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

Supplies and Other

Wednesday, May 25, 2011

Introduction and Overview

Approximately 60 people attended. The agenda included 20 items.

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

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

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

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

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

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

Centers for Medicare & Medicaid Services (CMS) Healthcare Common Procedure Coding System (HCPCS) Public Meeting Agenda for Supplies and "Other"
Wednesday, May 25, 2011, 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# 11.046
Request to establish a code for a Closed Reservoir Overflow System for Enteral Feeding Intolerance, Trade Name: Farrell Valve® System.

Primary Speaker: Jacqueline Wessel of Cincinnati Children's Hospital Medical Center

AGENDA ITEM #2
Attachment# 11.017
Request to establish 2 codes for a liquid medication dispenser: one for the Medibottle and one for the Medibottle+.

No Primary Speaker

AGENDA ITEM #3
Attachment# 11.049
Request to establish a code for an adhesive kit used with the external charger to recharge the Precision™ Plus rechargeable spinal cord stimulator (SCS), Trade Name: Precision ™ Plus Spinal Cord Stimulator Adhesive Kit.

Primary Speaker: Wendy Chan of Boston Scientific Corporation

AGENDA ITEM #4
Attachment# 11.024
Request to establish a code for a nasal expiratory positive airway pressure (EPAP) device, Trade Name: PROVENT Therapy.

Primary Speaker: James Walsh of St. Luke's Sleep Medicine and Research Center

AGENDA ITEM #5
Attachment# 11.006
Request to establish new HCPCS Level II codes for medical-grade honey in a tube: Trade Names: MANUKApli; impregnated in an absorbent poly-fiber dressing (with and without adhesive), Trade Name: MANUKAhd; and impregnated in a contact layer, Trade Name: MANUKAtex.

No Primary Speaker

AGENDA ITEM #6
Attachment# 11.083
Request to establish 2 HCPCS codes to identify the Madison Oral Strengthening Therapeutic (MOST) Device.

No Primary Speaker

AGENDA ITEM #7
Attachment# 11.007
Request to assign medical food, Trade Name: AquaCareH2O, to existing HCPCS code category B4100 "Food Thickener, Administered Orally, Per Ounce."

No Primary Speaker

AGENDA ITEM # 8
Attachment# 11.038
Request to assign existing HCPCS code B4160 to PediaSmart®SOY Complete Organic Nutrition™, Trade Name: PediaSmart®.

No Primary Speaker

AGENDA ITEM #9
Attachment# 11.029
Request to establish a code for a massager and ice pack, Trade Name: Buzzy®.

Primary Speaker: Dr. Amy Baxter of Pediatric Emergency Medicine Associates

AGENDA ITEM #10
Attachment# 11.008
Request to establish a code for a therapeutic computer mouse, Trade Name: T-Mouse™.

No Primary Speaker

AGENDA ITEM #11
Attachment# 11.088
Request to breakdown existing code T1505 which identifies the Electronic Medication Management Assistant system, and instead implement 3 HCPCS codes to describe its component parts. Trade Name: EMMA®.

Primary Speaker: Chris Bossi of INRange Systems, Inc.

AGENDA ITEM #12
Attachment# 11.004
Request to establish a code for a monthly pill organizer, Trade Name: The MedCenter System.

Primary Speaker: Paul Brelo of MedCenter Systems, LLC

AGENDA ITEM #13
Attachment# 11.086
Request to establish a code for a kit of textiles that contain chlorine, Trade Name: PerfectCLEAN with Micrillon® Infection Prevention Kit.

Primary Speaker: George Clarke of UMF Corporation

AGENDA ITEM #14
Attachment# 11.064
Request to establish a code for Closed System Drug Transfer Device (CSTD) technology, Trade Name: PhaSeal System.

No Primary Speaker

AGENDA ITEM #15
Attachment# 11.082
Request to establish a code for a dural sealant, Trade Name: DuraSeal Xact Sealant System.

No Primary Speaker

AGENDA ITEM #16
Attachment# 11.081
Request to establish a code for a hysteroscopic tissue morcellator, and removal device, Trade Name: MyoSure™ Tissue Removal Device.

Primary Speaker: Dr. James Presthus of Hologic, Inc.

AGENDA ITEM #17
Attachment# 11.011
Request to establish a code for an internal bone stabilization device, Trade Name: HyProCure®.

Primary Speaker: Dr. Michael Graham of GraMedica

AGENDA ITEM #18
Attachment# 11.125
Request to establish a code for an Infant Ear Correction System. Trade Name: EarWell™.

No Primary Speaker

AGENDA ITEM #19
Attachment# 11.087
Request to establish a code for dose optimization analysis for infusional 5-FU, Trade Name: OnDose®.

Attachment# 11.089
Request to establish HCPCS Level II code to identify two mutation MYH gene analysis for MYH-Associated Polyposis (MAP), Trade Name: MYH Mutation Panel.

Attachment# 11.090
Request to establish a HCPCS Level II code for Gene sequence and large rearrangement analysis of MSH6, Trade Name: MSH6 analysis.

Attachment# 11.092
Request to revise the verbiage of code S3831 which currently reads: SINGLE-MUTATION ANALYSIS (IN AN INDIVIDUAL WITH A KNOWN MLH1 OR MSH2 MUTATION IN THE FAMILY) FOR HEREDITARY NONPOLYPOSIS COLORECTAL CANCER (HNPCC) GENETIC TESTING" to instead read: "Single-mutation analysis in an individual with a known Lynch Syndrome mutation in the family".
Attachment# 11.093
Request to eliminate the 'female-only' designation from code S3820 "COMPLETE BRCA1 AND BRCA2 GENE SEQUENCE ANALYSIS FOR SUSCEPTIBILITY TO BREAST AND OVARIAN CANCER".

Attachment# 11.094
Request to eliminate the 'female-only' designation from code S3823 "THREE-MUTATION BRCA1 AND BRCA2 ANALYSIS FOR SUSCEPTIBILITY TO BREAST AND OVARIAN CANCER IN ASHKENAZI INDIVIDUALS".

Attachment# 11.091
Request to establish a HCPCS Level II code for a test that identifies large rearrangements in the BRCA1 and BRCA2 genes, Trade Name: BRACAnalysis® Rearrangement Test (BART)™.

Attachment# 11.095
Request to revise the verbiage of code S3830 which currently reads: "COMPLETE MLH1 AND MSH2 GENE SEQUENCE ANALYSIS FOR HEREDITARY NONPOLYPOSIS COLORECTAL CANCER (HNPCC) GENETIC TESTING" to instead read: "'Complete MLH1, MSH2, MSH6, PMS2 and TACSTD1 gene analysis for Lynch Syndrome genetic testing".

No Primary Speaker

AGENDA ITEM #20
Attachment# 11.126
Request to: 1) revise existing code S9900 which currently reads: SERVICES BY AUTHORIZED CHRISTIAN SCIENCE PRACTITIONER FOR THE PROCESS OF HEALING, PER DIEM; NOT TO BE USED FOR REST OR STUDY; EXCLUDES IN-PATIENT SERVICES," to instead read: "Service by a journal-listed christian science practitioner for the purpose of healing;" and 2) establish 3 new codes for religious non-medical health care.

No Primary Speaker

HCPCS Public Meeting Agenda Item #1
May 25, 2011

Attachment# 11.046

Topic/Issue:

Request to establish a code for a Closed Reservoir Overflow System for Enteral Feeding Intolerance, trade name: Farrell Valve® System.

Background/Discussion:

According to the requester, the Farrell Valve® System (FVS) is a disposable, closed reservoir overflow system for children and adults receiving enteral feeding. The FVS includes a reservoir container with filter and tubing with a "Y" connector to attach to any standard enteral feeding system while the patient is receiving enteral therapy. The FSV is indicated for patients with reduced or impaired gastric motility. Reduced or impaired gastric motility can result in gastric reflux, putting the patient at risk for aspirating stomach contents, and abdominal distention which can result in pain, discomfort and inhibited lung expansion. The addition of the closed reservoir overflow system provides a channel for gastric contents (air, formula, medication) to exit the stomach and backflow into the FVS, then when the gastric pressure reduces, the retained nutritional formula and medications in the FVS flow back into the stomach and then is processed at the patient's own digestive rate to complete the enteral feeding therapy. The FVS is used in conjunction with standard enteral feeding supplies for patients who cannot tolerate feedings due to severe distention, prolonged pain, gastric reflux or vomiting. According to the requester, syringes used to vent air [chimney approach] are included in the routine supply allocation for all enteral feeding patients, along with the enteral feeding bag, tubing, connectors, tape or other anchoring devices. However, the Farrell Valve System (FVS) is not included in the feeding supply kits coded at B4034 - B4036.

CMS HCPCS Preliminary Decision:

Existing enteral feeding kit codes B4034 ENTERAL FEEDING SUPPLY KIT; SYRINGE, PER DAY, B4035 ENTERAL FEEDING SUPPLY KIT; PUMP FED, PER DAY and B4036 ENTERAL FEEDING SUPPLY KIT; GRAVITY FED, PER DAY, (based on feeding mechanism), are intended to include the products that are the subject of this request.

Medicare Payment:

The payment rules associated with the existing codes apply to this product if covered.
Pricing = 39

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with CMS' preliminary decision. The speaker stated that a code is needed in order to provide options for patients who struggle with EN therapy; to enable payers to identify use; and to enable providers to separately bill for the Farrell Valve. The speaker described the “pop off” system that is part of the Farrell Valve system, and that this “pop off” system is the only closed mechanism to capture backflow. Other systems in use are “jury rigged”. The speaker discussed that a pop off system is needed by patients who cannot well tolerate continuous feeding and who are at risk of aspiration or other complications related to gastric compression.

HCPCS Public Meeting Agenda Item #2
May 25, 2011

Attachment# 11.017

Topic/Issue:

Request to establish 2 codes for a liquid medication dispenser: one for the Medibottle and one for the Medibottle+.

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 makes this medication delivery system more than a matter of convenience. The Medibottle is not identified in the existing code set.

CMS HCPCS Preliminary Decision:

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

Medicare Payment:

Based on 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 #3
May 25, 2011

Attachment# 11.049

Topic/Issue:

Request to establish a code for an adhesive kit used with the external charger to recharge the Precision™ Plus rechargeable spinal cord stimulator (SCS), Trade Name: Precision ™ Plus Spinal Cord Stimulator Adhesive Kit. Applicant's suggested language: "Patch, double sided adhesive, for external neurostimulator pulse generator charger, per box".

Background/Discussion:

According to the requester, the adhesive kit is indicated for use with the Precision SCS system. The Precision SCS adhesive patch kit is a box of 26 double-sided single-use adhesive patches. One patch is used each time the implanted pulse generator (IPG) is recharged. The patch is biocompatible and it adheres to the charger and to the skin directly over the implanted IPG battery so it can recharge the implanted IPG via radiofrequency. The patch is strong enough to hold the external charging system in place for extended periods of time to allow the patient to recharge the IPG without compromising the patient's ability to be mobile during the process. It also ensures that the patch will not move or change its position relative to the IPG. According to the requester, the high volume use of this item and insurer policies support the need for a specific HCPCS code. There are no existing codes to adequately describe this product. The requester commented that existing code A4450 describes general use medical tape and therefore does not describe these adhesive patches.

CMS HCPCS Preliminary Decision:

Existing code A4450 "TAPE, NON-WATERPROOF, PER 18 SQUARE INCHES" together with modifier AV "ITEM FURNISHED IN CONJUNCTION WITH A PROSTHETIC DEVICE, PROSTHETIC OR ORTHOTIC" adequately describes the product that is the subject of this request.

Medicare Payment:

The payment rules associated with the existing code for a supply furnished in conjunction with a prosthetic device apply to this product if covered.

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with CMS' preliminary decision. The speaker stated that the adhesive kit is used in conjunction with the external charger and is not properly described in code A4450. According to the speaker, the adhesive patch is a unique, biocompatible,

reinforced, double sided adhesive patch specifically designed to adhere to the charger and to the skin directly over the implanted IPG battery so the charger stays in a fixed position on the skin, relative to the battery, without causing irritation or burning. Without the ability to recharge the IPG, the patient's battery will cease to function and the therapy will be compromised. The speaker stated that this is the primary medical reason for a new HCPCS code. While a belt to hold the charger to the patients' skin is provided to every patient, most patients find tape to be more convenient. The speaker commented generally that, depending on where the battery is, not all patients can use the belt.

HCPCS Public Meeting Agenda Item #4
May 25, 2011

Attachment# 11.024

Topic/Issue:

Request to establish a code for a nasal expiratory positive airway pressure (EPAP) device, Trade Name: PROVENT Therapy. Applicant's suggested language: "Nasal expiratory positive airway pressure (EPAP) device, used to increase pressure in airway during expiration, per box of 30".

Background/Discussion:

According to the requester, PROVENT Therapy is a product for the treatment of Obstructive Sleep apnea (OSA). It is a discreet nasal device proven to significantly reduce the Apnea Hypopnea Index (AHI), Oxygen Desaturation Index (ODI), and Epworth Sleepiness Score (ESS). Its breakthrough microvalve design creates EPAP that keeps the airway open for better quality sleep and better daytime function. This is a disposable product, placed over the nostrils nightly, held in place by adhesive. Each single use nasal device functions by increasing the pressure in the airway during expiration, thereby decreasing the AHI. Valves in the device attach over each nostril and are secured using a hypoallergenic adhesive. Patients affix the device to the nose nightly before going to sleep. Once asleep, patients generally breathe through their nose and thus through the device. 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, as evidenced by the use of miscellaneous codes in claims submissions.

CMS HCPCS Preliminary Decision:

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

Medicare Payment:

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

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with CMS' preliminary decision. The speaker stated that a HCPCS code is needed in order to track utilization and conduct comparative effectiveness

studies. The speaker also claimed that a billing code is needed to preserve patient access. The speaker commented that since this product supports the pharyngeal airway during expiration (keeps airway open during sleep), it should be considered a prosthetic.

HCPCS Public Meeting Agenda Item #5
May 25, 2011

Attachment# 11.006

Topic/Issue:

Request to establish new HCPCS Level II codes for medical-grade honey: in a tube, Trade Names: MANUKApli; impregnated in an absorbent poly-fiber dressing (with and without adhesive), Trade Name: MANUKAhd; and impregnated in a contact layer, Trade Name: MANUKAtex.

Background/Discussion:

According to the requester, Manuka honey is 100% medical grade honey. It can be used on burn and on surgical, vascular, arterial, pressure and trauma wounds. Manuka honey is formulated into hydrocolloids and highly absorbent dressings with and without borders and non-adherent layers. Manuka honey is bacteriostatic and creates an environment that is not conducive for bacteria to reproduce. It neutralizes odor and prevents ammonia and sulfur from forming in a wound bed. It autolytically debrides due to the high osmotic action in the honey. According to the requester, existing HCPCS codes are based on dressing characteristics and size, and do not place emphasis on the honey or its properties.

CMS HCPCS Preliminary Decision:

Existing code A6250 "SKIN SEALANTS, PROTECTANTS, MOISTURIZERS, OINTMENTS, ANY TYPE, ANY SIZE" adequately describes medical grade honey in a tube.

Existing code A6234 "HYDROCOLLOID DRESSING, WOUND COVER, STERILE, PAD SIZE 16 SQ. IN. OR LESS, WITHOUT ADHESIVE BORDER, EACH DRESSING;" A6235 "HYDROCOLLOID DRESSING, WOUND COVER, STERILE, PAD SIZE MORE THAN 16 SQ. IN. BUT LESS THAN OR EQUAL TO 48 SQ. IN., WITHOUT ADHESIVE BORDER, EACH DRESSING;" or; A6236 "HYDROCOLLOID DRESSING, WOUND COVER, STERILE, PAD SIZE MORE THAN 48 SQ. IN., WITHOUT ADHESIVE BORDER, EACH DRESSING," (depending on the size of the pad), adequately describes Manuka HD without border.

Existing code A6237 "HYDROCOLLOID DRESSING, WOUND COVER, STERILE, PAD SIZE 16 SQ. IN. OR LESS, WITH ANY SIZE ADHESIVE BORDER, EACH DRESSING;" A6238 "HYDROCOLLOID DRESSING, WOUND COVER, STERILE, PAD SIZE MORE THAN 16 SQ. IN. BUT LESS THAN OR EQUAL TO 48 SQ. IN., WITH ANY SIZE ADHESIVE BORDER, EACH DRESSING;" or A6239 "HYDROCOLLOID DRESSING, WOUND COVER, STERILE, PAD SIZE MORE THAN 48 SQ. IN., WITH ANY SIZE ADHESIVE BORDER, EACH DRESSING", (depending on the size of the pad), adequately describes Manuka HD with border.

Existing code A6206 "CONTACT LAYER, STERILE, 16 SQ. IN. OR LESS, EACH DRESSING;" A6207 "CONTACT LAYER, MORE THAN 16 SQ. IN. BUT LESS THAN OR EQUAL TO 48 SQ. IN., EACH DRESSING;" or A6208";CONTACT LAYER, STERILE, MORE THAN 48 SQ. IN., EACH DRESSING" (depending on size), adequately describes the Manuka Tex.

Medicare Payment:

The payment rules associated with the existing codes apply to these products if covered.
For code A6250, Pricing=00
For codes A6234 -A6238, A6207, A6208, Pricing = 35
For codes A6206 & A6239, Pricing =46

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item #6
May 25, 2011

Attachment# 11.083

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 reusable portable, handheld device used to diagnose and treat swallowing abnormalities and a second code to describe a custom molded five bulb sensor oral component.

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 that describe this device and no CPT codes that specifically describe a device with 5 sensors that are placed against the hard palate and intended to diagnose and evaluate swallowing function.

CMS HCPCS Preliminary Decision:

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

Medicare Payment:

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

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item #7
May 25, 2011

Attachment# 11.007

Topic/Issue:

Request to assign medical food, Trade Name: AquaCareH2O, to existing HCPCS code category B4100 "Food Thickener, Administered, Orally, Per Ounce."

Background/Discussion:

According to the requester, AquaCareH2O is pre-packaged, ready to use thickened liquid indicated for people with dysphagia, (swallowing difficulties). It is liquid available in nectar and honey consistencies. Thickened liquids enable people with dysphagia to drink without choking. Xanthan gum is the thickening agent that is added to allow water to be as clear as regular water and be utilized like water. AquaCareH2O contains no calories, sugar or gluten, and can be frozen or heated without affecting the product. The prepared liquid can be pureed with different foods to give Dysphagia patients the proper consistency for the foods they eat without altering the taste of the food. The AquaCareH2O product line includes pre-packaged, thickened water; apple, cranberry and orange juice; and coffee, all available in both nectar and honey consistencies. All products have a 14-day shelf life upon opening and a 1 year shelf life when unopened. They are packaged in 4/64 oz bottles per case and 24/8 oz bottles per case. According to the applicant, if existing code B4100 "FOOD THICKENER, ADMINISTERED ORALLY, PER OUNCE" is modified to include "ready to use products," it would be applicable to these products.

CMS HCPCS Preliminary Decision:

Existing code B4100 "FOOD THICKENER, ADMINISTERED ORALLY, PER OUNCE" is intended to describe thickeners only. A national program operating need was not identified by Medicare, Medicaid or the Private Insurance Sector to establish or revise a code to describe "ready to use" thickened food products. 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 #8
May 25, 2011

Attachment# 11.038

Topic/Issue:

Request to assign existing HCPCS code B4160 to PediaSmart®SOY Complete Organic Nutrition™, Trade Name: PediaSmart®.

Background/Discussion:

According to the requester, PediaSmart®SOY Complete Organic Nutrition™ is the only soy-based organic beverage on the U.S. market offering dairy free complete organic nutrition and is comparable to leading brands such as Bright Beginnings™ Soy. PediaSmart SOY is an alternative to cow's milk. It is recommended for children ages 1 through 13 years. This product is not intended for infants less than 12-months of age unless directed by a healthcare professional. PediaSmart®SOY meets or exceeds 100% of the Dietary Reference Intakes for protein, fat, carbohydrate, vitamins and minerals. PediaSmart®SOY is USDA certified organic by OneCert™ regulatory agency. It can be used as a nutritional supplement to complement a child's diet or prescribed by a healthcare professional as a medical food for a child in need of extra calories and nutrients. PediaSmart®SOY can also be used as a sole source of nutrition and for tube feedings under the supervision of a healthcare professional. It is not for parenteral use.

CMS HCPCS Preliminary Decision:

Existing code B4160 ENTERAL FORMULA, FOR PEDIATRICS, NUTRITIONALLY COMPLETE CALORICALLY DENSE (EQUAL TO OR GREATER THAN 0.7 KCAL/ML) WITH INTACT NUTRIENTS, INCLUDES PROTEINS, FATS, CARBOHYDRATES, VITAMINS AND MINERALS, MAY INCLUDE FIBER, ADMINISTERED THROUGH AN ENTERAL FEEDING TUBE, 100 CALORIES = 1 UNIT" adequately describes the product formulation 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 #9
May 25, 2011

Attachment# 11.029

Topic/Issue:

Request to establish a code for a massager and ice pack, Trade Name: Buzzy®.

Background/Discussion:

According to the requester, Buzzy® is a palm-sized vibrating bee with a removable ice pack and center slot for an optional tourniquet. It is used to help overcome needle anxiety. When placed proximal to a painful procedure, the combination of cold and vibration block transmission of sharp pain. The device also buzzes like a bee, which provides an auditory distraction. The Buzzy Deluxe Kit includes: neoprene Cold-to-Go Tote, Buzzy® and Bee Stractors™ (distraction device), a Velcro strap, 2 AAA batteries, a set of Blue Gel Wings and two White Ice Wings for longer procedures. Frozen inserts are also included to keep the bag and the frozen wings cold. Buzzy's housing is composed of durable GE Lexan polycarbonate material and may be cleaned with germicidal disposable wipes. According to the requester "there are currently no codes as this is not a third party billable item."

CMS HCPCS Preliminary Decision:

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

Medicare Payment:

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

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with CMS' preliminary decision. The speaker stated that Buzzy is a unique, reusable device that saves healthcare dollars and lives. The speaker claimed children do feel pain, children do remember pain, IV's fail one out of three times and untreated pain builds phobias. Needle pain management is a "mandate".

HCPCS Public Meeting Agenda Item #10
May 25, 2011

Attachment# 11.008

Topic/Issue:

Request to establish a code for a therapeutic computer mouse, Trade Name: T-Mouse™.

Background/Discussion:

According to the requester, the T-Mouse™ is a therapeutic wireless hand held computer mouse shaped to support the hand in a relaxed, handshake position and eliminate arm twisting. The T-Mouse™ does not require movement of the complete wrist or hand. Only very small motions of the thumb are required to exert control over the cursor. The buttons are quickly and easily accessed by the user's fingers on the right side of the T-Mouse™. The user is not confined to a particular work surface and can change position frequently. According to the requester, the T-Mouse system reduces the likelihood of developing repetitive strain injuries; and prevents and will not aggravate the medical conditions of Carpal Tunnel Syndrome and Tendonitis related to using a PC. Use of the T-Mouse gives employees in certain job classes who suffer from a Cumulative Trauma Disorder, Carpal Tunnel Syndrome or tendonitis the option to return to work. The T-Mouse™ also serves as a hand massager. According to the requester, there is no code to describe this product.

CMS HCPCS Preliminary Decision:

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

Medicare Payment:

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

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item #11
May 25, 2011

Attachment# 11.088

Topic/Issue:

Request to breakdown existing code T1505 which identifies the Electronic Medication Management Assistant system, and instead implement 3 HCPCS codes to describe its component parts. 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 MEDICATION COMPLIANCE MANAGEMENT DEVICE, BASE UNIT (EACH); and establish codes Txxx1 ELECTRONIC MEDICATION COMPLIANCE MANAGEMENT DEVICE, EXPANSION UNIT (EACH); and Txxx2 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. Typically, these patients suffer from chronic diseases and are prescribed medications that require frequent adjustment. Depending on the requirements of the patient, EMMA is configured as just a base unit, or, if the patient is taking more than 10 medications, one or more expansion units (providing additional capacity in increments of 10 medications). Each base unit is equipped with a cellular two-way web-based communications software that allows a physician, pharmacist or nurse to remotely manage prescriptions stored and released by the patient-operated EMMA. 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) cartridges. If the patient's treatment involves more than 10 prescription medications, an expansion unit is prescribed. The EMMA Device identifies each medication automatically - no patient input is required. The system allows for compliance monitoring and real-time dose adjustments through its wireless software capabilities. It maintains the patient's complete medication history and provides clinicians with vital information about medication dosing, adjustments, refills, missed doses and treatment responses. EMMA® is remotely programmed, including all dosage changes, by a licensed medical professional such as a pharmacist or nurse to insure accurate delivery of the patient's medications as prescribed. CMS established code T1505 "Electronic Medication Compliance Management Device, includes all components and accessories", effective January 2011, to describe the EMMA system. However, there are three separate and unique items that may be prescribed. In addition, the use of EMMA requires a disposable cartridge which is supplied and billed monthly based on the actual number of medications managed by the EMMA device. 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.

CMS HCPCS Preliminary Decision:

Existing code T1505 "ELECTRONIC MEDICATION COMPLIANCE MANAGEMENT DEVICE, INCLUDES ALL COMPONENTS AND ACCESSORIES, NOT OTHERWISE CLASSIFIED" as written and intended, includes all necessary components and supplies.

Medicare Payment:

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 there are three essential components (base unit, expansion unit and disposable cartridge) and each component is billed separately and replaced in varying frequencies, therefore, separate codes are needed to identify the component parts of the system.

HCPCS Public Meeting Agenda Item #12
May 25, 2011

Attachment# 11.004

Topic/Issue:

Request to establish a code for a monthly pill organizer, Trade Name: The MedCenter System.

Background/Discussion:

According to the requester, the MedCenter System is a monthly pill organizer that organizes 31 day's worth of medications by up to four daily dosage times. The system includes a base and 31 cassettes that are color coded and labeled. Each cassette includes 4 components and each compartment holds up to 15 pills/capsules. The system also includes a reminder alarm and a talking clock. The requester considers the system to be "interactive" because the user must press the acknowledgment button on top of the clock to shut off the alarm for each medication period. According to the requester, there are many pill organizers on the market that are similarly priced to the MedCenter but none of them offer the ease of setup, use, and multiple ways to insure the proper dosage. There are currently no HCPCS codes to describe this product.

CMS HCPCS Preliminary Decision:

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

Medicare Payment:

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

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with CMS' preliminary decision. The speaker has asked the workgroup to reconsider and assign a HCPCS code or the development of a new category for this unique system. The speaker asked for a code regardless of whether insurers would pay for the system because a code “gives credibility in the market place”, and the establishment of a HCPCS code might convince private insurers to pay for this system.

HCPCS Public Meeting Agenda Item #13
May 25, 2011

Attachment# 11.086

Topic/Issue:

Request to establish a code for a kit of textiles that contain chlorine, Trade Name: PerfectCLEAN with Micrillon® Infection Prevention Kit.

Background/Discussion:

According to the Requester, The PerfectCLEAN with Micrillon® Hospital Associated Infection (HAI) Prevention Kit is an ensemble of high performance, color coded, re-chargeable, micro-denier textiles incorporating the most highly effective EPA registered, CDC recommended antimicrobial - Chlorine. These products have been developed to deal with every environmental disinfection challenge in healthcare environments. The PerfectCLEAN with Micrillon Infection Prevention textiles are made from polyester and polyamide and are designed to be re-laundered and re-kitted thereby: (1) removing the organic matter that was Trapped and Eliminated and then, (2) recharging the chlorine receptor sites built into the fibers returning the textile's efficacy to 100%. Micrillon products can be processed and re-kitted approximately 50 times. These unique products remove bacteria, bacterial spores and viruses from environmental surfaces, eliminating the risk of room-to-room cross contamination. The PerfectCLEAN with Micrillon® HAI Prevention Kit includes: one pair of disposable gloves, 2 Antimicrobial wipes, 2 Antimicrobial mops, one Antimicrobial mitt, one Antimicrobial duster cover and an instruction sheet for use by trained personnel. The requester recommends an infection prevention strategy that deploys one kit per room and that implements "Hygienist Specialist Training." According to the requester, there are no existing HCPCS codes that identify the disinfection method used by PerfectCLEAN products.

CMS HCPCS Preliminary Decision:

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

Medicare Payment:

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

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with CMS' preliminary decision. The speaker claimed that Micrillon PerfectCLEAN products are not janitorial products, rather they should be considered infection prevention products. A HCPCS code would enable tracking of this product. The speaker stated that the PerfectCLEAN with Micrillon Infection Prevention Kit® is distinct from all environmental surface cleaning supplies, and further, it is classified by hospital purchasing agents and GPOs as an Infection Prevention product in a category separate from cleaning supplies.

HCPCS Public Meeting Agenda Item #14
May 25, 2011

Attachment# 11.064

Topic/Issue:

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

Background/Discussion:

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

CMS HCPCS Preliminary Decision:

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

Medicare Payment:

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

Summary of Primary Speaker Comments at the Public Meeting:

The applicant submitted written comments stating that the FDA created a new product code for closed system transfer devices and the FDA confirms that CSTD technology is distinct from

fluid transfer systems, and as such, a new HCPCS code is warranted. [The FDA documentation however; does not reflect these claims.]

HCPCS Public Meeting Agenda Item #15
May 25, 2011

Attachment# 11.082

Topic/Issue:

Request to establish a code for a dural sealant, Trade Name: DuraSeal Xact Sealant System. Applicant's suggested language: "DuraSeal Xact, polyethethylene glycol (PEG), surgical sealant system, per unit".

Background/Discussion:

According to the requester, DuraSeal Xact is a synthetic, absorbable hydrogel used for dural sealing to prevent cerebral spinal fluid (CSF) leaks of the dura mater. It is indicated as an adjunct to sutures for repair in spine surgery. DuraSeal Xact is sprayed onto a target tissue site as a two-component liquid system through an applicator attached to two syringes. During application, the two liquids mix and react to form a flexible, absorbable hydrogel suitable for sealing the dura mater. DuraSeal Xact is supplied as a kit containing two pre-filled syringes, a powder vial, and an applicator. The powder vial contains PEG, which is reconstituted by the first syringe to create a PEG ester solution. The second syringe contains a trilysine amine solution polymerization to form a biocompatible absorbable hydrogel. According to the requester, there is no existing code to describe a PEG formulation or item used to seal CSF leaks.

CMS HCPCS Preliminary Decision:

HCPCS Level II is not the appropriate coding jurisdiction for this product that is used as an adjunct to spinal surgery. CMS suggests that the applicant contact the American Medical Association (AMA) for CPT coding guidance.

Medicare Payment:

If payment were made for these services, we believe it may be included in some other Medicare service or procedure.

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item #16
May 25, 2011

Attachment# 11.081

Topic/Issue:

Request to establish a code for a hysteroscopic tissue morcellator and removal device, Trade Name: MyoSure™ Tissue Removal Device.

Background/Discussion:

According to the requester, MyoSure™ tissue morcellator and removal device is a single-patient use device used in a physician's office in conjunction with a hysteroscope for intrauterine procedures. MyoSure™ enables incision less, fast and safe removal of submucosal fibroids to provide effective relief of abnormal uterine bleeding symptoms. It suctions, resects, and aspirates tissues from the intrauterine cavity into a vacuum canister tissue trap for pathological examination. Upon completion of the procedure, the MyoSure™ is discarded. MyoSure™ is comprised of a morcellator hand piece that features a suction tube, drive cable, drive mechanism and a rotating/reciprocating inner cutter tube encased in an outer tube which features a side-facing cutting window. The MyoSure™ drive cable is connected to an electrical control box which powers the device and its suction tube is connected to a vacuum source that aspirates resected tissue. According to the requester, there are no medical supply or medical equipment direct practice inputs included in CPT 58561 "HYSTEROSCOPY, SURGICAL; WITH REMOVAL OF LEIOMYOMATA". In addition, there is no existing HCPCS code to describe the MyoSure™. While miscellaneous codes exist, they do not allow for automation of claims processing, specific payer and provider contract administration and utilization data gathering.

CMS HCPCS Preliminary Decision:

HCPCS Level II is not the appropriate coding jurisdiction for this device which is used as part of a surgical procedure. CMS suggests that the applicant contact the American Medical Association (AMA) for CPT coding guidance.

Medicare Payment:

If payment were made for these services, we believe it may be included in some other Medicare service or procedure.

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with CMS' preliminary decision. The speaker stated that the MyoSure™ Tissue Removal Device is a sterile, disposable medical device that is designed for single patient use. The speaker also stated, that many private payers and State Medicaid payers cannot administer a site of service differential in the facility setting. This results in the payers

overpaying or underpaying. The speaker commented that other devices have a CPT code and also a HCPCS Level II code, and this code request is “in keeping with the AMA’s goal to move expensive devices to HCPCS II codes”.

HCPCS Public Meeting Agenda Item #17
May 25, 2011

Attachment# 11.011

Topic/Issue:

Request to establish a code for an internal bone stabilization device, Trade Name: HyProCure®. Applicant's suggested language: "Extra-Osseous Talar Tarsal Stabilization device".

Background/Discussion:

According to the requester, HyproCure® is a metallic internal extra-osseous stabilization device. It is composed of titanium alloy and is used in pediatric, adult, and geriatric patients who suffer with symptoms relating to flexible hind foot instability. HyproCure works by stabilizing the hindfoot structures to restore alignment and prevent excessive motion and strain to the structures of the foot and ankle. This prosthetic device acts as a stent which is inserted into a naturally occurring space (sinus tarsi), eliminating excessive ankle bone motion while allowing natural motion to occur. There are six different sizes of HyproCure® depending on size of the sinus tarsi. According to the requester, HyproCure® differs from similar devices by way of design and function. Talar tarsal stabilization devices are classified into Type I, Type II A, and Type II B and this is currently the only Type II B device. It sits deeper and is placed within both the canals and sinus portions of the sinus tarsi, and is angled along the orientation of the sinus tarsi. The Type II A devices are generally inserted purely lateral to medial. In addition, the talar stabilizing portion is located in the middle third of the device as compared to Type II A devices where it is located at the tip of the device. The outer third of the HyproCure® prevents the anterior deviation of the lateral process of the talus. The advantages offered by the HyProCure® due to its unique design and function warrant a unique code.

CMS HCPCS Preliminary Decision:

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

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 HyProCure should be considered a prosthetic and assigned to a specific “L” code. This device is usually used in a hospital but is rarely and unusually used in a physician’s office (e.g. “when a patient doesn’t have insurance”).

HCPCS Public Meeting Agenda Item #18
May 25, 2011

Attachment# 11.125

Topic/Issue:

Request to establish a code for an Infant Ear Correction System. Trade Name: EarWell™.

Background/Discussion:

According to the Requester, the EarWell™ Infant Ear Correction System is a disposable device used to re-shape deformed or malformed ears in newborn infants. The device includes a combination of a TPE elastomer shell that surrounds the ear; a Posterior Conformer residing behind the ear to unlock any deformity related to the Superior Limb of the triangular Fossa and the upper third of the Anthelix; a highly flexible Conchal Former which corrects Concha Cruz and over projection of the Concha; various Retractors which correct Helical Rim and Scapha deformities; and a proprietary, hypoallergenic, advanced double-sided medical grade adhesive. These components are collectively applied to the infant's ear by a trained physician following post-natal identification and diagnosis, within the first few weeks after birth. EarWell correctly and properly reshapes the infant deformity over four to twelve weeks of therapy. Upon removal of the device at the conclusion of therapy, the ear deformity is permanently corrected. Any hearing problems emanating from the deformity are eliminated. There is a CPT code 21086 for the physician service that relates to the custom preparation of an auricular prosthesis. There is a significant amount of custom preparation of the device by the physician. CPT code 21086 references the physician fabricating the device. While in the case of EarWell™ it is more than "fitted"; it is "custom prepared". There is concern that a payer could take issue with this code because of the fabrication reference. Further, it's unclear whether EarWell™ is a prosthesis, as there are several different definitions used by government programs and payers. Thus, according to the requester, it would seem more appropriate for EarWell™ to have an assigned HCPCS code that would be matched with an appropriate CPT code to document the physician component. Application of the EarWell™ typically occurs in a physician's office examination room. However, it can be applied in hospitals and/or clinics.

CMS HCPCS Preliminary Decision:

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

Medicare Payment:

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

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item #19
May 25, 2011

Attachment# 11.087

Topic/Issue:

Request to establish a code for dose optimization analysis for infusional 5-FU, Trade Name: OnDose®.

Background/Discussion:

According to the requester, OnDose helps oncologists to optimize infusional 5-FU therapy on an individual patient basis by providing data for pharmacokinetically-guided dose adjustments for patients with colorectal cancer. Numerous studies have demonstrated that body-surface area based dosing of chemotherapy agents including 5-fluorouracil leads to widely variable system concentrations between individuals. A patient's total drug exposure is better predicted by measurement of the steady-state plasma concentration, expressed as the area under the time-concentration curve (AUC). 5-FU plasma levels correlate well with both toxicity and clinical efficacy, and optimal target therapeutic ranges have been established. Using BSA-based dosing, the optimal plasma concentration is often not achieved. Pharmacokinetic monitoring and subsequent dose-adjustment guidelines allow the target range to be reached in the majority of patients, leading to increased objective response rates, decreased toxicity, and a trend toward longer overall survival for patients with colorectal cancer. The OnDose® assay is a competitive homogenous two-reagent nanoparticle agglutination immunoassay. It is a unique service that quickly delivers quantitative 5-FU AUC results to the oncologist, allowing for dose adjustment in subsequent treatment cycles to ultimately attain the optimal therapeutic range. OnDose® is currently being billed to payors with a miscellaneous CPT code (84999) which does not allow them to specifically track the utilization of OnDose® within their system. Therefore a unique code is requested.

CMS HCPCS Preliminary Decision:

Establish Sxxxx "DOSE OPTIMIZATION BY AREA UNDER THE CURVE (AUC) ANALYSIS, FOR INFUSIONAL 5-FLUOROURACIL

Medicare Payment:

We believe that there would be no Medicare payment for this item.

Summary of Primary Speaker Comments at the Public Meeting:

The applicant provided comments in support of CMS' preliminary decision.

HCPCS Public Meeting Agenda Item #19
May 25, 2011

Attachment# 11.089

Topic/Issue:

Request to establish HCPCS Level II code to identify two mutation MYH gene analysis for MYH-Associated Polyposis (MAP), Trade Name: MYH Mutation Panel.

Background/Discussion:

According to the requester, the MYH 2 mutation panel is a test that identifies 2 common mutations in the MYH gene known to cause MYH-associated polyposis (MAP). MAP causes significant polyposis to develop in a person's gastrointestinal tract which increases the risk for cancers of the colon, rectum and small intestine. MAP is inherited in an autosomal recessive manner and patients often have no family history of colon cancer or polyps in parents (although siblings may be affected). The current coding for this analysis is with genetic CPT® codes which do not allow payors to track utilization within their systems. Therefore, we request a new HCPCS Level II code specific for the MYH 2 mutation panel.

CMS HCPCS Preliminary Decision:

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

Medicare Payment:

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 #19
May 25, 2011

Attachment# 11.090

Topic/Issue:

Request to establish a HCPCS Level II code for Gene sequence and large rearrangement analysis of MSH6, Trade Name: MSH6 analysis.

Background/Discussion:

According to the requester, the MSH6 analysis is the test that identifies mutations in MSH6, one of the genes known to cause Lynch Syndrome (HNPCC). There are currently five genes known to cause Lynch Syndrome (MLH1, MSH2, MSH6, PMS2 and TACSTD1). There is an S code for MLH1 (S3828, Complete gene sequence analysis; MLH1 gene) and MSH2 (S3829, Complete gene sequence analysis; MLH2 gene), but MSH6 and PMS2 testing must use a modifier (OK) and some payor systems do not recognize a modifier. Additionally, since two genes use the same modifier, they are indistinguishable from a coding perspective. Therefore, we request a new HCPCS Level II code specific for MSH6.

CMS HCPCS Preliminary Decision:

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

Medicare Payment:

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 #19
May 25, 2011

Attachment# 11.092

Topic/Issue:

Request to revise the verbiage of code S3831 which currently reads: SINGLE-MUTATION ANALYSIS (IN AN INDIVIDUAL WITH A KNOWN MLH1 OR MSH2 MUTATION IN THE FAMILY) FOR HEREDITARY NONPOLYPOSIS COLORECTAL CANCER (HNPCC) GENETIC TESTING" to instead read: "Single-mutation analysis in an individual with a known Lynch Syndrome mutation in the family".

Background/Discussion:

According to the requester, existing code S3831 is specific for known mutations in MLH1 and MSH2. However, there are currently three other genes known to cause Lynch Syndrome (HNPCC), namely, MSH6, PMS2 and TACSTD1. The Single Site COLARIS® test analyzes a known familial mutation in a Lynch Syndrome gene through PCR-based sequencing. The proposed revision of S3831 would allow the use of the code regardless of the specific gene. The OK modifier can be used, but not all payer systems accept modifiers. The requested language change would also include the updated nomenclature of the syndrome by changing "hereditary nonpolyposis colorectal cancer (HNPCC)" to "Lynch Syndrome." According to the requester, from a coding perspective, it doesn't matter which gene is being evaluated, as the same techniques are used.

CMS HCPCS Preliminary Decision:

A national program operating need to revise HCPCS Level II code S3831 by omitting specification of MLH1 and MLH2 genes was not identified by Medicare, Medicaid or the Private Insurance Sector. CMS suggests that the applicant contact the American Medical Association (AMA) for CPT coding guidance for the genetic analysis series that is currently under way.

Medicare Payment:

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 #19
May 25, 2011

Attachment# 11.093

Topic/Issue:

Request to eliminate the 'female-only' designation from code S3820 "COMPLETE BRCA1 AND BRCA2 GENE SEQUENCE ANALYSIS FOR SUSCEPTIBILITY TO BREAST AND OVARIAN CANCER".

Background/Discussion:

According to the requester, the hereditary cancer syndrome associated with BRCA1 and BRCA2 mutations is known as hereditary breast and ovarian syndrome (HBOC) and is an autosomal dominant condition that can be inherited from either the maternal or paternal lineage. While the greatest cancer risks are borne by women, male mutation carriers are also at increased risk for cancer. While the female-only designation may have been appropriate when BRCA1 and BRCA2 testing first became available, research has found that men have increased risks for cancer and are appropriate candidates for testing. The 'female-only' designation in code S3820 creates an issue when billing a payer for testing that has been ordered for a male patient. Many times the claim is rejected citing "The procedure/revenue code is inconsistent with the patient's gender" and requires approval.

CMS HCPCS Preliminary Decision:

The language of existing code S3820 "COMPLETE BRCA1 AND BRCA2 GENE SEQUENCE ANALYSIS FOR SUSCEPTIBILITY TO BREAST AND OVARIAN CANCER" is not gender specific. Inquiries regarding a female-only designation that is based in insurer policy should be addressed to the individual insurer that developed the policy.

Medicare Payment:

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 #19
May 25, 2011

Attachment# 11.094

Topic/Issue:

Request to eliminate the 'female-only' designation from code S3823 "THREE-MUTATION BRCA1 AND BRCA2 ANALYSIS FOR SUSCEPTIBILITY TO BREAST AND OVARIAN CANCER IN ASHKENAZI INDIVIDUALS".

Background/Discussion:

According to the requester, the hereditary cancer syndrome associated with BRCA1 and BRCA2 mutations is known as hereditary breast and ovarian syndrome (HBOC) and is an autosomal dominant condition that can be inherited from either the maternal or paternal lineage. While the greatest cancer risks are borne by women, male mutation carriers are also at increased risk for cancer. While the female-only designation may have been appropriate when BRCA1 and BRCA2 testing first became available, research has found that men have increased risks for cancer and are appropriate candidates for testing. The 'female-only' designation in code S3823 creates an issue when billing a payer for testing that has been ordered for a male patient. Many times the claim is rejected citing "The procedure/revenue code is inconsistent with the patient's gender" and requires approval.

CMS HCPCS Preliminary Decision:

The language of existing code S3823 "THREE MUTATION BRCA1 AND BRCA2 ANALYSIS FOR SUSCEPTIBILITY TO BREAST AND OVARIAN CANCER IN ASHKENAZI INDIVIDUALS" is not gender specific. Inquiries regarding a female-only designation based on the insurer policy should be addressed to the individual insurer that developed the policy.

Medicare Payment:

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 #19
May 25, 2011

Attachment# 11.091

Topic/Issue:

Request to establish a HCPCS Level II code for a test that identifies large rearrangements in the BRCA1 and BRCA2 genes, Trade Name: BRACAnalysis® Rearrangement Test (BART)™.

Background/Discussion:

According to the requester, the BART™ is a laboratory test that analyzes rearrangements in the BRCA1 and BRCA2 genes that are not detected through standard PCR-based sequencing of the genes. This large rearrangement analysis is commercially known as the BRACAnalysis® Rearrangement Test (BART™). Large rearrangements are thought to represent approximately 8-18% of all deleterious mutations in BRCA1 and BRCA2. Just like point mutations in BRCA1 and BRCA2, these mutations lead to hereditary breast and ovarian cancer syndrome (HBOC) which is an autosomal dominant condition that can be inherited from either the maternal or paternal lineage. As more and more individuals are identified and tested for mutations in BRCA1 and BRCA2, the requests for large rearrangement analysis in addition to standard sequencing have grown. Full sequence analysis of BRCA1 and BRCA2 can be uniquely coded using HCPCS code S3820. However, there is no unique S code for BART™ thereby making it difficult for payors to track the utilization in their systems. Therefore, the requester is seeking a unique S code for BART™.

CMS HCPCS Preliminary Decision:

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

Medicare Payment:

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 #19
May 25, 2011

Attachment# 11.095

Topic/Issue:

Request to revise the verbiage of code S3830 which currently reads: "COMPLETE MLH1 AND MSH2 GENE SEQUENCE ANALYSIS FOR HEREDITARY NONPOLYPOSIS COLORECTAL CANCER (HNPCC) GENETIC TESTING" to instead read: "'Complete MLH1, MSH2, MSH6, PMS2 and TACSTD1 gene analysis for Lynch Syndrome genetic testing".

Background/Discussion:

According to the requester, existing code S3830 is specific for genetic analysis of MLH1 and MSH2. However, there are currently three other genes known to cause Lynch Syndrome (HNPCC), namely, MSH6, PMS2 and TACSTD1. The proposed revision of code S3830 will allow its use when complete Lynch Syndrome analysis is ordered. COLARIS® is a test that analyzes the MLH1, MSH2, and MSH6 genes for mutations known to cause Lynch Syndrome through PCR-based sequencing and quantitative multiplexed PCR. In April 2011, PMS2 and TACSTD1 analysis will be added to the test performed at Myriad Genetic Laboratories, Inc. PMS2 and TAACSTD1 are already performed in other laboratories. Additionally, the proposed language change would update the nomenclature of the syndrome by changing “HNPCC” to "Lynch Syndrome." According to the requester, the CPT codes used are generic for any type of molecular genetic testing, so the payers are not able to track the utilization within their systems. The OK or QP modifiers can be used, but not all payer systems accept modifiers.

CMS HCPCS Preliminary Decision:

A national program operating need to revise HCPCS Level II code S3830 was not identified by Medicare, Medicaid or the Private Insurance Sector. CMS suggests that the applicant contact the American Medical Association (AMA) for CPT coding guidance for the genetic analysis series that is currently under way.

Medicare Payment:

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 #20
May 25, 2011

Attachment# 11.126

Topic/Issue:

Request to: 1) revise existing code S9900 which currently reads: SERVICES BY AUTHORIZED CHRISTIAN SCIENCE PRACTITIONER FOR THE PROCESS OF HEALING, PER DIEM; NOT TO BE USED FOR REST OR STUDY; EXCLUDES IN-PATIENT SERVICES," to instead read: "Service by a journal-listed Christian Science practitioner for the purpose of healing;" and 2) establish 3 new codes for religious non-medical health care. Applicant's suggested language:

Code 1 "Religious non-medical health care institution (RNHCI) services in lieu of hospitalization, per diem"

Code 2 "Religious non-medical health care institution (RNHCI) nursing services in lieu of medically-prescribed skilled nursing facility services, per diem;

Code 3 "Religious non-medical nursing service, non-institutional".

Background/Discussion:

According to the requester, Christian Science practitioners treat patients using spiritual tenants and prayer in lieu of medical treatments. Existing code S9900 describes a per diem treatment and is only one of many different treatment options offered by a qualified Christian Science practitioner. The proposed revision to the language of code S9900 would: describe a system of healing that is spiritually based rather than medically based; enable broader use of the code by journal-listed practitioners; and eliminate a designated unit of service. The 3 additional codes requested are needed to better reflect the settings, time and resources in providing Christian Science Care.

CMS HCPCS Preliminary Decision:

A national program operating need to revise code S9900 or to establish the requested new codes 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:

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.

PAYMENT FOR DMEPOS

DMEPOS

The term DMEPOS, which stands for durable medical equipment (DME), prosthetics, orthotics and supplies, is used in the Medicare program to describe a set of Medicare Part B device and supply benefits for which claims are processed by four DME Medicare Administrative Contractors (DME MACs). The Part B device benefits covered by this term include:

- DME – equipment used in the home which can withstand repeated use, is primarily and customarily used to serve a medical purpose, and is generally not useful in the absence of an illness or injury;
- Prosthetic Devices – devices that replace all or part of an internal body organ, including ostomy, tracheostomy and urological supplies, parenteral and enteral nutrients, equipment and supplies (PEN), intraocular lenses (IOLs), and one pair of conventional eyeglasses or contact lenses after each cataract surgery;
- Prosthetics – artificial legs, arms, and eyes;
- Orthotics – rigid or semi-rigid leg, arm, back, and neck braces;
- Home Dialysis Supplies and Equipment
- Surgical Dressings
- Therapeutic Shoes and Inserts

Depending on the item or the setting in which the item is furnished, Medicare claims for some of these items may also be processed by local carriers, fiscal intermediaries and A/B MACs(e.g., claims for DME implanted in an ambulatory surgical center are processed by local carriers). Claims for DME and ostomy, tracheostomy and urological supplies furnished by a home health agency are processed by Regional Home Health Intermediaries (RHHIs)and A/B MACs.

Fee Schedule Payments

Prior to January 1, 1989, payment for most DMEPOS items and services was made on the basis of the reasonable charge methodology. Reasonable charges are calculated using suppliers' charges and are limited by an inflation adjustment factor. Payment is still made on a reasonable charge basis for home dialysis supplies and equipment and for IOLs inserted in a physician's office. There is a monthly limit per beneficiary on payments for home dialysis supplies and equipment. Payment for most of the other DMEPOS items and services is based on the lower of the actual charge for the item or a fee schedule amount. The Part B deductible and 20 percent coinsurance both apply to the DMEPOS items and services described above.

The Social Security Act requires that the DMEPOS fee schedule amounts be established based on average reasonable charges made during a base period (e.g., July 1, 1986 thru June 30, 1987 for prosthetic devices, prosthetics and orthotics). The fee schedule amounts are increased by annual update factors. Because the reasonable charge data required by the law in establishing fee schedule amounts does not exist for new DMEPOS items, the fee schedule amounts for new DMEPOS items are "gap-filled" using fees for comparable items, supplier price lists, manufacturer suggested retail prices, or wholesale prices plus a markup. The gap-filling methodology is used to estimate the average reasonable charge for the item from the base period.

DMEPOS Payment Categories/HCPCS Pricing Indicators

The Social Security Act separates DMEPOS into different Medicare payment categories, each with its own unique payment rules. The pricing indicators in the HCPCS identify which major payment category a code falls under. The pricing indicators applicable to DMEPOS are as follows:

- **Pricing = 00 Service Not Separately Priced**
  Items or services described by the HCPCS codes that are either not covered under Medicare Part B or for which payment is bundled into the payment some other Medicare service or procedure.

- **Pricing = 31 Frequently Serviced Items**
  Payment is generally made on a monthly rental fee schedule basis for items such as ventilators that require frequent and substantial servicing in order to avoid risk to the patient's health.

- **Pricing = 32 Inexpensive and Other Routinely Purchased Items**
  Payment is made on a purchase or rental fee schedule basis. This category includes items that have a purchase price of $150 or less, are generally purchased 75 percent of the time or more, or which are accessories used in conjunction with a nebulizer, aspirator, continuous airway pressure device, or intermittent assist device with continuous airway pressure device. The beneficiary has the option to acquire the item on a purchase or monthly rental basis. Total payments for the item cannot exceed the purchase fee schedule amount for the item.

- **Pricing = 33 Oxygen and Oxygen Equipment**
  Monthly fee schedule payments are made for furnishing oxygen and oxygen equipment. This monthly payment includes payment for all stationary oxygen equipment, supplies, and accessories and delivery of oxygen contents (stationary and portable). A monthly add-on to this payment is made for portable oxygen equipment only for those beneficiaries who require portable oxygen. The monthly payments for oxygen equipment cap after the 36th monthly payment is made, after

which payment for the ongoing delivery of contents continues for patient owned gaseous or liquid systems.

- **Pricing = 34 Supplies Necessary for the Effective Use of DME**
  Payment is made on a purchase fee schedule basis for supplies necessary for the effective use of DME (e.g., lancets that draw blood for use in blood glucose monitor).

- **Pricing = 35 Surgical Dressings**
  Payment is made on a purchase fee schedule basis for surgical dressings.

- **Pricing = 36 Capped Rental Items**
  Payment is made on a monthly rental fee schedule basis. For items furnished on or after January 1, 2006, the beneficiary takes over ownership of the item after the 13th rental payment is made. The rental fee for capped rental items other than power wheelchairs for each of the first 3 months of rental is equal to 10 percent of the purchase fee for the item. The rental fee for months 4 through 13 is equal to 7.5 percent of the purchase fee for the item. Effective for items furnished on or after January 1, 2011, the rental fee for power wheelchairs for each of the first 3 months of rental is equal to 15 percent of the purchase fee for the item. The rental fee for power wheelchairs for months 4 through 13 is equal to 6 percent of the purchase fee for the item. Effective for items furnished on or after January 1, 2011, only complex rehabilitative power wheelchairs can be purchased in the first month.

- **Pricing = 37 Ostomy, Tracheostomy and Urological Supplies**
  Payment is made on a purchase fee schedule basis for ostomy, tracheostomy and urological supplies.

- **Pricing = 38 Orthotics, Prosthetics, Prosthetic Devices, and Vision Services (Prosthetic Lenses)**
  Payment is made on a purchase fee schedule basis for orthotics, prosthetics, and prosthetic devices & lenses.

- **Pricing = 39 Parenteral and Enteral Nutrition (PEN)**
  Payment is made on a purchase fee schedule basis for parenteral and enteral nutrients and supplies. Payment is made on a purchase or rental fee schedule basis for parenteral and enteral equipment. The beneficiary has the option to acquire the item on a purchase or monthly rental basis.

- **Pricing = 45 Customized DME**

Payment is made for lump-sum purchase of DME that meets the Medicare regulatory definition of customized DME at 42 CFR 414.224. The payment amount is based on the carrier's individual consideration of the item.

- **Pricing = 46 Carrier Priced Item**
  For items falling under codes for miscellaneous or not otherwise classified items, the fee schedule or reasonable charge payment amount, whichever is applicable, is based on the carrier's individual consideration of the item.

- **Pricing = 52 Reasonable Charges**
  Payment continues to be made on a reasonable charge basis in accordance with Medicare regulations at 42 CFR 405.500 for blood products, transfusion medicine, splints, casts, and other devices used to reduce a fracture or dislocation, and intraocular lenses (IOLs) inserted in physician's offices.