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

Supplies and Other

Wednesday, May 28, 2014

Introduction and Overview

Approximately 60 people attended. The agenda included 19 items.

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

Joel Kaiser the Director of the Division of Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Policy, presented an overview of the methods used for setting the payment amount for DME, prosthetics, orthotics and supplies and when the different payment categories are used. The overview was also provided as a written document to the agenda and is attached to this summary. For additional information, the DME payment rules are located at Section 1834 (a) of the Social Security Act. The Medicare fee schedule for DME, Prosthetics, Orthotics and Supplies, and background information, can be accessed and downloaded free of charge at: http:www.cms.gov/DMEPOSFeeSched/.

Prior to the Public Meetings, over the course of several months, the CMS HCPCS Coding Workgroup convene, discuss, and establish preliminary coding recommendations, on all HCPCS code applications. CMS also assigns preliminary recommendations regarding the applicable Medicare payment category and methodology that will be used to set a payment amount for the items on the agenda. The preliminary coding and payment recommendations are posted on the CMS HCPCS web site at http://www.cms.gov/MedHCPCSGenInfo/08_HCPCSPublicMeetings.asp#TopOfPage, as part of the HCPCS public meeting agendas.

Information provided at the CMS HCPCS Public Meetings is considered by the CMS HCPCS Coding Workgroup at a subsequent workgroup meeting. The Workgroup reconvenes after the public meetings and reconsiders its preliminary coding recommendation in light of any new information provided, and formulates its final coding decisions. CMS maintains the permanent HCPCS Level II codes, and reserves final decision making authority concerning requests for permanent HCPCS codes. Final decisions regarding Medicare payment are made by CMS and must comply with the Statute and Regulations. Payment determinations for non-Medicare insurers, (e.g., state Medicaid Agencies or Private Insurers) are made by the individual state or insurer.

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

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

Centers for Medicare & Medicaid Services (CMS) Healthcare Common Procedure Coding System (HCPCS) Public Meeting Agenda for Supplies and "Other"
Wednesday, May 28, 2014, 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# 14.060
Request to establish a new Level II HCPCS code to identify a medical food indicated for patients with endothelial dysfunction and/or hyperhomocysteinemia, L-methylfolate, trade name: METANX. Applicant's suggested language:
AXXXX L-Methylfolate, Methylcobalamin, Pyrdoxal-5'-Phosphate, and Algal Oil, Per Capsule.

Attachment# 14.061
Request to establish a new Level II HCPCS code to identify a medical food indicated for the clinical dietary management of the metabolic imbalances associated with depression and schizophrenia, L-methylfolate calcium, trade name: Deplin. Applicant's suggested language:
AXXXX L-Methylfolate Calcium Algae-S Powder (Schizochytrium), Per Capsule.

Attachment# 14.062
Request to establish a new Level II HCPCS code to identify CerefolinNAC caplets, a medical food indicated for the clinical dietary management of metabolic imbalances associated with cognitive impairment (L-methylfolate), calcium, methylcobalamin, N-Acety1-L-Cysteine), trade name: CerefolinNAC®.

Primary Speaker: Marc Fluitt of Nestlé Health Science - Pamlab, Inc

AGENDA ITEM #2
Attachment# 14.059
Request to establish a new Level II HCPCS code to identify a nutritional shake for medical malnutrition that can be taken orally and via enteral tube, trade name: ENU.

No Primary Speaker

AGENDA ITEM #3
Attachment# 14.063
Request to establish 4 new Level II HCPCS codes to identify ostomy pouches that have pre-attached a standard wear hydrocolloid barrier with a waterproof foam pad cushion collar. Applicant's suggested language:

AXXX1 Pouch, Drainable, One-Piece, With Built In Convexity, Pre-Attached Standard Wear Hydrocolloid Barrier, Foam Pad Collar

AXXX2 Pouch, Urostomy, One-Piece, With Built In Convexity, Pre-Attached Standard Wear Hydrocolloid Barrier, Foam Pad Collar

AXXX3 Pouch, Drainable, One-Piece, Without Convexity, Pre-Attached Standard Wear Hydrocolloid Barrier, Foam Pad Collar

AXXX4 Pouch, Urostomy, One-Piece, Without Convexity, Pre-Attached Standard Wear Hydrocolloid Barrier, Foam Pad Collar

Attachment# 14.064
Request to split existing code A4396 "Ostomy Belt With Peristomal Hernia Support" into 3 codes based on varying belt width, by revising the text of code A4396 and establishing 2 new level II HCPCS codes, trade names: Nu-Hope Original Flat Panel Nu-Support Belt, and Nu-Hope Nu-Form Support Belts. Applicant's suggested language:

Revise existing code A4396 to read: Ostomy Belt With Peristomal Hernia Support, Width 3",4"

AXXX1 Hernia Support Belt With Or Without An Ostomy, Width 5",6",7"

AXXX2 Hernia Support Belt With or Without An Ostomy, Width 8"and Wider

Attachment# 14.065
Request to establish 4 new level II HCPCS codes to identify ostomy pouches with an extended wear barrier with foam cushion and hydrocolloid collar, trade names: Nu-Hope Nu-Comfort™ "43" Series (the hydrophilic extended wear barrier); Nu-Hope Nu-Comfort™ "46" Series (the hydrophilic extended wear barrier); and Nu-Hope Nu-Comfort™ "48" Series (the hydrophilic extended wear barrier). Applicant's suggested language:

AXXX1 Pouch, Drainable, One-Piece, With Built In Convexity, Extended Wear Barrier, Foam Pad With Hydrocolloid Collar

AXXX2 Pouch, Urostomy, One-Piece, With Built In Convexity, Extended Wear Barrier, Foam Pad With Hydrocolloid Collar

AXXX3 Pouch, Drainable, One-Piece, Without Convexity, Extended Wear Barrier, Foam Pad With Hydrocolloid Collar

AXXX4 Pouch, Urostomy, One-Piece, Without Convexity, Extended Wear Barrier, Foam Pad With Hydrocolloid Collar

Primary Speaker: Estelle Galindo of Nu-Hope Laboratories, Inc.

AGENDA ITEM #4
Attachment# 14.072
Request to establish 3 new Level II HCPCS codes to identify ostomy skin barrier system, trade name: Ostomy Vac. Applicant's suggested language:
AXXX1 Ostomy Vac Complete Kit

AXXX2 Ostomy Vac Reorder Kit

AXXX3 Ostomy Vac 30-Day Supply Kit

Primary Speaker: Ed Bourke of Osto Innovations

AGENDA ITEM #5
Attachment# 14.068
Request to make a coding distinction between hydrophilic coated and non-coated intermittent catheters, by revising existing codes A4351, A4352 and A4353 to remove references to coating; and establishing 3 new Level II HCPCS codes to specifically identify coated intermittent catheters, trade name: SpeediCath®. Applicant's suggested language:

A4351 Intermittent Urinary Catheter; Straight Tip, ~~With Or~~ Without Coating (Teflon, Silicone, Silicone Elastomer, ~~Or Hydrophilic,~~ etc.), Each

A4352 Intermittent Urinary Catheter; Coude Tip, ~~With Or~~ Without Coating (Teflon, Silicone, Silicone Elastomer, ~~Or Hydrophilic,~~ etc.), Each

A4353 Intermittent Urinary Catheter (Conventional Uncoated) With Insertion Supplies

AXXX1 Hydrophilic-Coated Urinary Catheter; Straight Tip, In Sterile Lubricating Coating, Each

AXXX2 Hydrophilic-Coated Urinary Catheter; Coude Tip, In Sterile Lubricating Coating, Each

AXXX3 Hydrophilic-Coated Urinary Catheter With Insertion Supplies

Primary Speaker: Daniel Graves, Ph.D., of University of Louisville College of Medicine

AGENDA ITEM #6
Attachment# 14.098
Request to establish 2 new level II HCPCS codes to identify a gastrointestinal tube and accessories, trade name: Peristeen Transanal Irrigation System (TAI). Applicant's suggested language:

XXXX1 Transanal Irrigation (TAI) System; and

XXXX2 Tansanal Irrigation (TAI) Catheter Kit

Primary Speaker: Dr. Steven Kirshblum of Kessler Institute for Rehabilitation

AGENDA ITEM #7
Attachment# 14.073
Request to establish new Level II HCPCS code to identify a stoma noise suppression device, trade name: Stoma Stifler.

Primary Speaker: Mark Bain of BEAMM LLC

AGENDA ITEM #8
Attachment# 14.103
Request to establish a new level II HCPCS code to identify an accessory used for jaw (mandibular) stabilization during Positive Airway Pressure (PAP) therapy, trade name: TAP PAP Nasal Pillow Mask Lower Mouthpiece. Applicant's suggested language: Mouthpiece Used With Positive Airway Pressure Device, Each.

No Primary Speaker

AGENDA ITEM #9
Attachment# 14.099
Request to establish two new level II HCPCS codes: one to identify a hyperbaric oxygen Wound Treatment System (WTS) for extremities; and another to identify caregiver's time and disposable supplies used in performing a Vaporous Hyperoxia Therapy (VHT) treatment in a hospital, clinic or home, trade name: 02Misly.

No Primary Speaker

AGENDA ITEM #10
Attachment# 14.066
Request to establish 2 new level II HCPCS codes: one to identify a handheld, programmable, lockable, tamper evident pill dispenser; and another to identify a medication refill pack, trade name: PillGuard™ Dispensing System.

No Primary Speaker

AGENDA ITEM #11
Attachment# 14.067
Request to establish a new Level II HCPCS code to identify ready to wear wet wrap therapy garments, trade name: Wrap-E-Soothe.

Primary Speaker: Anne McVey of AD RescueWear

AGENDA ITEM #12
Attachment# 14.071
Second request to establish new Level II HCPCS code to identify a palm-sized, battery operated vibrating device with a removable small ice-pack, trade name: Buzzy.

Primary Speaker: Dr. Amy Baxter of Medical College of Georgia/Georgia Regents University

AGENDA ITEM #13
Attachment# 14.074
Request to establish new level II HCPCS code to identify disposable trays used with a powered bone marrow biopsy system, trade name: OnControl®. Applicant's suggested language: Powered Bone Marrow Biopsy Kit.

Primary Speaker: Jeff Voigt of Medical Device Consultants of Ridgewood

AGENDA ITEM #14
Attachment# 14.082
Request to establish a new level II HCPCS code to identify an auricular point stimulation (Electro-Acupuncture Stimulator) device, trade name: P-STIM.

Primary Speaker: Srini Nageshwar of DyAnsys, Inc.

AGENDA ITEM #15
Attachment# 14.091
Second request to establish two new level II HCPCS codes to identify a mobile eye tracking device and associated hardware and software, trade name: Tobii Eyemobile and Eyemobile with PCEye Go. Applicant's suggested language:
EXXX1 Eye Tracking Device And Mounting Bracket Permitting Manipulation And Control Of A Computer
EXXX2 Eye Tracking Device, Mounting Bracket And Windows 8 Tablet

Attachment# 14.092
Second request to establish two new level II HCPCS codes to identify eye tracking and speech generating devices that are controlled through gaze interaction via an eye tracker, trade names: Tobii I-12 and I-15. Applicant's suggested language:
EXXX1 Eye Tracking Device With A Speech Generating Device And 12 Inch Screen
EXXX2 Eye Tracking Device With A Speech Generating Device And 15 Inch Screen

No Primary Speaker

AGENDA ITEM #16
Attachment# 14.100
Request to establish a new level II HCPCS code to identify a portable pneumatic long axis hip traction device for independent home use, trade name: HipTrac. Applicant's suggested language:
EXXXX Hip Joint Traction Equipment

Primary Speaker: Paul Kim of OBER/KALER

AGENDA ITEM #17
Attachment# 14.101
Request to establish two new level II HCPCS code to identify a wearable plantar pressure monitoring system, trade name: SurroSense RX. Applicant's suggested language:
AXXXX Plantar Pressure Inserts, Per Pair Of Inserts
EXXXX Plantar Pressure Monitoring System, Includes All Components

Primary Speaker: Dr. Lawrence A. Lavery of University of Texas Southwestern Medical Center

AGENDA ITEM #18
Attachment# 14.070
Fourth request to establish new Level II HCPCS code to identify a custom-fabricated foot orthosis for use by diabetic patients at high risk for plantar ulcers, trade name: TruContour. Applicant's suggested language: "For Diabetics Patients At High Risk For Plantar Ulcer Only, Multiple Density Orthosis, Custom Designed By Combining The Digital Three-Dimensional Shape Of Patient's Foot With Offloading Modification(s) Placed Relative To Identified Pressure Contours Measured During Walking From Dynamic Plantar Pressure Distribution Of Patient's Foot, Custom Fabricated, Each".

Primary Speaker: Dr. Peter Cavanagh of University of Washington Medical Center

AGENDA ITEM #19
Attachment# 14.069
Request to establish 2-5 new Level II HCPCS codes to identify viscoelastic bandages for upper and lower extremities (including wrists and ankles); and the cranial area, trade name: SportsBands. The applicant suggests that the products be described as Vibration and Shock Dampening Devices.

Primary Speaker: Charles Harris of SPORTSBAND, Inc.

HCPCS Public Meeting Agenda Item #1

May 28, 2014

Attachment# 14.060

Topic/Issue:

Request to establish a new Level II HCPCS code to identify a medical food indicated for patients with endothelial dysfunction and/or hyperhomocysteinemia, L-methylfolate, trade name: METANX. Applicant's suggested language:

AXXXX L-Methylfolate, Methylcobalamin, Pyrdoxal-5'-Phosphate, and Algal Oil, Per Capsule.

Background/Discussion:

According to the requester Metanx is a medical food dispensed by prescription under medical supervision and direction. It is indicated for the clinical dietary management of the metabolic imbalances associated with diabetic peripheral neuropathy and distinct nutritional requirements of patients who present with loss of protective sensation and neuropathic pain. Metanx increases nitric oxide (NO) and lowers homosysteine (Hcy), both of which are associated with improved vascular function and increased rates of wound healing. The usual adult dose may be taken as one capsule twice daily (1 capsule B.I.D); or two capsules once daily (2 capsule QD); or as directed under medical supervision. Metanx is supplied in a bottle of 90 capsules for oral use. Each Metanx capsule contains 3 mg of L-Methylfolate calcium, 90.314 mg of algae-s powder (schizochytrium), 35 mg of pyridoxal-5'-phosphate, and 2.0 mg of methlycobalamin.

Preliminary Decision:

Existing code A9153, Multiple vitamins, with or without minerals and trace elements, oral, per dose, not otherwise specified, adequately describes the product that is 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 applicant offered a brief comment at the public meeting agreeing with CMS' preliminary decision.

HCPCS Public Meeting Agenda Item #1

May 28, 2014

Attachment# 14.061

Topic/Issue:

Request to establish a new Level II HCPCS code to identify a medical food indicated for the clinical dietary management of the metabolic imbalances associated with depression and schizophrenia, L-methylfolate calcium, trade name: Deplin. Applicant's suggested language:

AXXXX L-Methylfolate Calcium Algae-S Powder (Schizochytrium), Per Capsule.

Background/Discussion:

According to the requester Deplin 7.5 and Deplin 15 capsules are medical foods dispensed by prescription under medical supervision and direction, and indicated for the clinical dietary management of the metabolic imbalances associated with depression and schizophrenia. Deplin is indicated for the distinct nutritional requirements of individuals who have suboptimal L-methlyfolate levels in the cerebrospinal fluid, plasma, and/or red blood cells and have major depressive disorder (MDD) with particular emphasis as adjunctive support for individuals who are on an antidepressant. Deplin is also indicated for the distinct nutritional requirements of individuals who have or are at risk for hyperhomocysteinemia and have schizophrenia who present with negative symptoms and/or cognitive impairment, with particular emphasis as an adjunctive support for individuals who have stabilized on antipsychotics. Each Deplin 7.5 capsule contains 7.5 mg of L-methylfolate calcium and 90.134 mg algae-S powder (schizochytrium). Each Deplin 15 capsule contains 15 mg of L-methylfolate calcium and 90.314 mg alfae- S-powder. The usual adult dose is one or two Deplin 7.5 capsule (s) given daily with or without food or as directed under medical supervision.

Preliminary Decision:

Existing code A9153, Multiple vitamins, with or without minerals and trace elements, oral, per dose, not otherwise specified, adequately describes the product that is 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 applicant offered a brief comment at the public meeting agreeing with CMS' preliminary decision.

HCPCS Public Meeting Agenda Item #1

May 28, 2014

Attachment# 14.062

Topic/Issue:

Request to establish a new Level II HCPCS code to identify CerefolinNAC caplets, a medical food indicated for the clinical dietary management of metabolic imbalances associated with cognitive impairment (L-methylfolate), calcium, methylcobalamin, N-Acety1-L-Cysteine), trade name: CerefolinNAC®.

Background/Discussion:

According to the requester CerefolinNAC is a medical food dispensed by prescription under medical supervision and direction and is indicated for the clinical dietary management of the metabolic imbalances associated with mild or moderate cognitive impairment that present with an increased risk for neurovascular oxidative stress and/or hyperhomocysteinemia; and/or suboptimal L-methylfolate and/or vitamin B12 levels in the cerebrospinal fluid, and/or red blood cells. CerefolinNAC is supplied in a bottle of 90 caplets for oral use. Each CerefolinNAC Caplet contains 6mg of L-methylfolate calcium and 90.314 mg of algae S-powder (schizochytrium), 2 mg of methylcobalamin, and 600 mg of N-Acetyl-Cysteine. The usual adult dosage is one caplet daily.

Preliminary Decision:

Existing code A9153, Multiple vitamins, with or without minerals and trace elements, oral, per dose, not otherwise specified, 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:

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

HCPCS Public Meeting Agenda Item #2

May 28, 2014

Attachment# 14.059

Topic/Issue:

Request to establish a new Level II HCPCS code to identify a nutritional shake for medical malnutrition that can be taken orally and via enteral tube, trade name: ENU.

Background/Discussion:

According to the requester Answer-No, ENU is a novel, well balanced macro-nutrient beverage comprised of highly bioavailable whey protein isolates, complex carbs (quinoa, brown rice, and tapioca) and healthy fats (coconut oil) making it different than other products in the functional beverage category. ENU is designed for beneficiaries with high caloric & protein needs associated with medical malnutrition (i.e. beneficiaries undergoing cancer treatment, Celiac's disease, sarcopenia, etc.). While ENU has no official "indications for use" as a drug or biologic would, its intended use is as an enteral nutrition food for supplemental nutrition needs for beneficiaries requiring nutrition support who require feeding assistance through an enteral feeding system/process. ENU is supplies as a pre-mixed ready-to-drink shake in 330mL (11 oz.) individual Tetra Pak containers that are aseptically sealed in the manufacturing process for extended shelf life

Preliminary Decision:

Existing code B4152, Enteral formula, nutritionally complete, calorically dense (equal to or greater than 1.5 kcal/ml) with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit, adequately describes the subject of this request. Use BO modifier if taken orally.

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.

HCPCS Public Meeting Agenda Item #3

May 28, 2014

Attachment# 14.063
Topic/Issue:

Request to establish 4 new Level II HCPCS codes to identify ostomy pouches that have pre-attached a standard wear hydrocolloid barrier with a waterproof foam pad cushion collar. Applicant's suggested language:

AXXX1 Pouch, Drainable, One-Piece, With Built In Convexity, Pre-Attached Standard Wear Hydrocolloid Barrier, Foam Pad Collar

AXXX2 Pouch, Urostomy, One-Piece, With Built In Convexity, Pre-Attached Standard Wear Hydrocolloid Barrier, Foam Pad Collar

AXXX3 Pouch, Drainable, One-Piece, Without Convexity, Pre-Attached Standard Wear Hydrocolloid Barrier, Foam Pad Collar

AXXX4 Pouch, Urostomy, One-Piece, Without Convexity, Pre-Attached Standard Wear Hydrocolloid Barrier, Foam Pad Collar

Background/Discussion:

According to the requester, the Nu-Hope "Nu Comfort" pouching system provides a hydrocolloid barrier directly adjacent to the stoma to protect the peristomal skin from the caustic effluent. The wet tack of the hydrocolloid allows it to stick to irritated skin, to promote healing and absorb moisture. The barrier is attached to a foam cushion pad that is coated with a waterproof adhesive. The foam is flexible, moves with the skin and cushions for comfort. The foam pad extends beyond the hydrocolliod barrier creating a waterproof adhesive collar that can eliminate the need to "picture frame" with tape. The requester comments that the Nu Comfort system is different from barriers included in existing codes A4388; A4390; A4391 and A4393 in that the Nu Comfort foam pads provide a waterproof seal, whereas the tape collar used in other products is not waterproof. In addition, the Nu Comfort appliances can be bent to conform to the wear's body contours, creases and/or skin folds, whereas the plastic injection molded supports used in other appliances are more rigid and do not conform. The requester claims that use of the Nu Comfort appliances with the waterproof foam pad cushion collar confer a significant therapeutic distinction in that they prevent seepage of ostomy output and leakage; and as such, new codes are warranted.

Preliminary Decision:

Existing code A4388, Ostomy pouch, drainable, with extended wear barrier attached, (1 piece), each; A4390, Ostomy pouch, drainable, with extended wear barrier attached, with built-in convexity (1 piece), each; A4391, Ostomy pouch, urinary, with extended wear barrier attached (1 piece), each, or A4393, Ostomy pouch, urinary, with extended wear barrier attached, with built-in convexity (1 piece), each; depending on product attributes and use, adequately describes the product that is subject of this request.

Medicare Payment:

The payment rules associated with the existing codes apply to these products if covered.
Pricing = 37

Summary of Primary Speaker Comments at the Public Meeting:

The applicant disagreed with CMS' preliminary decision not to establish HCPCS codes, stating that the current code does not account for the "additional hydrocolloid". The speaker stated that the pre-attached barrier minimizes the need for the wearer to have separately purchase and add another hydrocolloid to the pouch. According to the speaker, A4396 code adequately covers the prevention and management of the small hernia(s) with or without an ostomy. Large hernias require large supports with options for additional support. The applicant would like the workgroup to consider instead of the requested 4 new codes for pouching requests; the use of the current extended wear code plus the addition of another hydrocolloid code to capture (and reimburse) "additional" hydrocolloid..

HCPCS Public Meeting Agenda Item #3

May 28, 2014

Attachment# 14.064

Topic/Issue:

Request to split existing code A4396 "Ostomy Belt With Peristomal Hernia Support" into 3 codes based on varying belt width, by revising the text of code A4396 and establishing 2 new level II HCPCS codes, trade names: Nu-Hope Original Flat Panel Nu-Support Belt, and Nu-Hope Nu-Form Support Belts. Applicant's suggested language:

Revise existing code A4396 to read: Ostomy Belt With Peristomal Hernia Support, *Width 3",4"*

AXXX1 Hernia Support Belt With Or Without An Ostomy, *Width 5",6",7"*

AXXX2 Hernia Support Belt With or Without An Ostomy, *Width 8"and Wider*

Background/Discussion:

According to the requester the Nu-Hope hernia support belts are primarily used to provide support to help maintain the hernia(s) in a reduced state to minimize the hernia from enlarging and for comfort to those patients with either peristomal and/or abdominal hernia(s). The belts help to decrease the hernia protrusion by an ostomy, stabilizing the peristomal plan and thus assisting in maintaining the pouching system seal. The Nu-Hope Hernia Support Belts come in a variety of girths and widths to accommodate the physical characteristics of the patient and the hernia size. The requester comments that existing codes do not address larger belts, which give therapeutic support to impaired abdominal muscle wall defect(s), and prevent the intestines from bulging through the defect(s).

Preliminary Decision:

Existing code A4396, Ostomy belt with peristomal hernia support, adequately describes the belts that are the subject of this request, in all widths.

Medicare Payment:

The payment rules associated with the existing code apply to this product if covered.
Pricing = 37

Summary of Primary Speaker Comments at the Public Meeting:

The applicant disagreed with CMS' preliminary decision not to establish additional HCPCS codes. According to the applicant, code A4396 adequately "covers" the prevention and management of the small hernia(s) with or without an ostomy. Large hernias require larger supports with options for additional support. The applicant suggested that lack of new, unique codes for larger supports limits their availability; and that these belts might otherwise be inappropriately billed as orthotics.

HCPCS Public Meeting Agenda Item #3

May 28, 2014

Attachment# 14.065

Topic/Issue:

Request to establish 4 new level II HCPCS codes to identify ostomy pouches with an extended wear barrier with foam cushion and hydrocolloid collar, trade names: Nu-Hope Nu-Comfort™ "43" Series (the hydrophilic extended wear barrier); Nu-Hope Nu-Comfort™ "46" Series (the hydrophilic extended wear barrier); and Nu-Hope Nu-Comfort™ "48" Series (the hydrophilic extended wear barrier). Applicant's suggested language:

AXXX1 Pouch, Drainable, One-Piece, With Built In Convexity, Extended Wear Barrier, Foam Pad With Hydrocolloid Collar

AXXX2 Pouch, Urostomy, One-Piece, With Built In Convexity, Extended Wear Barrier, Foam Pad With Hydrocolloid Collar

AXXX3 Pouch, Drainable, One-Piece, Without Convexity, Extended Wear Barrier, Foam Pad With Hydrocolloid Collar

AXXX4 Pouch, Urostomy, One-Piece, Without Convexity, Extended Wear Barrier, Foam Pad With Hydrocolloid Collar

Background/Discussion:

According to the requester, the Nu-Hope Comfort pouching system provides a hydrocolloid barrier directly adjacent to the stoma to protect the peristomal skin from the caustic effluent. The Nu-Hope Comfort comes with different hydrocolloid barriers to accommodate the needs of the wearer. The type of barrier used depends on the type and quantity of the effluent output. The skin condition and amount of tack required to obtain an appropriate seal is also considered. The requester states that existing codes A4388, A4390, A4391 and A4393 do not address the foam pad (currently coded as an extended wear barrier) with the pre-attached extended wear hydrocolloid barrier seal disc. The foam pad cushions and flexes with the wearer and provides a waterproof foam collar seal; whereas products categorized at A4388, A4390, A4391 and A4393 have a tape collar which is not waterproof.

Preliminary Decision:

Existing code A4388, Ostomy pouch, drainable, with extended wear barrier attached, (1 piece), each; A4390, Ostomy pouch, drainable, with extended wear barrier attached, with built-in convexity (1 piece), each; A4391, Ostomy pouch, urinary, with extended wear barrier attached (1 piece), each; or A4393, Ostomy pouch, urinary, with extended wear barrier attached, with built-in convexity (1 piece), each, depending on product attributes, adequately describes the product is the subject of this request.

Medicare Payment:

The payment rules associated with the existing codes apply to these products if covered.
Pricing = 37

Summary of Primary Speaker Comments at the Public Meeting:

The applicant disagreed with CMS' preliminary decision not to establish 4 HCPCS codes. According to the speaker the current code does not account for the additional hydrocolloid. The applicant asked CMS to consider permitting the use of the current extended wear code with the addition of a hydrocolloid code to capture (and reimburse) "additional" hydrocolloid.

HCPCS Public Meeting Agenda Item #4

May 28, 2014

Attachment# 14.072

Topic/Issue:

Request to establish 3 new Level II HCPCS codes to identify ostomy skin barrier system, trade name: Ostomy Vac. Applicant's suggested language:

AXXX1 Ostomy Vac Complete Kit

AXXX2 Ostomy Vac Reorder Kit

AXXX3 Ostomy Vac 30-Day Supply Kit

Background/Discussion:

According to the requester, the Ostomy Vac is a durable, reusable vacuum system used to enhance the adhesive bond that secures ostomy pouches to the body. The system is comprised of a soft, medical grade silicone skin barrier flange that adheres to the abdomen and conforms to the stoma perimeter; and a fully automated vacuum pump called the Ovac. The Ovac includes a micro vacuum pump, controls, and battery. The flange and the Ovac are connected using medical grade tubing. The Ovac draws down vacuum level until a target value is achieved, making a solid seal around the peristomal skin. The requester comments that the use of a vacuum system improves the performance of the adhesive and allows for a smaller device having significantly less adhesive in contact with the skin. The Ostomy Vac system is indicated for persons with a colostomy, ileostomy or urostomy. It remains in constant use, with 2 alternatives for showering/bathing: 1) a 6' tether; or 2) a water-tight "dry box" to hold the Ovac. The Ostomy Vac is supplied as a Complete Kit; a Reorder Kit; and a 30-Day Supply Kit (used with either the complete or the reorder kit). The initial issue complete kit includes 2 skin barrier flanges; 2 vacuum pumps; 4 3.6V LIR 2450 batteries; 1 battery charger; 1 6' tether; 2 liquid separators and 2 ostomy belts, (all under a 1-year warranty), plus additional items covered under a 2-year warranty, including 1 syringe; 1 cotton membrane applicator tool; 1 battery removal tool and 1 dry box. All the above items that have a 1-year warranty comprise the Reorder Kit. The 30-Day Supply Kit includes 20 disposable cotton membranes and 20 disposable adhesive discs.

Preliminary Decision:

A national program operating need was not identified by Medicare, Medicaid, or the private insurance sector to establish a code to identify this device.

Medicare Payment:

Payment will be based on the carrier's determination regarding which coverage and payment rules are applicable.

Summary of Primary Speaker Comments at the Public Meeting:

The applicant disagreed with CMS' preliminary decision not to establish 3 new codes to identify the Ostomy Vac skin barrier system. According to the speaker, the current HCPCS codes that pertain to ostomy skin barriers do not accurately describe the new Ostomy Vac. The speaker stated vacuum pumps and membranes are not used with any other skin barrier products, making these components unique to OstomyVac, which warrants the issuance of separate codes.

HCPCS Public Meeting Agenda Item #5

May 28, 2014

Attachment# 14.068

Topic/Issue:

Request to make a coding distinction between hydrophilic coated and non-coated intermittent catheters, by revising existing codes A4351, A4352 and A4353 to remove references to coating; and establishing 3 new Level II HCPCS codes to specifically identify coated intermittent catheters, trade name: SpeediCath®. Applicant's suggested language:

A4351 Intermittent Urinary Catheter; Straight Tip, ~~With Or~~ Without Coating (Teflon, Silicone, Silicone Elastomer, ~~Or Hydrophilic,~~ etc.), Each

A4352 Intermittent Urinary Catheter; Coude Tip, ~~With Or~~ Without Coating (Teflon, Silicone, Silicone Elastomer, ~~Or Hydrophilic,~~ etc.), Each

A4353 Intermittent Urinary Catheter (Conventional Uncoated) With Insertion Supplies

AXXX1 Hydrophilic-Coated Urinary Catheter; Straight Tip, In Sterile Lubricating Coating, Each

AXXX2 Hydrophilic-Coated Urinary Catheter; Coude Tip, In Sterile Lubricating Coating, Each

AXXX3 Hydrophilic-Coated Urinary Catheter With Insertion Supplies

Background/Discussion:

According to the requester SpeediCath is a technologically advanced, ready-to-use hydrophilic-coated intermittent urinary catheter(IC), pre-packaged in a sterile saline solution. Unlike conventional uncoated catheters, SpeediCath eliminates the need for additional lubricants, while providing a near friction-free insertion and withdrawal. It is made of a layer of polymer, bound evenly to the catheter surface, consisting of Polyvinlpyrrolidone (PVP), salt and Polyurethane (PU). The process of fully bonding the PVP to the catheter ensures there is no irregularity, and thus the coating cannot migrate or slough off from the catheter during insertion or withdrawal. The requester claims that the SpeediCath design improves patient's lifelong clinical outcomes by reducing Urinary Tract Infection (UTI) complications and promoting a better quality of life and IC regimen compliance. While virtually all catheter users would benefit from use of SpeediCath catheters; a specific subset of patients, such as those with Spina Bifida and Spinal Cord Injury, truly require SpeediCath, because of their life-long medical reliance on catheters. Distinct codes are necessary in order to ensure unfettered access to SpeediCath when medically indicated.

Preliminary Decision:

Existing codes A4351, Intermittent urinary catheter; straight tip, with or without coating (teflon, silicone, silicone elastomer, or hydrophilic, etc.), each and A4352, Intermittent urinary catheter; coude (curved) tip, with or without coating (teflon, silicone, silicone elastomeric, or hydrophilic, etc.), each; (depending on whether straight or coude tip), adequately describes products that are the the subject of this request.

Medicare Payment:

The payment rules associated with the existing codes apply to these products if covered.
Pricing = 37

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with CMS' preliminary decision not to establish 3 new HCPCS codes and revise 3 existing codes, to distinguish intermittent urinary catheters made with hydrophilic materials from those that are not. The speaker provided commentary that existing codes A4351, A4352 and A4353 do not adequately describe hydrophilic-coated catheters; and that strong new evidence has been published demonstrating medical benefits and proven reduction of urinary tract infections with the use of hydrophilic-coated catheters. According to the speaker, hydrophilic-coated catheter technology conveys significantly improved medical outcomes for users.
-significantly delayed the onset of first urinary tract infection
-reduced the odds of getting a urinary tract infection
-reduced the incidence of hospital acquired urinary tract infections by 21%
-reduced the daily risk of developing the first urinary tract infection by 33%
-reduced the odds of hematuria
Many State Medicaid and private insurance agencies recognize the benefits of hydrophilic-coated catheters and have developed a coding "work around".

HCPCS Public Meeting Agenda Item #6

May 28, 2014

Attachment# 14.098

Topic/Issue:

Request to establish 2 new level II HCPCS codes to identify a gastrointestinal tube and accessories, trade name: Peristeen Transanal Irrigation System (TAI). Applicant's suggested language:

XXXX1 Transanal Irrigation (TAI) System; and

XXXX2 Tansanal Irrigation (TAI) Catheter Kit

Background/Discussion:

According to the requester, Peristeen is an innovative portable Transanal Irrigation System (TAI) developed for outpatient use for Neurogenic Bowel Dysfunction (NBD), who are able to be seated for the treatment, to prevent fecal incontinence and chronic severe constipation. Portable Peristeen uses a hydrophilic-coated balloon catheter, control unit and manual squeeze bulb pump to provide minimally-invasive TAI of lukewarm water to the distal colon, effectively controlling the evacuation of feces from the bowel. Peristeen is a portable system, designed to be carried out independently by the user or with the assistance of a caregiver, at home or away. The TAI system includes a manual control unit with squeeze-bulb pump; 2 plastic tubes with connectors; a screw-on lid with flip top and suction tubes; 1 water bag; 2 straps; and 1 storage case. The TAI Catheter Kit includes 15 hydrophilic coated rectal balloon catheters; and 1 water bag.

One tube connects the water bag to the rectal catheter; the other connects the air pump to the balloon. The lid keeps water in the bag. The suction tube draws water from the bag into the tubing. The straps hold the control unit and tubes to the user's leg. The storage case holds all system components and makes it portable. The Peristeen system differs from other enema-like or pulsed irrigation systems in that it is portable; intended for self-administration; and is designed to be used with the patient sitting upright, as opposed to lying in bed. The requester comments that the Peristeen system provides a more complete cleansing of the distal colon, and as such, fewer accidents can be expected and treatments may be needed less often. The requester comments that no existing codes describe the Peristeen TAI system; and the reimbursement process is unpredictable due to the lack of a HCPCS code, policy or fee schedule.

Preliminary Decision:

Existing code A4458 "Enema bag with tubing, reusable" adequately describes the product tht 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:

The primary speaker disagreed with CMS' preliminary decision not to establish a new unique HCPCS code for this enema system. According to the speaker, Peristeen is a treatment option when conventional methods (such as Enema's with tubing) have failed. Enema devices coded at A4458 typically do not benefit patients with neurological disease; neurogenic bowel dysfunction (NBD); and those with impaired or complete loss of sphincter control. The speaker reiterated the original request to establish two new HCPCS codes.

HCPCS Public Meeting Agenda Item #7

May 28, 2014

Attachment# 14.073

Topic/Issue:

Request to establish new Level II HCPCS code to identify a stoma noise suppression device, trade name: Stoma Stifler.

Background/Discussion:

According to the requester, the Stoma Stifler is a "non-disposable" stoma noise suppressor and guard for ostomates. It consists of a flexible and dense polyurethane foam cup which connects to the torso with a magnet on a rectangular anchor plate. The Stoma Stifler suppresses embarrassing and inadvertent stoma noise, thus increasing confidence allowing the ostomates to resume full productivity of daily routine. The product acts as a replacement or aesthetic prosthetic for the sphincter and also protects the stoma from impact.

Preliminary Decision:

A national program operating need was not identified by Medicare, Medicaid, or the private insurance sector to establish a code to identify this device.

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 not to establish a new HCPCS code to identify the Stoma Stifler. The speaker stated that this device replaces part of the function of the anal sphincter, giving the ostomate backhis/her original ability to manage flatus without compromising stool flow. According to the speaker, the Stoma Sifler meets the Medicare statutory requirement of "reasonable and necessary for the diagnosis or treatment of illness or injury, or to improve the functioning of a malformed body member". The speaker commented that the Stoma Stifler meets the Medicare definition of a prosthetic device and warrants "Medicare differentiation" through the creation of a new HCPCS code.

HCPCS Public Meeting Agenda Item #8

May 28, 2014

Attachment# 14.103
Topic/Issue:

Request to establish a new level II HCPCS code to identify an accessory used for jaw (mandibular) stabilization during Positive Airway Pressure (PAP) therapy, trade name: TAP PAP Nasal Pillow Mask Lower Mouthpiece. Applicant's suggested language: Mouthpiece Used With Positive Airway Pressure Device, Each.

Background/Discussion:

According to the requester the TAP PAP Nasal Pillow lower mouthpiece is a plastic tray fitted to a patient's dentition, attached to a TAP PAP mask. The lower mouthpiece is engaged with the mask to stabilize the mandible in a neutral position by securing the lower jaw. The mouthpiece keeps the mandible from receding during sleep, which narrows the airway and drives up the pressure required to splint the airway open. Typical outcomes of use of the TAP PAP device include lowered therapeutic pressures combined with improved PAP tolerance and compliance. The PAP pressure can be reduced by up to 45% (studies show an average of 28% pressure reduction). The lower mouthpiece is used during PAP therapy when jaw stabilization is required. It is indicated for patients with Severe Obstructive Sleep Apnea (OSA) who are typically on high PAP pressures. The requester comments that there are no existing codes that describe the lower mouthpiece.

Preliminary Decision:

Existing code A7035 "Headgear used with positive airway pressure device" 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 = 32

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item, however; the applicant submitted written comments which disagreed with CMS' preliminary decision not to establish another HCPCS code to identify the device that is the subject of this application. According to the applicant, the TAP PAP lower mouthpiece performs a very specific function that is not related to headgear. It is used to stabilize the mandible. Also, the lower mouthpiece is only required in severe cases where the lack of mandibular stabilization creates pressure related intolerance to PAP therapy. According to the applicant, no existing code describes mandibular stabilization for PAP.

HCPCS Public Meeting Agenda Item #9

May 28, 2014

Attachment# 14.099

Topic/Issue:

Request to establish two new level II HCPCS codes: one to identify a hyperbaric oxygen Wound Treatment System (WTS) for extremities; and another to identify caregiver's time and disposable supplies used in performing a Vaporous Hyperoxia Therapy (VHT) treatment in a hospital, clinic or home, trade name: 02Misly.

Background/Discussion:

The WTS-200 Wound Treatment System provides humidified hyperbaric oxygen to open, chronic wounds as an adjunct therapy in wound management. It can also provide heat, massage, moisture and light therapy. The system is composed of a rigid plastic shell of sufficient size to house controls and a chamber to accommodate the patient's foot. The chamber includes 4 fittings: one to fill the chamber with oxygen; a pressure sensor; one to allow mist to enter chamber; and one for water transfer. The system is portable institutional equipment that may be used in a hospital or clinic, or transported by truck for a remote (in-home) treatment. VHT delivers a humid vapor followed by hyperoxia treatment, to which a physician may add their choice of antimicrobial therapies. The treatment is used to for a variety of recalcitrant chronic lower extremity wounds including diabetic foot ulcers, decubitus ulcers, burn grafts, frostbite and amputations. The requester comments that although the WTS-2000 was determined by the FDA to be substantially equivalent to a Hyperbaric Oxygen Chamber; existing codes identify chambers that entirely enclose the patient, and extremity-only or wound-only chambers are not covered.

Preliminary Decision:

A national program operating need was not identified by Medicare, Medicaid, or the private insurance sector to establish a code to identify this device.

Medicare Payment:

There would be no payment for these items and services under level II of the HCPCS.

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item #10

May 28, 2014

Attachment# 14.066

Topic/Issue:

Request to establish 2 new level II HCPCS codes: one to identify a handheld, programmable, lockable, tamper evident pill dispenser; and another to identify a medication refill pack, trade name: PillGuard™ Dispensing System.

Background/Discussion:

According to the requester, the PillGuard is a handheld, lockable, programmable, tamper evident pill dispenser that is prescribed by physicians, nurse practioners or physician assistants, and filled and dispensed at pharmacies. It is designed to dispense the right dose to the right patient at the right time. It is meant to replace the standard pill vial at the pharmacy when a prescriber writes a prescription for it along with a controlled substance or medication for which the physician wishes to track compliance. To access the medication, the patient must enter a PIN. The PillGuard Medication Dispenser Assembly consists of two major components: and dispenser body and a refill pack assembly.

Preliminary Decision:

A national program operating need was not identified by Medicare, Medicaid, or the private insurance sector to establish codes to identify this device.

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 #11

May 28, 2014

Attachment# 14.067

Topic/Issue:

Request to establish a new Level II HCPCS code to identify ready to wear wet wrap therapy garments, trade name: Wrap-E-Soothe.

Background/Discussion:

According to the requester, AD Rescue Wear is the first and only US Company to manufacture and sell wet wrap therapy products for the treatment of childhood atopic dermatitis/eczema. The garment fabric is 94% Tencel/lyocell and 6% Spandex. Tencel/lyocell holds 50% more moisture than cotton, while the spandex stays close to the skin for extremely effective wet wrap therapy. When applied over skin that has emollients or creams and/or prescribed medication from their physician, the infusion of the intense moisture helps to re-hydrate the skin, calm the itch, reduce the redness and inflammation, provide more restful sleep and decrease Staphylococcus Aureus (staph) bacteria found on the skin. The AD Rescue Wear can be applied in less than 2 minutes and, unlike gauze, is reusable. The garment can be machine washed and reused 75-100 times. The Wrap-E-Soothe product line includes a suit; top; bottom; and sleeves. The requester states there are no existing codes that describe these products, and a single code that would apply to the 4 items in the product line is needed.

Preliminary Decision:

A national program operating need was not identified by Medicare, Medicaid, or the private insurance sector to establish codes to identify this product.

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 commented that in one study, children with severe atopic dermatitis who had not responded to other treatments and were treated with wet-wrap therapy experienced significant improvements. The speaker stated the

cost analysis shows savings in allowing parents to wet wrap at home under the supervision of a doctor or nurse instead of the costly hospital and emergency room wet wrap therapy treatments. The applicant request a “coverable code”.

HCPCS Public Meeting Agenda Item #12

May 28, 2014

Attachment# 14.071

Topic/Issue:

Second request to establish new Level II HCPCS code to identify a palm-sized, battery operated vibrating device with a removable small ice-pack, trade name: Buzzy.

Background/Discussion:

According to the requester, Buzzy is a palm-sized, vibrating bee shaped device which, through a combination of vibration and ice, "takes the sting out of shots" and minimizes other sharp pains, like starting an IV; drawing blood; giving an injection; extracting a splinter; bee stings; and everyday cuts and scrapes. The device relies on a high RPM vibration motor to create the mechanical stimulus necessary to confuse the body's nervous system. The motor creates a buzzing sound. The buzzy "bee" character rationalizes the buzzing sound as a normal thing a bee would do, and reinforces Buzzy as a "friendly toy". In a randomized controlled trial in children, patients using Buzzy experienced a statistically significant reduction of venipuncture pain by half, compared to the use of a fast-acting pain reliever spray.

Preliminary Decision:

A national program operating need was not identified by Medicare, Medicaid, or the private insurance sector to establish a code to identify this product.

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 coding decision. According to the speaker, without coverage of this device patients with "needle phobia" do not have access to this device and suffer in silence and are ridiculed by their care providers. Covering Buzzy would reduce the use of topical anesthetics and opioids, thereby reducing overall health care expenses. The speaker stated that since the Buzzy is an over- the- counter device, patients can bring their Buzzy with them to the doctor and reuse it over and over without medical waste.

HCPCS Public Meeting Agenda Item #13

May 28, 2014

Attachment# 14.074

Topic/Issue:

Request to establish new level II HCPCS code to identify disposable trays used with a powered bone marrow biopsy system, trade name: OnControl®. Applicant's suggested language: Powered Bone Marrow Biopsy Kit.

Background/Discussion:

According to the requester, Vidacare's OnControl is a battery powered aspiration and bone marrow biopsy system. The entire system includes: a reusable power driver (similar to a power drill), connector and bone marrow biopsy tray. The sterile trays are supplied in a box of 6. Each tray includes a biopsy needle; scissors; and connector attached to a sterile bag (to cover powered driver). The requester comments that existing HCPCS codes C1830 "Powered Bone Marrow Biopsy Needle" and G0364 "Bone Marrow Aspiration Performed With Bone Marrow Biopsy Through The Same Incision On The Same Date Of Service" do not adequately describe this product for use in a physician's office setting.

Preliminary Decision:

A national program operating need was not identified by Medicare, Medicaid, or the private insurance sector to establish a new Level II HCPCS code to identify this device. CMS refer s the requester to the AMA for CPT coding guidance.

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 not to establish another HCPCS code, and provided information stating that for use in the physician's office due to approximately 260,000 bone marrow biopsies are performed in the physician office setting and also that the OnControl ® system is not available inadequate payment for it. Currently HCPCS code C1830 is available for use in the hospital outpatient setting. The use of the OnControl® system in the physician office setting is a more cost effective than in the hospital outpatient setting. The applicant stated there is a significant decrease in the pain score experienced by patients with the OnControl® system versus manual methods. However; physicians will not uses the OnControl®

system in the office setting because they lose money (costs of services exceed their reimbursed amount). The applicant suggested that CMS establish a "G" code for the powered bone marrow biopsy service and an "A" code to identify the OnControl® device.

HCPCS Public Meeting Agenda Item #14

May 28, 2014

Attachment# 14.082

Topic/Issue:

Request to establish a new level II HCPCS code to identify an auricular point stimulation (Electro-Acupuncture Stimulator) device, trade name: P-STIM.

Background/Discussion:

According to the requester, the P-STIM device is a miniaturized, single-use device designed to administer auricular point stimulation treatment over several days. The device itself is a percutaneous auricular neurostimulator with 3 needles applied in between measurements of the sympathovagal balance. Sympathovagal balance measurements are made before and after application of the device. Point stimulation is mainly used to treat pain. Use of the device is recommended for the pre-operative pain therapy, as well as for the treatment of chronic pain. The patient wears the device for a period of several days while being monitored. The requester claims that there are no existing HCPCS codes that adequately describe this device.

Preliminary Decision:

A national program operating need was not identified by Medicare, Medicaid, or the private insurance sector to establish another code to identify a P-STIM, Electro-Acupuncture Stimulator device. Existing code S8930 "Electrical stimulation of auricular acupuncture points; each 15 minutes of personal one-on-one contact with the patient" is available for assignment to insurers if they deem appropriate, to identify the service.

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 not to establish another HCPCS code stating that code S8930 does not apply to the P-STIM procedure but applies to a very different procedure. The P-STIM device is "already being reimbursed (in the thousands per month) through the inventive use of existing codes (though not necessarily correctly)", and a new HCPCS code is needed in order to "remove reimbursement obstacles" to its use. They have separate reimbursement codes for the procedure and device. The speaker is recommended a new HCPCS code to for reimbursement of the P-STIM device.

HCPCS Public Meeting Agenda Item #15

May 28, 2014

Attachment# 14.091

Topic/Issue:

Second request to establish two new level II HCPCS codes to identify a mobile eye tracking device and associated hardware and software, trade name: Tobii Eyemobile and Eyemobile with PCEye Go. Applicant's suggested language:

EXXX1 Eye Tracking Device And Mounting Bracket Permitting Manipulation And Control Of A Computer
EXXX2 Eye Tracking Device, Mounting Bracket And Windows 8 Tablet

Background/Discussion:

According to the requester, The Tobii EyeMobile and mounting bracket is an eye control unit for alternative computer access. It is designed to attach to a PC and provide individuals a hands free way of controlling their computer's mouse and keyboard. The user can type a message, e-mail, search the internet, etc…. The EyeMobile can be operated with precision regardless of glasses, contact lenses, eye color or light conditions. The EyeMobile is connected to a standard USB port and can be used with any PC using a Windows operating system. The Eyemobile may be used by persons with Spinal Cord Injuries, Cerebral Palsy, ALS, Traumatic Brain Injury, Rett Syndrome, Autism, Downs Syndrome, and various repetitive strain injuries. The requester comments that this technology is new, and as yet not coded.

Preliminary Decision:

A national program operating need was not identified by Medicare, Medicaid or the Private Insurance Sector to establish a code to identify the products that are the subject of this request.

Medicare Payment:

Payment will be based on the carrier's determination regarding which coverage and payment rules are applicable.

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item #15

May 28, 2014

Attachment# 14.092

Topic/Issue:

Second request to establish two new level II HCPCS codes to identify eye tracking and speech generating devices that are controlled through gaze interaction via an eye tracker, trade names: Tobii I-12 and I-15. Applicant's suggested language:

EXXX1 Eye Tracking Device With A Speech Generating Device And 12 Inch Screen
EXXX2 Eye Tracking Device With A Speech Generating Device And 15 Inch Screen

Background/Discussion:

According to the requester, the Tobii I-12/I-15 devices combine eye tracking with speech generation. They enable individuals to manipulate a computer with their eyes, rather than their hands, and will generate speech. The individual can speak, type a message, e-mail, search the internet, etc…. The I-12/I-15 can be operated with precision regardless of glasses, contact lenses, eye color or light conditions. The Tobii I-12/I-15 device can improve the patient's quality of life of allowing them the ability to communicate (speak) their needs, interface with their healthcare providers, their families, friends and co-workers. The I-12/I15 devices may be used for patients with spinal cord injuries, cerebral palsy, ALS, Traumatic Brain Injury, Rett Syndrome, Autism and Downs Syndrome. Depending on the patient's needs there are two different sized screens available 12 inch or 15 inch. The requester claims that Private Insurers and State Medicaid Agencies "have requested codes" to identify these devices.

Preliminary Decision:

A national program operating need was not identified by Medicare, Medicaid or the Private Insurance Sector to establish a code to identify the products that are subject of this request.

Medicare Payment:

Payment will be based on the carrier's determination regarding which coverage and payment rules are applicable.

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item #16

May 28, 2014

Attachment# 14.100

Topic/Issue:

Request to establish a new level II HCPCS code to identify a portable pneumatic long axis hip traction device for independent home use, trade name: HipTrac. Applicant's suggested language:

EXXXX Hip Joint Traction Equipment

Background/Discussion:

According to the requester, the HipTrac is a durable, portable, light-weight long-axis hip traction device independently used by the patient at home to mobilize/stretch the restricted joint capsule; stretch surrounding musculature; decrease intra-articular pressure in the joint; decrease pain; create a neuromuscular relaxation of surrounding musculature; and improve mobility. Suggested use is for hip osteoarthritis and other intra-articular hip joint pathologies. The device does not replace manual therapy and therapeutic exercise. Using the HipTrac at home between visits will continue the capsular mobilization and stretching, lessening the rebound effect and decreasing pain. The device includes a leg support that can be locked into angles of 10, 20 or 30 degrees of flexion; a binding to hold the leg on the leg support; a foam pad; a hand pump and gauge to adjust traction force; and a slide carriage to accommodate leg length. To use the device, the patient lays on the floor in front of the device, puts their leg on the support, and uses the hand pump and gauge to deliver traction and adjust the force as recommended. The requestor claims that the HipTrac is not a preventive or recreational exercise device and should be coded and covered as a traction device.

Preliminary Decision:

Existing code A9300 "Exercise 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:

The primary speaker disagreed with CMS' preliminary decision not to establish a unique HCPCS code. According to the speaker, the HipTrac requires a prescription. It mimics long axis hip traction therapy performed by physicians and physical therapist on patients suffering from hip osteoarthritis and other hip joint alignments. HipTrac is categorized as a Class I medical device and is not an exercise device.

HCPCS Public Meeting Agenda Item #17

May 28, 2014

Attachment# 14.101
Topic/Issue:

Request to establish two new level II HCPCS code to identify a wearable plantar pressure monitoring system, trade name: SurroSense RX. Applicant's suggested language:

AXXXX Plantar Pressure Inserts, Per Pair Of Inserts
EXXXX Plantar Pressure Monitoring System, Includes All Components

Background/Discussion:

According to the requester, SurroSense RX system is comprised of wearable, sensor embedded inserts placed inside shoes that monitor plantar pressure to help actively prevent peripheral neuropathy complications. Pressure data is collected from the foot through eight pressure sensors located in the insert; this data is wirelessly sent to a smart watch that provides pressure feedback from feet. When dangerous pressure levels (35mmHg) and time thresholds (15 minutes) have been exceeded, the smart watch alerts the user, so that the behavior causing the excess pressure can be changed and damage avoided, (e.g., the person can offload their feet). The SurroSense RX is a tool designed to help actively prevent peripheral neuropathy complications and track progress. The device is indicated for use by persons with peripheral neuropathy, who experience a loss of sensation in their feet. The system includes right and left SurroSense inserts; wireless-enabled shoe pads; a smart watch; charging cables; an AC adapter and supplementary educational mobile downloads. The inserts have a 12-month life expectancy.

Preliminary Decision:

Existing code A9279 "Monitoring feature/device, stand-alone or integrated, any type, includes all accessories, components and electronics, not otherwise classified" 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:

The primary speaker disagreed with CMS' preliminary decision not to establish aunique HCPCS code. According to the speaker, SurroSense Rx™ should be considered a prosthetic device. It replaces sensory nerve structures of the feet. The speaker asked CMS to revise the incoming application to instead request an "L" code.

HCPCS Public Meeting Agenda Item #18

May 28, 2014

Attachment# 14.070

Topic/Issue:

Fourth request to establish new Level II HCPCS code to identify a custom-fabricated foot orthosis for use by diabetic patients at high risk for plantar ulcers, trade name: TruContour. Applicant's suggested language:

"For Diabetics Patients At High Risk For Plantar Ulcer Only, Multiple Density Orthosis, Custom Designed By Combining The Digital Three-Dimensional Shape Of Patient's Foot With Offloading Modification(s) Placed Relative To Identified Pressure Contours Measured During Walking From Dynamic Plantar Pressure Distribution Of Patient's Foot, Custom Fabricated, Each".

Background/Discussion:

According to the requester, TrueContour custom diabetic foot orthoses operate by offloading targeted regions of the foot with customized surface modifications that are designed using a scientifically validated and clinically tested algorithm. The TrueContour approach incorporates both the patient's foot shape and their plantar pressure distribution in the design of the novel offloading features. An independent study concluded at the Cleveland clinic has shown TrueContour custom diabetic foot orthoses reduce loading in areas of high pressure in the metatarsal head (MTH) region of the plantar surface of the patient's foot significantly better than other products coded at A5513. The target population for TrueContour is diabetic patients who have been certified by their treating physician to be in need of therapeutic shoes and inserts, and for whom the plantar metatarsal (MTH) areas are of specific concern.

Preliminary Decision:

Existing code A5513: "For diabetics only, multiple density insert, custom molded from model of patient's foot, total contact with patient's foot, including arch, base layer minimum of 3/16 inch material of shore a 35 durometer or higher), includes arch filler and other shaping material, custom fabricated, each", 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 = 38

Summary of Primary Speaker Comments at the Public Meeting:

The primary disagreed with CMS' preliminary decision not to establish another HCPCS code to describe this product. According to the speaker, TrueContour® unload the forefoot better than other insoles coded at A5513, and this difference in pressure confers a significant therapeutic distinction in terms of a reduction in forefoot ulcers.

HCPCS Public Meeting Agenda Item #19
May 28, 2014

Attachment# 14.069

Topic/Issue:

Request to establish 2 to5 new Level II HCPCS codes to identify viscoelastic bandages for upper and lower extremities (including wrists and ankles); and the cranial area, trade name: SportsBands. The applicant suggests that the products be described as Vibration and Shock Dampening Devices.

Background/Discussion:

According to the requester, SportsBands is a muscle wrap that helps the body heal itself through vibration dampening and shock absorption. The viscoelastic band "absorbs" the body's natural vibrations, allowing the body to heal itself without the need for pharmaceutical pain reducers. The SportsBands product line includes: Belt band, Migraine band, Arm/Leg band, and Wrist/ankle band. The requester comments that existing code A4466 "Garment, Belt, Sleeve Or Other Covering, Elastic Or Similar Stretchable Material, Any Type, Each"; does not describe what the SportsBand accomplishes.

Preliminary Decision:

A national program operating need was not identified by Medicare, Medicaid or the Private Insurance Sector to establish a new code to identify the product that is the subject of this request. Existing code A4466 "Garment, Belt, Sleeve Or Other Covering, Elastic Or Similar Stretchable Material, Any Type, Each" is available for assignment by insurers if deemed appropriate.

Medicare Payment:

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

Summary of Primary Speaker Comments at the Public Meeting:

The applicant offered comments at the public meeting disagreeing with CMS' preliminary decision.

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;
- Surgical Dressings
- Therapeutic Shoes and Inserts

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 for most DMEPOS items and services is now 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 or supplier price lists. 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. Payment for E0935 is based on a daily rental fee schedule basis since coverage of this device is limited to 21 days.

- **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, were purchased 75 percent of the time or more from July 1986 through June 1987,or which are accessories used in conjunction with a nebulizer, aspirator, continuous airway pressure device, or respiratory assist device. The beneficiary has the option to acquire the item on a purchase or monthly rental basis. Total payments for the item cannot exceed the purchase fee schedule amount for the item.

- **Pricing = 33 Oxygen and Oxygen Equipment**
  Monthly fee schedule payments are made for furnishing oxygen and oxygen equipment. This monthly payment includes payment for all stationary oxygen equipment, supplies, and accessories and delivery of oxygen contents (stationary and portable). A monthly add-on to this payment is made for portable oxygen equipment only for those beneficiaries who require portable oxygen. The monthly payments for oxygen equipment cap after the 36th monthly payment is made, after which payment for the ongoing delivery of contents continues for 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. 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. 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. Complex rehabilitative power wheelchairs can also 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 and judgment of a reasonable payment amount, which, at a minimum, includes a review of the costs of labor and material used in constructing the equipment.

- **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.