation loads to prevent ejection from the wheelchair and impact with the vehicle interior. A crash-tested transportation securement hardware package that is ANSI/RESNA WC19-compliant enables the wheelchair to be secured to the vehicle floors that are equipped with appropriate wheelchair tie-down and occupant restraint system (WTORS). The addition of an integrated WC19-compliant pelvic belt increases the safety of the user during transit. The four securement hardware brackets, the restraint belt anchors and the WC19-compliant pelvic belt restraint are properly placed on the wheelchair frame in the manner that is compliant with WC19 requirements. The system is tested and if the product passes the required tests, it is considered to be WC-19 complaint. The WC19-compliant transportation securement hardware package and the WC19 compliant pelvic restraint belt when used in conjunction with the securement hardware package are only useful for individuals that require wheeled mobility and who must be transported in their wheelchair. According to the requester, there is no code that adequately describes this product. Payers are currently using K0108 "WHEELCHAIR COMPONENT OR ACCESSORY, NOT OTHERWISE SPECIFIED".

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 applicant disagreed with CMS' preliminary coding decision and the informal benefit category determination. The applicant stated that the WC-19 Transit Option is a wheelchair accessory. The applicant claimed that a need code is needed to track utilization of this product and this can't be done using miscellaneous code K0108.

HCPCS Public Meeting Agenda Item #9
May 9, 2012

Attachment# 12.078

Topic/Issue:

Request to establish a code for a padded surface attachment for an existing wheelchair footplate, trade name: Wheel Comfort A Padded Footplate.

Background/Discussion:

According to the requester, Wheel Comfort is a single construction of close-cell water proof foam adhered to a plastic molded bottom, which attaches to a wheelchair footplate with a hook and loop fastener. Wheel Comfort items are standard widths (7.5"), only the lengths vary to accommodate different footplates. SM fits the small single footplate design at 9.7", LG fits 11.5" and the Splits are 7.5" each. All construction is 1" depth. Wheel Comfort provides pressure relief for bare feet as they rest on a metal footplate. It is intended to provide pressure relief for people who have foot and ankle wounds. According to the requester, there are no products, or codes to identify products, that provide pressure relief to existing foot and ankle wounds.

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 applicant disagreed with CMS' preliminary coding decision and Medicare payment recommendation. The applicant stated that the Wheel Comfort helps to prevent pressure ulcers and addresses pressure, sheer and moisture. And, since other types of pressure ulcer care is covered, this device should also be covered, and placed in an “E” or “K” code, with other wheelchair accessories.

HCPCS Public Meeting Agenda Item #10
May 9, 2012

Attachment# 12.080

Topic/Issue:

Request to establish a code to identify a set of wheels that provide a new option to improve the safety of 3 wheel POVs, trade name: Active Stabilizer™. Applicant's suggested language: "Sudden turn tip prevention wheels for 3 wheel power operated vehicles".

Background/Discussion:

According to the requester, Active Stabilizer Wheels are swivel caster wheel/fork assemblies attached to the outer edge of each side of the frame of a 3 wheel POV, designed to receive them, in line with the POV's steerable front wheel. They have 2 sets of opposing magnets incorporated in the design of the assembly whose magnetic field causes them to hold the stabilizer wheel in a forward, centered position when not in use. Stabilizer wheels are positioned 1/2" above the ground and do not touch the ground when the POV is steering straight or is at rest. The Active Stabilizer comes with a limited lifetime guarantee (excluding the polyurethane wheel). They are guaranteed to outlast the life cycle of any 3 wheel POV on which they are installed (the average life cycle of a POV is 3-5 years). Existing codes do not adequately describe the product of this new technology for sudden turn tip prevention wheels for POVs. The patient population for whom the product is clinically indicated includes "beneficiaries with mobility limitations that significantly impairs their ability to perform activities of daily living within the home. Active Stabilizer Wheel technology can prevent serious injuries caused by accidental side tipovers prevalent on 3 wheel POVs (HCPCS codes K0800, K0801, K0802, K0806, K0807, K0808).

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. Existing code A9900 MISCELLANEOUS DME SUPPLY, ACCESSORY, AND/OR SERVICE COMPONENT OF ANOTHER HCPCS CODE" is available for assignment to describe this safety feature which is included in the initial issue of the POV.

Medicare Payment:

No separate payment. Payment for this product is included in the payment for the POV base code.

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with CMS' preliminary decision to use existing code A9900 stating that Active Stabilizer Wheels are not included with the initial issue of POVs, but are retrofitted after initial issue. The speaker claimed that there is no existing code to describe this unique product. According to the speaker, a new code is warranted because Active Stabilizer Wheels provide dynamic lateral stability to 3-wheel POVs and stop tipovers on sudden turns and turns on slopes.

HCPCS Public Meeting Agenda Item #11
May 9, 2012

Attachment# 12.086

Topic/Issue:

Request to establish a code for nasal expiratory positive airway pressure (EPAP) therapy for Obstructive Sleep Apnea, (OSA), trade name: Provent Sleep Apnea Therapy. Applicant's suggested language: "Nasal expiratory positive airway pressure (EPAP) device, per box of 30 pairs".

Background/Discussion:

According to the requester, the PROVENT Sleep Apnea Therapy device decreases the Apnea Hypopnea Index (AHI), improving sleep quality and decreasing sleepiness. The device consists of an adhesive ring that surrounds a one-way valve. Each night, the patient sticks one device on each nostril. The devices are discarded after single-use. Assuming that "once asleep, patients generally breathe through their nose and thus through the device": the one-way valve permits nearly unobstructed inspiration; and increases resistance during expiration, creating EPAP. This is the mechanism that decreases the AHI. According to the requester, this EPAP supports the function of the impaired oropharynx, restoring the conduit to the trachea and lungs, and as such, the Provent devices should be categorized as a prosthetic. Provent Therapy is an alternative for treating patients who refuse, reject or are intolerant of continuous positive airway pressure (CPAP) therapy. According to the requester, there is no existing HCPCS category to describe this device.

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 these items.

Summary of Primary Speaker Comments at the Public Meeting:

The applicant disagreed with CMS' preliminary decision. The applicant stated that a new code is needed to describe Provent because: "1) clinically proven alternatives to CPAP therapy are

needed to allow effective therapy for patients with OSA; 2) nasal EPAP is supported by 5 years of clinical research; 3) nasal EPAP should become a medically necessary benefit for Medicare beneficiaries; 4) the requested HCPCS codes will be equally important for other U.S. patients; and 5) Provent has close analogies to device types already classified as prostheses."

HCPCS Public Meeting Agenda Item #12
May 9, 2012

Attachment# 12.019

Topic/Issue:

Request to establish HCPCS code(s) to describe a medication labeling and identification system, trade name: Codonics Safe Labeling System that includes "Perioperative medication preparation and labeling" and a "Safe medication (anesthesia or analgesia) labeling system accessory".

Background/Discussion:

According to the requester, Codonics Safe Labeling System (SLS) is an integrated medication labeling and identification system used to assist in drug preparation and administration in the perioperative environment. The Codonics SLS hardware and SLS software provides a simple computer-based bar code scanning and printing system to automatically verify drug identity from NDC and other drug vial UDI barcodes, and to print labels for prepared drugs and other items used for patients during surgical procedures. An integrated formulary database confirms vial barcodes with both audible and visual display of the drug name and concentration. The SLS system produces waterproof, American Society of Anesthesiologists (ASA) compliant color labels with 2-D barcodes. The SLS also produces labels for IVs and other artifacts used during a surgical procedure. According to the requester, no existing HCPCS codes describe this system. The system includes the hardware. The master drug database/formulary administration tool is separately licensed to the site. Consumables include special ink cartridges and ISO compliant labels, plus operating costs per label or per surgical procedure. The system can also be integrated to function with AIMS System workflow to provide real-time documentation of drug administration when the syringe "2D Barcode" is read.

Preliminary Decision:

The Codonics Safe Labeling system is institutional equipment and as such, it is not appropriate for separate billing or coding in HCPCS Level II.

Medicare Payment:

Based on our preliminary benefit category analysis, we believe that there would be no separate Medicare payment for this item.

Summary of Primary Speaker Comments at the Public Meeting:

The applicant disagreed with CMS' preliminary HCPCS coding and Medicare payment recommendations decision. The applicant provided comments related to the durability and cost-effectiveness of the device, claiming that its use reduces errors and controls waste.

HCPCS Public Meeting Agenda Item #13
May 9, 2012

Attachment# 12.059

Topic/Issue:

Request to have a description change for "T1505" which identifies the Electronic Medication Management Assistant system and a separate T-code for the EMMA® disposable cartridge. Trade Name: EMMA®. Applicant's suggested language: Revise existing code T1505 which currently reads ELECTRONIC MEDICATION COMPLIANCE MANAGEMENT DEVICE, INCLUDES ALL COMPONENTS AND ACCESSORIES, NOT OTHERWISE CLASSIFIED to instead read ELECTRONIC MEDICATON COMPLIANCE MANAGEMENT DEVICE, BASE UNIT (EACH); and establish code Txxxx DISPOSABLE CARTRIDGE FOR THE ELECTRONIC MEDICATION MANAGEMENT UNIT (PER CARTRIDGE).

Background/Discussion:

According to the requester, the Electronic Medication Management Assistant, (EMMA) is an in-home; remote medication management tool indicated for high-risk patients with poly-pharmacy management issues. EMMA utilizes a cellular two-way web-based communications software that allows a physician, pharmacist or nurse to remotely program and manage prescriptions stored and released by the patient-operated system. The EMMA medication administration cartridges are specially perforated, encoded and solely for use in the EMMA device. Each Base Unit can hold a month's supply of up to ten (10) medication cartridges. If the patient's treatment involves more than 10 prescription medications, an expansion unit is used to accommodate additional cartridge(s). The system allows for compliance monitoring and real-time dose adjustments through its wireless software capabilities. It stores the patient's complete medication history and provides clinicians with vital information about medication dosing, adjustments, refills, missed doses and treatments responses. CMS established code T1505 "ELECTRONIC MEDICATION COMPLIANCE MANAGEMENT DEVICE, includes all components and accessories" effective January 2011, to describe the EMMA system. However, the applicant views the system as three separately billable and unique components that may or may not be used. In addition, the disposable cartridges are supplied and billed monthly, based on the actual number of medications managed. According to the requester, separate HCPCS codes are required because the EMMA® Base Unit, the EMMA® Expansion Unit and the EMMA® Medication Administration Cartridge (disposable DME Supply) have a significantly different price structure as well as a distinct frequency of billing.

Preliminary Decision:

Existing code T1505 "ELECTRONIC MEDICATION COMPLIANCE MANAGEMENT DEVICE, INCLUDES ALL COMPONENTS AND ACCESSORIES, NOT OTHERWISE CLASSIFIED" as written and intended, includes all components and accessories needed by the patient.

Medicare Payment:

Based on guidance contained in an informal 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 CMS' preliminary decision. The speaker stated that the single code T1505 identifies the base device purchase, but does not properly reflect consumable supplies, such as disposable cartridges and data contained on them; and medical analysis, cell communication and support service associated with the EMMA device. The speaker requested a second code for the consumable supply and suggested that CMS realign the codes to match the FDA's definition of a medication system.

HCPCS Public Meeting Agenda Item #14
May 9, 2012

Attachment# 12.064

Topic/Issue:

Request to establish a code for a web-based patient monitoring and care coordination device, Trade Name: Health Buddy appliance. Applicant's suggested language: "Technology enabled chronic care coordination with clinical content, behavior assessment, education, remote monitoring, equipment rental, software, connections, maintenance, per month".

Background/Discussion:

According to the requester, the Health Buddy (HB) is a web-based telehealth system that facilitates remote monitoring, patient education and behavior assessments to support care management for chronically ill patients, and improve patient-self-management. The HB appliance is the patient interface portion of the communication system. It is a user-friendly display device that connects to a data center via telephone or ethernet connection. It is used by patients in conjunction with an online service to furnish information to health care professionals between office visits. The HB appliance provides standardized questions and the patient responds to the questions by pressing buttons. The Health Buddy can also be activated to function with blood glucose meters, blood pressure cuffs, weight scales, peak flow meters and pulse oximeters. HB communicates the health status of patients to care managers; provides patient education; supports adherence with medication and other treatment approaches; and improves patient self-management skills and satisfaction with care. Each work day, care managers log onto HB Clinician Interface to review patient's results which have been risk-stratified using color coded risk tags. The HB can be cleaned, refurbished and "scrubbed" of patient information and clinical content to allow customization for subsequent patient use. According to the requester, HCPCS code S9109 is the only HCPCS code available to track related services.

Preliminary Decision:

A national program operating need to establish a new code for this product was not identified by Medicare, Medicaid or the Private Insurance Sector. Existing code S9109 "CONGESTIVE HEART FAILURE TELEMONITORING, EQUIPMENT RENTAL, INCLUDING TELESCALE, COMPUTER SYSTEM AND SOFTWARE, TELEPHONE CONNECTIONS, AND MAINTENANCE, PER MONTH" is available for assignment by insurers if they deem appropriate.

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 applicant disagreed with CMS' preliminary decision. The applicant proposed a new code that is not specific to a particular disease state, in order to: 1) provide standardization for payers operating in multiple states; 2) promote physician adoption; 3) allow management of multiple conditions, as defined by payers; 4) address clinical coordination provided by care manager and supported by physician; and 5) emphasize role of clinical content, behavior assessment and patient education.

HCPCS Public Meeting Agenda Item #15
May 9, 2012

Attachment# 12.075

Topic/Issue:

Request to establish a code for a dynamic jaw splint, trade name: Jaw Dynasplint® System. Applicant's suggested language: Exxxx "Dynamic adjustable jaw stretching device."

Background/Discussion:

According to the requester, the Jaw Dynasplint System (JDS) is a spring-loaded dynamic splinting device with adjustable tension settings that provide low-load, prolonged stretch to connective tissue of the jaw. It is used to treat stiffness and contracture of the temporomandibular joint. The JDS aids in restoring physical function and quality of life to patients suffering from joint and muscle stiffness and limited range of motion in the posterior mandibular or temporomandibular region. JDS helps the patient regain more complete oral function and dramatically improves the fundamental functions needed to: maintain oral hygiene; chew food; speak; and insert and remove obturators and other oral prostheses. The system can be hand held, but is usually used with counter-balance bars to enable the patient to use it completely hands free. The patient selects the appropriate force. The patient uses the system for several sessions. The typical treatment session is approximately 5 to 10+ minutes. Each time the patient uses the system the session time increases until it reaches 30-45 minutes. According to the requester, code E1700 describes a category of devices which have design, function and clinical utilization which is entirely different from that of a dynamic splinting device for the jaw.

Preliminary Decision:

Existing code E1700 “JAW MOTION REHABILITATION” adequately describes the device that is the subject of this request.

Medicare Payment:

The payment rules associated with the existing code apply to this product if covered.
Pricing = 32

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with CMS’ preliminary decision that existing code E1700 describes the JDS. According to the speaker, the JDS does not match the form or function of the predicate device for code E1700, rather, this dynamic splinting device is identical in form and

function to devices codes at E1800 – E1840. The speaker reiterated the original request to establish a code in the E1800 series and place it in the Medicare capped rental payment category.

HCPCS Public Meeting Agenda Item #16
May 9, 2012

Attachment# 12.056

Topic/Issue:

Request to establish 2 HCPCS codes to identify the Madison Oral Strengthening Therapeutic (MOST) Device. The applicant requests one code to describe the custom molded mouthpiece that incorporates bulb sensors to measure tongue pressure, and a second code to describe the device that provides manometric/pressure readings from the bulbs imbedded in the mouthpiece.

Background/Discussion:

According to the Requester, the Madison Oral Strengthening Therapeutic (MOST) device is used by physicians as a screening tool to identify risk for dysphagia, and used by patients to perform progressive resistance lingual press exercises to strengthen the muscles of the tongue and oropharynx. The device consists of a single-patient use, pliable mouthpiece component that incorporates sensors to measure tongue pressure, and a portable, DC battery powered hand-held device that measures and records manometric readings from the sensors embedded in the mouthpiece. The physician/diagnostic component involves fitting the oral component's sensory receptors against the patient's hard palate, instructing the patient, and evaluating the lingual press measurements. After a patient has used the MOST device at home, they return it to the physician who downloads the lingual press measures from the device. The physician analyzes the information and recommends a lingual strengthening exercise regimen. The information can also be used by the physician to monitor patient compliance and progress. Patients who may benefit from the use of the MOST device are those diagnosed with dysphagia secondary to stroke or other neuromuscular condition, those who have had prolonged endotracheal intubation after cardiac surgery, those demonstrating difficulty swallowing after chemotherapy, or patients presenting with age-related changes. According to the requester, there are no HCPCS Level II codes and no CPT codes that describe the use of durable medical equipment similar to the MOST.

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 #17
May 9, 2012

Attachment# 12.002

Topic/Issue:
Request to establish a code for an oral/nasal suction catheter tips, trade names: Bebeonkers I (16-1) and Bebonkers II (16-2).

Background/Discussion:
According to the requester, the Bebeonkers oral and nasal suction tips attach to the end of normal suction tubing to create a safe way to suction a fragile infant's mouth and nose. They quickly remove secretions from the nose or mouth of young pediatric, newborn and preterm infants. Bebeonkers are inserted into the mouth or nose and begin suction upon contact with secretions, eliminating the need to put the device too far into the nose or mouth. According to the request, Bebeonkers' patented design is uniquely superior to other suction devices used in hospital newborn intensive care units because its three whole configuration at the distal end virtually eliminates trauma to the oral mucosa. The Bebeonkers is the only suction device that has multiple holes to prevent the device from grabbing the tongue or the sensitive mucosa of the oral cavity. There is currently no code to describe these products and no codes are currently being billed for these products.

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. Catheter tips are included with the catheter coded at A4628 "OROPHARYNGEAL SUCTION CATHETER, EACH."

Medicare Payment:

No separate payment. Payment for this product is included in the payment for the catheter.

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item #18
May 9, 2012

Attachment# 12.049

Topic/Issue:

Request to establish a code for an ear pressure relief device, trade name: EarPopper Home Version Ep-2100. Applicant's suggested code language: "EarPopper Home Version EP-2100 is covered when prescribed by a healthcare provider for recipients with otitis media with effusion or Eustachian tube dysfunction."

Background/Discussion:

According to the requester, the EarPopper Home Version EP-2100 is a small hand held device that uses a gentle stream of continuous, regulated air to open the Eustachian Tube. It consists of a medical grade air pump housed in a plastic case, powered by 4 AAA batteries. The EarPopper is intended to help treat the common ear pressure problems (i.e. Eustachian Tube dysfunction, Otitis Media with effusion) as an alternative to medications or surgery. The device is inserted in one nostril while the other nostril is pinched closed. While the device is running, the patient will swallow, directing the air pressure to open blocked/closed Eustachian tubes. This happens because during the swallow the soft pallet seals the back of the throat momentarily, diverting the air pressure up the blocked/closed Eustachian tubes. This treatment is self-administered and is normally done twice a day when treating an effusion or "as needed" when symptoms of ear pressure or diminished hearing are present. According to the requester, there is no existing code to describe this product.

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 CMS' preliminary decision stating that there is a national need to establish a code for the EarPopper. The speaker also stated that ear pressure is a common condition with covered treatments including antibiotics and surgical procedures.

According to the speaker, the EarPopper “eliminates unnecessary pain, combats antibiotic resistance, avoidable surgical procedures and overall medical bills.”

HCPCS Public Meeting Agenda Item #19
May 9, 2012

Attachment# 12.050

Topic/Issue:

Request to establish 11 new codes to describe a category of personal FM/DM auditory devices, trade names: MyLink+, MLxi, ML15i, ML14i, ML13i, ML12i, ML11i, ML10i, ML9i, MLxi BAHA, MLxi, Micro Link Freedom, iSense micro, iSense classic, iCOM, ZoomLInk+, EasyLink+, SmartLink+, Inspiro, AS9, AS10, AS11, AS12, AS13, AS15, DynaMic, iLapel, and Easy Boom. Applicant's suggested language:

xxxx1 "Assistive listening device, personal fm/dm system, monaural, (1 receiver, transmitter, microphone), any type"

xxxx2 "Assistive listening device, personal fm/dm system, binaural, (2 receivers, transmitters, microphones), any type"

xxxx3 "Assistive listening device, personal fm/dm neck, loop induction receiver"

xxxx4 "Assistive listening device, personal fm/dm, ear level receiver"

xxxx5 "Assistive listening device, personal fm/dm, direct audio input receiver"

xxxx6 "Assistive listening device, personal blue tooth fm/dm receiver"

xxxx7 "Assistive listening device, personal fm/dm receiver, unspecified"

xxxx8 "Assistive listening device, personal fm/dm transmitter assistive listening device"

xxxx9 "Assistive listening device, personal fm/dm adapter/boot coupling device for receiver, any type"

xxx10 "Assistive listening device transmitter microphone, any type"

xxx11 "Assistive listening device, fm/dm accessory any type".

Background/Discussion:

According to the requester, FM/DM auditory devices are most often used in conjunction with hearing aids to improve the signal to noise ratio to allow the listener to hear better in the presence of background noise. They are intended to reduce or eliminate distance, background noise, and poor room acoustics as adverse factors in effective listening. These devices are also utilized for other types of auditory processing disorders. In certain listening situations, traditional hearing

aids alone do not provide the necessary level of audibility. With the use of FM/DM technologies the sound signal is directed from a transmitting device (FM/DM transmitter) via a frequency or digitally modulated signal to a receiving device (FM/DM receiver) which is coupled to a hearing device. There are some FM/DM technologies that are dedicated units that do not couple to amplification. These units are self-contained units that are designed to be used without being coupled to personal amplification and are used by individuals that present normal peripheral hearing but present other medical challenges such as auditory processing, attention deficit, and/or autism spectrum disorders. A complete FM/DM system typically consists of a transmitter and a receiving device. The requester is proposing an entire code family to identify personal FM/DM systems and accessories to expand the current assistive listening device code set (V5268-V5274). FM/DM technology is therapeutically distinct because it greatly enhances hearing due to the decrease of background noise, and increases an individual's ability to carry out normal daily activities and to function both mentally and physically at a higher level than allowed by other similar items.

Preliminary Decision:

Establish 10 new "V" codes and revise existing V5267 which currently reads "HEARING AID SUPPLIES / ACCESSORIES" to instead read "HEARING AID OR ASSISTIVE LISTENING DEVICE / SUPPLIES / ACCESSORIES, NOT OTHERWISE SPECIFIED".

Vxxx1 "Assistive listening device, personal fm/dm system, monaural, (1 receiver, transmitter, microphone), any type"

Vxxx2 "Assistive listening device, personal fm/dm system, binaural, (2 receivers, transmitters, microphones), any type"

Vxxx3 "Assistive listening device, personal fm/dm neck, loop induction receiver, for replacement only"

Vxxx4 "Assistive listening device, personal fm/dm, ear level receiver, for replacement only"

Vxxx5 "Assistive listening device, personal fm/dm, direct audio input receiver, for replacement only"

Vxxx6 "Assistive listening device, personal blue tooth fm/dm receiver"

Vxxx7 "Assistive listening device, personal fm/dm receiver, unspecified, for replacement only"

Vxxx8 "Assistive listening device, personal fm/dm transmitter assistive listening device"

Vxxx9 "Assistive listening device, personal fm/dm adapter/boot coupling device for receiver, any type"

Vxx10 "Assistive listening device transmitter microphone, any type, for replacement only"

Medicare Payment:

Based on Section 1862(a)(7) of the Social Security Act, we believe there would be no Medicare payment for these items.

Summary of Primary Speaker Comments at the Public Meeting:

The applicant agreed with the workgroup's preliminary decision to establish codes but suggested revisions to the descriptors of proposed codes Vxxx2, Vxxx3, Vxxx4, Vxxx5, Vxxx7, and Vxx10. The applicant requested that "transmitters, microphones" be changed to singular in code Vxxx2; and that "replacement only" be removed from the descriptors of codes Vxxx3, Vxxx4, Vxxx5, Vxxx7, and Vxx10.

HCPCS Public Meeting Agenda Item #20
May 9, 2012

Attachment# 12.052

Topic/Issue:

Request to establish a new HCPCS code for the Shower Shirt, and to classify it as DME. The Shower Shirt is a water resistant garment intended to prevent surgical drain sites from becoming wet in the shower.

Background/Discussion:

According to the requester, the Shower Shirt is a machine washable, water resistant garment, intended to prevent post-surgical/mastectomy drain sites from getting wet while showering. It is a short sleeve shirt/jacket with elastic around all perimeters. It has a turtle-neck lined with micro-fiber (to absorb any water drops, a Velcro strap, and a drawstring under the jaw line to assure a snug fit around the neck. In the front there is a zipper with weather flap, capped sleeves, drain pockets to host drain bulbs, and Velcro loops that support the weight of drain tubes. The product extends 2 to 4 inches below the breast line and fits loosely, to avoid pressure on drains sutured into the armpits or chest/torso region. The Shower Shirt minimizes the risk of infection. It is indicated for status/post Mastectomy patients needing to protect drain sites; patients with dialysis catheters or Savi Catheters for radiation; patients with other chest or abdominal drains or central lines; and for patients using wound vacs, infusion pumps and other external catheters.

The timeframe that a patient would utilize the product can be anywhere from 3 weeks, up to a year, depending on the type of medical paraphernalia needing protection from water. The Shower Shirt can withstand repeated use.

Preliminary Decision:

A national program operating need to establish a code 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, contract 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 applicant disagreed with CMS' preliminary decision. The applicant stated that use of the Shower Shirt helps to avoid post-surgical infections and promotes the physical and psychological aspects of healing. As such, it should be deemed a medical necessity, and not a "convenience."

HCPCS Public Meeting Agenda Item #21
May 9, 2012

Attachment# 12.055

Topic/Issue:

Request to establish a code for a cast and skin protector, trade name: WaterGuard® Cast & Skin Protectors.

Background/Discussion:

According to the requester, WaterGuard® is a watertight, waterproof limb protecting sleeve that comfortably slips over casts and wounds, enabling them to stay dry during showers and baths. It is used to keep casts, skin, bandages, cuts, abrasions, and wounds clean and dry while keeping dirt and moisture out. The watertight sealing keeps water out and keeps topical treatments in. Waterguard is applied by putting your limb through the designated opening and adjusting it to fit over cast or wound dressing. The expandable opening then contracts around the limb to seal the opening without constricting blood flow. Waterguard is offered in thirteen varieties to accommodate all patients, body size, wound types and application. According to the requester, there are no codes for products within the same category as the Waterguard.

Preliminary Decision:

A national program operating need to establish a code for this product was not identified by Medicare, Medicaid or the Private Insurance Sector. For coding guidance, contact the entity in whose jurisdiction a claim would be filed. For private insurers, contact the individual private insurance contractor. For Medicaid, contact the Medicaid Agency in the state in which a claim would be filed. For Medicare, contact the Medicare contractor.

Medicare Payment:

Based on guidance contained in an informal benefit category 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 #22
May 9, 2012

Attachment# 12.058

Topic/Issue:

Request to establish three codes for uniquely numbered, bar-coded surgical sponges, trade names: SM-1818 Safety-Sponge® (18 "x18"); SM-4416 Safety-Sponge® (4 "x4"); and SM-6005 Safety-Sponge® (towel).

Background/Discussion:

According to the requester, Safety Sponges numbered and bar-coded surgical sponges are, for the most part, identical to everyday surgical cotton sponges and towels that are used to collect bodily fluids and to drape patients during surgical procedures. Safety Sponges are indicated for used in any surgical procedure and service where their size is appropriate. The key differences between Safety Sponges and generic sponges are the data matrix bar codes that are fused into each sponge and the new technology and count protocol that lies therein. The sponges are scanned "in" using the SurgiCounter™ mobile scanning computers at the beginning of a procedure, as staff are performing their initial sponge count. As the case draws to an end and staff performs their "count out", staff again scan the sponges using the SurgiCounter. The requester claims that use of safety sponges and the sponge counter prevents instances of retained sponges. According to the requester, there is no code that accurately captures the technology and process included in Safety Sponges.

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 surgical procedure.

Medicare Payment:

Based on our preliminary benefit category analysis, we believe that there would be no separate 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 #23
May 9, 2012

Attachment# 12.060

Topic/Issue:

Request to: 1) revise existing code A4215 which currently reads: "NEEDLE, STERILE, ANY SIZE, EACH" to instead read "Needle for use with standard single use or reusable syringe, sterile, any size, each"; 2) establish Axxxx "Needle for use with pen injector, any size, sterile, each"; and 3) establish Axxxx "Needle system for use with pen injector, with automated safety cover, any size, sterile, each" to identify the pen needle, trade name: BD Nano Ultra-Fine Pen Needle & BD AutoShield Duo.

Background/Discussion:

According to the requester, the BD Pen Needles are single use medical devices that consists of a three-step process that shapes the tip of every BD needle as finely as possible for easier penetration. They are designed to be used in conjunction with pen injectors and pen cartridges only. BD Pen Needles are offered in various gauge sizes (29G, 30G, and 31G) and lengths (4mm, 5mm, 8mm, 12.7mm). According to the requester, the BD Pen Needle has a significant therapeutic distinction over other needles because they are: proven effective for all patients; proven less painful; and shown to be less intimidating. According to the requester, the 4mm x 32G pen needle provides predictable insulin absorption and equivalent glycemic control as compared to intramuscular injections, which are painful and can lead to erratic insulin absorption and increase the patient's risk of hypoglycemia. Existing code A4215 does not describe the Pen Needle because it describes needles used with standard syringes.

Preliminary Decision:

Existing code A4215 "NEEDLE, STERILE, ANY SIZE, EACH" adequately describes the products that are the subject of this request.

Medicare Payment:

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

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with CMS' preliminary decision stating that there are major differences in device design, use, and performance and patient acceptance between detachable-needle syringes and insulin pen needles. According to the speaker, existing code A4215 does not

provide meaningful distinction amongst the wide variety of needled delivery systems employed today for insulin therapy and payers cannot distinguish them. The speaker claimed that differentiation amongst these products is critical to encourage and track successful patient self-management of their diabetes.

HCPCS Public Meeting Agenda Item #24
May 9, 2012

Attachment# 12.010

Topic/Issue:

Request to establish 3 codes for high compression inelastic, non-knitted/non-woven bandages with sub-bandage pressure 30 - 50 mmHg. Applicant's suggested language:

Axxx1 "High compression bandage, inelastic, non-knitted/non-woven, sub-bandage pressure 30 - 50 mmHg, width less than three inches, per yard"

Axxx2 "High compression bandage, inelastic, non-knitted/non-woven, sub-bandage pressure 30 - 50 mmHg, width greater than three inches and less than five inches, per yard"

Axxx3 "High compression bandage, inelastic, non-knitted/non-woven, sub-bandage pressure 30 - 50 mmHg, width greater than or equal to five inches, per yard".

Background/Discussion:

According to the requester, 3M™ Coban™ 2 Layer Compression System is a multi-layer compression bandaging system used for the treatment of venous leg ulcers, lymphedema and other conditions where compression therapy is appropriate. Each compression system contains two rolls, comfort layer (inner layer) and compression layer (outer layer). The inner comfort layer consists of polyurethane foam laminated to cohesive non-woven material. The outer compression layer is a latex-free cohesive, inelastic, non-woven material designed to provide short stretch compression. The inner layer is applied with the foam side against the skin. The outer layer coheres to the inner layer and reduces potential for slipping, sustaining compression for up to 7 days. When applied, this system provides compression to reduce edema in the lower extremities by: reducing blood pressure in the superficial venous system, aiding venous return of blood to the heart by increasing the velocity of flow in the deep veins, and reducing the pressure differences between the capillaries and the tissue to prevent backflow. The compression layer provides recommended compression levels of 30-50 mmHG. According to the requester, 3M™ Coban™ 2 Layer Compression System has a significant therapeutic distinction over similar products because it: 1) has lower application variability; 2) provides effective compression with only 2 thin layers; 3) is easier to apply and remove; 4) is inelastic; 5) is easier to perform; 6) has lower slippage; 7) shows an improvement in patients' daily living scores; and 8) shows sustained effective compression better than other bandage systems. There are no existing codes to describe this bandaging system. Although there are codes for garments and wraps that are inelastic and provide pressure of 30 - 50 mmHg, there are no existing codes for similar compression bandages. Existing codes for compression bandages do not specify the sub-bandage pressure ranges.

Preliminary Decision:

Existing code A6441 "PADDING BANDAGE, NON-ELASTIC, NON-WOVEN/NON-KNITTED, WIDTH GREATER THAN OR EQUAL TO THREE INCHES AND LESS THAN FIVE INCHES, PER YARD" adequately describes the product that is the subject of this request, which is supplied in a 4 inch width.

Medicare Payment:

The payment rules associated with the existing code apply to this product if covered.
Pricing = 35

Summary of Primary Speaker Comments at the Public Meeting:

The applicant disagreed with CMS' preliminary decision that existing code A6441 describes this product, stating that 3M's comfort layer is very different from padding bandages used in multi-layer compression bandaging systems in both material composition and clinical performance. The 3M product is patented, therefore it is novel. The 3M foam is not the same as cotton used in other products. The 3M product grips the skin and therefore minimizes slippage. In addition, the existing codes are based on pad size and per dressing and therefore do not identify 3M products which are supplied on a roll and are measured per yard.

HCPCS Public Meeting Agenda Item #24
May 9, 2012

Attachment# 12.012

Topic/Issue:

Request to establish 3 new HCPCS codes for specialty foam with self-adherent fiber bandage, trade name: 3M™ Coban™ 2 Layer Compression System. Applicant's suggested language:

Axxx1 "Specialty foam with self adherent fiber bandage, non-woven/non-knitted, inelastic, width less than three inches, per yard"

Axxx2 "Specialty foam with self adherent fiber bandage, non-woven/non-knitted, inelastic, width greater than or equal to three inches and less than five inches, per yard"

Axxx3 "Specialty foam with self adherent fiber bandage, non-woven/non-knitted, inelastic, width greater than or equal to five inches, per yard".

Background/Discussion:

According to the requester, the 3M Coban™ 2 Layer Compression System is used for the treatment of venous leg ulcers, lymphedema, chronic edema and other conditions where compression therapy is appropriate. Coban 2 Layer provides fast reduction in edema, pain and exudation and thereby increases the mobility of patient. It is a multi-layer compression bandaging system containing two rolls, a comfort layer (inner layer) and compression layer (outer layer). The comfort layer consists of open cell polyurethane foam laminated to cohesive, latex-free non-woven material. The capillary action of the open cell polyurethane foam helps absorb and wick away skin moisture, reducing the risk of skin maceration. The comfort layer is applied with the foam side against the skin which provides a soft comfortable layer that mechanically grips to the skin without any external fasteners. It coheres to the outer compression layer and reduces potential for slipping, thereby providing an effective, sustained compression for up to 7 days. The outer compression layer provides short stretch compression. This product has a significant therapeutic distinction over similar products because it: 1) consists of integrated specialty foam with self-adherent fiber bandage that adheres to the compression layer by application of single layer with 10% overlap; 2) has significantly less slippage and bunching; 3) is quicker and easier to apply; and 4) provides effective compression with only two thin layers. According to the requester, existing codes A6441-A6447 describe padding or conforming bandages made of cotton, crepe or polyester based orthopedic wool. None of the codes describes specialty foam with self adherent fiber bandage.

Preliminary Decision:

Existing code A6454 "SELF-ADHERENT BANDAGE, ELASTIC, NON-KNITTED/NON-WOVEN, WIDTH GREATER THAN OR EQUAL TO THREE INCHES AND LESS THAN

FIVE INCHES, PER YARD" adequately describes the product that is the subject of this request, which is supplied in a 4 inch width.

Medicare Payment:

The payment rules associated with the existing code apply to this product if covered.

Pricing = 35

Summary of Primary Speaker Comments at the Public Meeting:

The applicant disagreed with CMS' preliminary decision that existing code A6454 describes this product stating that 3M's comfort layer is very different from self-adherent bandages used in multi-layer compression bandaging systems. Specifically, 3M's compression layer is a high compression bandage made of latex free cohesive, non-elastic, non-woven material. The speaker also stated that current HCPCS codes for high compression bandages are not for products that are non-elastic or non-woven/non-knitted. According to the applicant, existing codes do not recognize the industry standard for measuring low, medium and high compression, which are based on mmHg. The applicant also commented that additional sizes (widths) will be available in 2013.

HCPCS Public Meeting Agenda Item #24
May 9, 2012

Attachment# 12.057

Topic/Issue:

Request to establish a code for silicone-based adhesive tape, trade name: 3M™ Kind Removal Silicone Tape. Applicant's suggested language: "Axxxx Tape, silicone-based adhesive, per 18 square inches".

Background/Discussion:

According to the requester, 3M™ Kind Removal Silicone Tape is a new silicone-based adhesive tape that offers reliable yet pliable fixation, remains in place and removes cleanly without disrupting fragile skin layers. 3M Kind tape is gentle to skin, breathable, hypoallergenic and is not made out of materials containing natural rubber. It is indicated for patients with fragile, compromised or at-risk skin or repeated application and removal over the same area. 3M Kind tape is used to minimize pain and help maintain skin health and barrier function, without sacrificing reliable, consistent adhesion. 3M Kind tape can be repositioned and neatly torn by hand across or down the tape. According to the requester, 3M Kind tape is therapeutically superior to other products because silicone based adhesive inherently has a lower surface tension compared with traditional acrylate adhesive and lends itself to be more compatible with human skin which also has lower surface tension. In addition, the thickness of silicone-based adhesive tape ranges from four to ten times that of traditional acrylate adhesive tape. Due to the lower surface tension and thicker adhesive, the silicone-based adhesive is more conformable or pliable to skin leading to better adhesion compared with acrylate adhesive. Existing code A4452 " WATERPROOF TAPE" does not adequately describe this product because 3M Kind tape is therapeutically superior in performance and provides significantly improved clinical outcomes compared to standard waterproof medical tapes.

Preliminary Decision:

Existing code A4452 "TAPE, WATERPROOF, PER 18 SQUARE INCHES" 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 if covered.

Summary of Primary Speaker Comments at the Public Meeting:

The applicant disagreed with CMS' preliminary decision stating that the 3M Kind Removal Silicone Tape is very different from all other medical tapes currently used. The applicant stated that differentiating (existing) HCPCS codes based on waterproof and non-waterproof product

attributes does not recognize the significant therapeutic distinctions between 3M’s silicone based tape and the others that are paper, plastic or silk based.

HCPCS Public Meeting Agenda Item #25
May 9, 2012

Attachment# 12.061

Topic/Issue:

Request to establish a code for a liquid medication dispenser, trade names: MediBottle and Medibottle +acc21000.

Background/Discussion:

According to the requester, the Medibottle is a medication delivery system designed for infants. A care-giver measures an accurate dose of oral, liquid medication, loads an oral dispenser with the medicine, fills the Medibottle like a regular baby bottle, and attaches a nipple. The caregiver inserts the loaded oral medication dispenser into the inner sleeve of the bottle. The sleeve's tip has a very precise tolerance that restricts the flow of medicine, creating a small and powerful jet or "little squirt" each time the dispenser plunger is pressed. These small amounts of medicine displace the liquid in the very tip of the nipple. According to the requester, in a study involving 76 hospitalized infants, the Medibottle was found to be 85% more likely to deliver 100% of the prescribed dosage than an oral syringe. The requester comments that the difference in successful delivery of the full dose results in improved compliance which leads to higher quality and safer care and as such, use of the Medibottle confers a significant therapeutic distinction when compared with the use of an oral syringe. The requester also comments that accurate dosing is more than a matter of "convenience". The Medibottle is not identified in the existing code set.

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 these items.

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item #26
May 9, 2012

Attachment# 12.053

Topic/Issue:

Request to establish for toddler formula, trade name: Baby's Only Organic® Dairy with DHA & ARA Toddler Formula.

Background/Discussion:

According to the requester, Baby's Only Organic with DHA & ARA Toddler Formula is designed to meet the complete nutritional needs of a toddler in conjunction with an appropriate daily diet to provide nutritional support for maintenance of growth and development. It can also be used under the guidance of a healthcare professional as an infant formula. Baby's Only Organic is intended for children 1 to 3 years of age to compliment a diet that includes table foods. It is made with organic nonfat milk and contains organic brown rice syrup and naturally occurring lactose. Baby's Only Organic also contains organic high oleic sunflower and/or organic high oleic organic safflower oil, organic coconut oil, and organic soy oil. Many use Baby's Only Organic as a sole source of nutrition before solid foods are introduced or as a source of enteral nutrition in medical situations where a complete nutritional dairy product is needed. According to the requester, a HCPCS code has not been assigned to Baby's Only Organic with DHA & ARA Toddler Formula.

Preliminary Decision:

Existing code B4158 "ENTERAL FORMULA, FOR PEDIATRICS, NUTRITIONALLY COMPLETE WITH INTACT NUTRIENTS, INCLUDES PROTEINS, FATS, CARBOHYDRATES, VITAMINS AND MINERALS, MAY INCLUDE FIBER AND/OR IRON, ADMINISTERED THROUGH AN ENTERAL FEEDING TUBE, 100 CALORIES = 1 UNIT" together with modifier BO "ORALLY ADMINISTERED NUTRITION, NOT BY FEEDING TUBE" 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 if covered.
Pricing = 46

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item #27
May 9, 2012

Attachment# 12.054

Topic/Issue:

Request to establish a code to describe "nutritionally incomplete" enteral formulae for the special needs of those with inherited metabolic disorders, trade name: PhenylAde 60 Drink Mix. Applicant's suggested language: "Enteral formula, nutritionally incomplete amino acid formulas, for special metabolic needs for inherited disease of metabolism with intentionally reduced caloric content. May or may not include fats, carbohydrates, fiber, vitamins and minerals, administered orally or through an enteral feeding tube. 100 calories - 1 unit"

Background/Discussion:

Phenylketonuria (PKU) is a genetic metabolic disorder due to a defect in the enzyme responsible for the metabolism of the amino acid phenylalanine (PHE). The primary treatment for PKU is lifelong nutritional therapy revolving around the strict control of phenylalanine intake in conjunction with modified amino acid medical foods. PhenylAde 60 is designed to meet 80% of the total amino acid needs for an individual with PKU, allowing the remaining 20% to come from specially formulated low-protein foods or foods naturally low in protein. This formula provides a PHE free source of amino acids, complete with vitamins and minerals and low in carbohydrates and fat to: control plasma PHE levels; promote normal growth and development; and avoid iatrogenic nutritional deficiencies when balanced with a natural food source of fat and carbohydrates. It is recommended for any individual with proven PKU over one year old, but is more applicable for individuals that are old enough to consume adequate carbohydrates and fat from natural sources. The most fundamental difference between PhenylAde 60 and similar products is the high concentration of amino acids relative to the total caloric content and the concentration of carbohydrates, fat, vitamins and minerals. According to the requester, existing code B4155 "ENTERAL FORMULA, NUTRITIONALLY INCOMPLETE/MODULAR NUTRIENTS, INCLUDES SPECIFIC NUTRIENTS, CARBOHYDRATES (EG, GLUCOSE POLYMERS), PROTEINS/AMINO ACIDS (EG, GLUTAMINE, ARGININE), FAT (EG, MEDIUM CHAIN TRIGLYCERIDES) OR COMBINATION, ADMINISTERED THROUGH AN ENTERAL FEEDING TUBE, 100 CALORIES = 1 UNIT" for formulae is inadequate to describe this product because 1) it does not describe a formula that is intentionally low in calories relative to amino acid protein equivalents; and 2) since reimbursement is based on calories, the resultant reimbursement is below the cost of the formula.

Preliminary Decision:

Existing code B4157 "ENTERAL FORMULA, NUTRITIONALLY COMPLETE, FOR SPECIAL METABOLIC NEEDS FOR INHERITED DISEASE OF METABOLISM, INCLUDES PROTEINS, FATS, CARBOHYDRATES, VITAMINS AND MINERALS, MAY INCLUDE FIBER, ADMINISTERED THROUGH AN ENTERAL FEEDING TUBE, 100

CALORIES = 1 UNIT" or B4162 "ENTERAL FORMULA, FOR PEDIATRICS, SPECIAL METABOLIC NEEDS FOR INHERITED DISEASE OF METABOLISM, INCLUDES PROTEINS, FATS, CARBOHYDRATES, VITAMINS AND MINERALS, MAY INCLUDE FIBER, ADMINISTERED THROUGH AN ENTERAL FEEDING TUBE, 100 CALORIES = 1 UNIT," depending on whether it is intended for an adult or a child, adequately describes the product that is the subject of this request. Modifier BO "ORALLY ADMINISTERED NUTRITION, NOT BY FEEDING TUBE" is used together with the HCPCS code when the product is administered orally.

Medicare Payment:

The payment rules associated with the existing codes apply to these products if covered.

For B4157, Pricing = 39

For B4162, Pricing = 46

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with CMS' preliminary decision stating that codes B4157 and B4162 specify protein content, whereas PhenylAde has no intact protein. As such, these codes do not describe PhenylAde. Intact proteins are toxic to people with phenylketonuria, the intended users of this formula. The speaker also stated that the dose descriptor "100 calories = 1 unit" is inappropriate because PhenylAde satisfies amino acid protein requirements, not caloric content. The speaker reiterated the original request to establish a new code and suggested that the unit of measure be based on the amino acid content.

HCPCS Public Meeting Agenda Item #28
May 9, 2012

Attachment# 12.051

Topic/Issue:

Request to assign a nutritional shake, trade name: Orgain, to existing code B4150.

Background/Discussion:

According to the requester, Orgain is a ready-to-drink, nutrient dense nutritional shake for cancer patients. It is intended to provide complete balanced nutrition through nutrient dense calories, and includes protein, carbohydrate, fat, vitamins and minerals. Each shake provides 255 calories, 16 grams of protein, 30 grams of carbohydrates, 7 grams of fat and 24 vitamins and minerals. It offers complete nutrition for patients that do not have an appetite to maintain a healthy body weight. This product is used orally and is made at an FDA approved facility. Each unit is 11 ounces. According to the requester, Orgain is similar to Ensure and Boost, except Orgain is certified organic and has a higher protein content. It is available by prescription.

Preliminary Decision:

Existing code B4150 "ENTERAL FORMULA, NUTRITIONALLY COMPLETE WITH INTACT NUTRIENTS, INCLUDES PROTEINGS, FATS, CARBOHYDRATES, VITAMINS AND MINERALS, MAY INCLUDE FIBER, ADMINISTERED THROUGH AND ENTERAL FEEDING TUBE, 100 CALORIES = 1 UNIT" together with modifier BO "ORALLY ADMINISTERED NUTRITION, NOT BY FEEDING TUBE" 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 if covered.
Pricing = 39

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

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, has an expected life of at least 3 years 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 IOLs inserted in a physician's office. 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 36^{th} 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.