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

Supplies and Other

Friday, May 22, 2015

Introduction and Overview

Approximately 30 people attended. The agenda included 12 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"
Friday, May 22, 2015, 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# 15.074
Request to establish a Level II HCPCS code to identify a product used to plug pleural punctures associated with percutaneous, transthoracic needle lung biopsies, Trade Name: BioSentry® Tract Sealant System. Applicant's suggested language: AXXXX Absorbable lung biopsy plug, with delivery system, each.

No Primary Speaker

AGENDA ITEM #2
Attachment# 15.067
Request to establish three new Level II HCPCS codes to identify single patient-use disposable supplies for use with Sedasys®, a Computer-Assisted Personalized Sedation (CAPS) System. Applicant's suggested language:

AXXX1 - Sterile Drug Delivery Cassette, single patient use, with direct propofol via extraction, barcode identification acceptance and T-site detection to prevent free-flow, autopriming for use with computer-assisted personalized sedation (CAPS) system.

AXXX2 - Oral/Nasal Cannula with three gas sampling ports, oral and nasal oxygen delivery, automatic detection of O2 and CO2 with earpiece for auditory messaging to patients.

AXXX3 - Bite Block with oxygen cannula opening compatible with esophageal dilator or scope used with computer-assisted personalized sedation system.

Primary Speaker: Dr. Michael Weinstein of George Washington University Medical Center

AGENDA ITEM #3
Attachment# 15.071
Request to establish a unique Level II HCPCS Q-code to identify Suction Lipoplasty System, trade name: REVOLVE™ System. Applicant's suggested language: QXXXX - REVOLVE™ System single-patient use, high-volume fat processing system.

No Primary Speaker

AGENDA ITEM #4
Attachment# 15.066

Request to establish a unique Level II HCPCS code to identify a single-use cervicometer, Trade Name: CerviLenz®.

No Primary Speaker

AGENDA ITEM #5
Attachment# 15.070
Request to establish a unique Level II HCPCS code to identify a topical liquid hydrogel used in cataract surgery and intraoperative lens placement, Trade Name: Re-Sure Sealant®

Primary Speaker: Elizabeth McMeniman of Ocular Therapeutix, Inc.

AGENDA ITEM #6
Attachment #s: 15.087, 15.088 and 15.089
Three separate, related requests, each to establish a unique Level II HCPCS code to identify one of the 3 components of the Spiration® (IBV) Valve System Reloadable Deployment Catheter System and Extended Shelf-Life for Airway Sizing Kit, marketed under the Trade Name Spiration®: (1) Valve System Airway Sizing Kit; (2) Spiration Valve, Umbrella; and (3) Deployment Catheter and Loader. Applicant's suggested language:

15.087 XXXX1 Airway sizing kit for umbrella bronchial valve, including 500µL syringe and calibrator.

15.088 XXXX2 Bronchial Valve, Umbrella

15.089 XXXX3 Deployment Catheter and Loader System, for Placement of Umbrella Bronchial Valve

Primary Speaker: Dr. Robert Kruklitis

AGENDA ITEM #7
Attachment# 15.096
Request to establish a unique Level II HCPCS code to identify a reusable (rechargeable) cooling bandage, Trade Name: Physicool.

Primary Speaker: Guy Moshe of Moshe & Associates

AGENDA ITEM #8
Attachment# 15.101
Request to establish a unique Level II HCPCS code to identify reusable, waterproof, leak and stain resistant panties, Trade Name: Vv SkiVvys.

Primary Speaker: Valerie Strange of Vv Apparel LLC

AGENDA ITEM #9
Attachment# 15.098
Request to establish a unique Level II HCPCS code to identify the CardioMEMS™ Patient Electronic System (a component of the CardioMEMS™ Heart Failure System (HF system)). Applicant's suggested language: LXXXX - Patient electronics system (external) for use with implanted pulmonary artery pressure and heart rate sensor, replacement only.

Primary Speaker: Mark Domyahn of St. Jude Medical, Inc.

AGENDA ITEM #10
Attachment# 15.093
Request to establish a unique Level II HCPCS code to identify the Intra-oral tactile biofeedback device, Trade Name: Speech Buddies®, and to consider the device Durable Medical Equipment. Applicant’s suggested language: EXXXX - Intra-oral tactile biofeedback systems and devices to teach proper tongue placement and coordination for speech training.

No Primary Speaker

AGENDA ITEM #11
Attachment# 15.097
Request to establish a unique Level II HCPCS code to identify the “CBT4CBT” web-based training program for Cognitive Behavioral Therapy. Applicant's suggested language: Use of CBT4CBT for treatment of patients with substance use disorders (SUDs).

No Primary Speaker

AGENDA ITEM #12
Attachment# 15.094
Request to establish a unique Level II HCPCS code to identify a salivary phosphate binder, Trade Name: RenaGum. Applicant's suggested language: AXXXX - Salivary phosphate binder, 50 mg.

No Primary Speaker

HCPCS Public Meeting Agenda Item #1

May 22, 2015

Attachment# 15.074

Topic/Issue:

Request to establish a Level II HCPCS code to identify a product used to plug pleural punctures associated with percutaneous, transthoracic needle lung biopsies, Trade Name: BioSentry® Tract Sealant System.

Applicant's suggested language: AXXXX Absorbable lung biopsy plug, with delivery system, each.

Background/Discussion:

Surgical Specialties Corporation submitted a request to establish a HCPCS code to identify the BioSentry Tract Sealant System. This system is intended to provide accuracy in marking a biopsy location for visualization during surgical resection and closure of pleural punctures associated with percutaneous, transthoracic needle lung biopsies. It includes a pre-formed dehydrated hydrogel plug and a delivery system designed to deploy it in the proper position. Upon deployment into the biopsy tract, the plug expands to fill the biopsy void and remains in place until resorbed. The system is furnished with two pre-formed dehydrated hydrogel plugs (in case the first plug is unusable), each mounted on a coaxial adapter; and one single-use delivery system. The plug is deployed through a 19 gauge coaxial needle, which is used in conjunction with either a 20 gauge core biopsy instrument and/or a 20 or 22 gauge fine need aspiration (FNA) biopsy needle.

The requester comments that existing codes for plugs and sealants are for specific areas of the body and cannot be used to describe a lung biopsy plug.

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 Biosentry Tract Sealant System, which is included in the procedure.

Medicare Payment:

Included in procedure.

Summary of Primary Speaker Comments at the Public Meeting:

The applicant sent in written comments that disagreed with CMS preliminary decision, stating that the BioSentry Tract Sealant System has been proven to significantly reduce the risk of pneumothoraces and the need for further interventions following a percutaneous lung biopsy. The BioSentry reduces the incidence of pneumothoraces and need for interventions to diagnose and treat that condition, including radiographs, chest tube placement, and hospitalization. You commented that the BioSentry has only recently been widely distributed in the market, and you expect that providers and payers will exhibit increased interest in using it in the coming months. In addition, you strongly encouraged CMS to establish a unique code.

for treatment of oral wounds, it ought to be included in a Medicare benefit category.

Final Decision:

The CMS HCPCS Workgroup reconvened to consider all of the input provided, and CMS revised its recommendations, as follows:

Newly established code C2613, "'Lung biopsy plug with delivery system", effective 7/1/2015, adequately describes the product that is the subject of your request and is available for assignment by insurers if they deem appropriate.

HCPCS Public Meeting Agenda Item #2

May 22, 2015

Attachment# 15.067

Topic/Issue:

Request to establish three new Level II HCPCS codes to identify single patient-use disposable supplies for use with Sedasys®, a Computer-Assisted Personalized Sedation (CAPS) System.

Applicant's suggested language:
AXXX1 - Sterile Drug Delivery Cassette, single patient use, with direct propofol via extraction, barcode identification acceptance and T-site detection to prevent free-flow, autopriming for use with computer-assisted personalized sedation (CAPS) system.

AXXX2 - Oral/Nasal Cannula with three gas sampling ports, oral and nasal oxygen delivery, automatic detection of O2 and CO2 with earpiece for auditory messaging to patients.

AXXX3 - Bite Block with oxygen cannula opening compatible with esophageal dilator or scope used with computer-assisted personalized sedation system.

Background/Discussion:

Ethicon Endo-Surgery, Inc. submitted a request to create 3 HCPCS codes to identify single-patient-use disposable supplies used with the Sedasys® system. On background, Sedasys provides comprehensive patient monitoring and oxygen delivery consistent with American Society of Anesthesiologists (ASA) Practice Guidelines for Sedation and Analgesia by Non-Anesthesiologists. This Computer-Assisted Personalized Sedation (CAPS) system is indicated for IV administration of 1% (10mg/mL) propofol injectable emulsion for initiation and maintenance of minimal to moderate sedation, as defined by the ASA Continuum of Depth of Sedation, in ASA physical status I and II adult patients undergoing colonoscopy and esophagogastroduodenoscopy (EGD) procedures. Sedasys integrates physiological monitoring and drug delivery during surgery via a computer interface which facilitates drug titration to

individual needs and provides safeguards against over-sedation. Use of Sedasys enables persons who are not trained in the administration of general anesthesia to safely achieve and maintain minimal-to-moderate sedation with propofol for indicated procedures and patients. The member of the "physician-led team" who administers sedation must be trained in managing cardiorespiratory effects of propofol when administered using CAPS. Training must include pharmacology of propfol; identifying high-risk patients; recognizing levels of sedation progression and actions necessary to return a patient to intended levels of sedation; use of capnometry and determining adequate ventilation; and managing airway obstruction and hypoventilation. The FDA restricts use of Sedasys to hospitals and/or facilities where a practitioner trained in the administration of general anesthesia is immediately available to the user for assistance or consultation as needed. State Practice Acts restrict who may legally provide sedation. The Centers for Medicare and Medicaid Services hospital Conditions of Participation at CFR 482.52 define Federal requirements of hospitals which furnish anesthesia.

The CAPS system includes 4 components: (1) Bedside monitoring Unit (BMU) which monitors the patients' blood pressure, heart rate and O2 saturation; (2) Procedure Room Unit (PRU) which provides for monitoring and display of the patients' physiologic parameters, user input of patient data, dose rate and hardware and software for propofol and oxygen delivery; (3) multiple patient-use devices (pulse oximeter, blood pressure cuff, ECG leads and an "automated responsiveness monitor" hand set for patients to squeeze on command); and (4) single-patient-use devices (drug cassette, oral/nasal cannula with ear piece, and bite block) which are the subject of this request.

This request is for one new HCPCS code to identify each single-patient use item: 1) 1% propofol interface/cassette that allows the PRU infusion pump module to extract propofol from the drug vial for patient delivery; 2) oral/nasal cannula which is the patient/device interface for oxygen delivery and serves as the collection unit for the capnometer module of the PRU to assess respiratory activity. The ear piece on the cannula provides audio input to the patient as part of the Automated Responsiveness Monitor; and 3) bite block for EGD procedures to enable proper function of the Oral/Nasal Cannula in the presence of a scope or esophageal dilator.

The requester comments that the disposable, single patient use components (oral/nasal cannula, drug delivery cassette and bite block): are distinctively designed with unique features not found in other disposables; are exclusive to CAPS; and are not described by any existing codes. As such, separate new codes are needed to ensure that providers capture all relevant charges.

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 drug delivery cassette, oral/nasal cannula, or bite block that are the subject of this request. These supplies are included in the procedure.

Medicare Payment:

Included in procedure.

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with CMS' preliminary decision; described the Sedasys Computer-Assisted Personalized Sedation (CAPS) System components and uses; and stated that disposable supplies are not included in any primary (endoscopic) procedure or moderate sedation codes, and should be valued and reimbursed separately from the procedure code. The speaker stated that "there is no way for hospitals and ASCs to be reimbursed for disposable supplies". The speaker stated that codes are also needed for tracking purposes.

Final Decision:

The CMS HCPCS Workgroup reconvened to consider all input provided and upheld its decision not to establish codes:

This request to establish Level II HCPCS codes to separately identify supplies (drug delivery cassette, oral/nasal cannula with earpiece, and bite block) has not been approved because these products are an integral part of a procedure. Payment for the procedure includes payment for these supplies, if used.

HCPCS Public Meeting Agenda Item #3

May 22, 2015

Attachment# 15.071

Topic/Issue:

Request to establish a unique Level II HCPCS Q-code to identify Suction Lipoplasty System, trade name: REVOLVE™ System.

Applicant's suggested language: QXXXX - REVOLVE™ System single-patient use, high-volume fat processing system.

Background/Discussion:

LifeCell Corporation submitted a request to establish a HCPCS code to identify the REVOLVE™ system manufactured by GID Group, Inc., a single-use, high volume fat processing system designed for use by surgeons to process harvested adipose tissue for grafting. The device filters and strains lipoaspirate during mechanical washing; mixes fat with solution, sweeps though the fat and collects stringy tissue that would clog injection and transfer syringes. Catheter tips or luer lock syringes used to extract the processed material for use for use in the following surgical specialties when the aspiration of soft-tissue is desired: plastic and reconstructive surgery, neurosurgery, gastrointestinal and affiliated organ surgery, urological surgery, general surgery, orthopedic surgery, gynecological surgery, thoracic surgery, and laparoscopic surgery. The processing must be done in a sterile field and the system should be used with a legally marketed vacuum or aspirator apparatus as a source of suction. The system processes up to 800 mL of adipose in less than 15 minutes.

The requester comments that no existing Level II HCPCS codes identify a gat grafting device. The unique design of the device offers a combination of decantation, staining, and active collagen strands removal, therefore increasing speed of processing and leading to high fat quality. For greater documentation and accuracy; to recognize the uniqueness of the device; and in recognition of the 1998 Federal Breast Reconstruction Law, a new and distinct HCPCS code is needed to identify the Revolve™ fat processing system.

Preliminary Decision:

A national program operating need was not identified by Medicare, Medicaid or the Private Insurance sector to establish a code to identify a fat processing system, which is included in the procedure.

Medicare Payment:

Included in procedure.

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

Final Decision:

The CMS HCPCS Workgroup reconvened to consider all input provided and upheld its decision not to establish codes:

This request to establish Level II HCPCS codes to separately identify supplies (drug delivery cassette, oral/nasal cannula with earpiece, and bite block) has not been approved because these products are an integral part of a procedure. Payment for the procedure includes payment for these supplies, if used.

CMS upheld its decision not to establish a code. This request to establish a Level II HCPCS code to separately identify a fat processing system has not been approved, because this system is an integral part of a procedure. Payments for the procedure include payment for a fat processing system, if used.

HCPCS Public Meeting Agenda Item #4

May 22, 2015

Attachment# 15.066

Topic/Issue:

Request to establish a unique Level II HCPCS code to identify a single-use cervicometer, Trade Name: CerviLenz®.

Background/Discussion:

CerviLenz, Inc., manufacturer of the CerviLenz (a single use device used to measure vaginal cervical length during pregnancy), submitted a request to establish a HCPCS code to identify this device. According to the requester, the CerviLenz consists of a handle with a button lock, and extending from the handle, a measurement probe with a sliding sleeve and a flange. A scale marked in millimeters is on the measurement probe near the handle. These calibrated markings correspond to vaginal cervical length, with an accuracy of +/- 1 mm. During a speculum examination, the cervicometer is inserted into the vagina toward the cervix, with the measurement probe extended beyond the flange and advanced along the lateral wall of the cervix until meeting slight resistance at the vaginal fornix. Then, the flange is advanced until it rests gently on the cervix and the measurement probe is locked. The device is removed and the measurement is read and recorded. This device is used as a screening device in the second trimester (18-24 weeks of gestation) to identify short cervix in women with singleton pregnancies who have not had a prior spontaneous preterm birth; and for women who show signs or symptoms of preterm labor.

According to the requester, a product-specific code is necessary to track utilization or outcomes.

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, which is included in the procedure.

Medicare Payment:

Included in procedure.

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

Final Decision:

CMS upheld its decision not to establish a code. This request to establish a Level II HCPCS code to separately identify a Cervicometer has not been approved, because this product is an integral part of a surgical procedure and payments for that service includes payment for the Cervicometer, if it is used.

HCPCS Public Meeting Agenda Item #5

May 22, 2015

Attachment# 15.070

Topic/Issue:

Request to establish a unique Level II HCPCS code to identify a topical liquid hydrogel used in cataract surgery and intraoperative lens placement, Trade Name: Re-Sure Sealant®

Background/Discussion:

Ocular Therapeutix, Inc. submitted a request to establish a HCPCS code to identify Re-Sure Sealant, a topical liquid hydrogel that creates a temporary sealant for intraoperative management of clear corneal incisions (up to 3.5 mm) with a demonstrated wound leak for which a temporary dry surface can be achieved, in order to prevent postoperative fluid egress from such incisions following cataract surgery with intraocular lens (IOL) placement in adults. According to the requester, Re-Sure sealant is formed by combining polyethylene glycol succinimidyl succinate (PEG SS), trilysine acetate and a diluent solution. The components, mixed by the surgeon, initiate a crosslinking reaction to form a biocompatible, absorbable hydrogel. Re-Sure Sealant is applied by the surgeon to the corneal incision as a liquid using an atraumatic foam-tipped applicator. The applicator applies a conformal coating that adheres to the ocular tissue through mechanical interlocking of the hydrogel with the tissue surfaces. The applied liquid solidifies within 20 seconds into a soft, pliable hydrogel that remains on the corneal surface for approximately 7 days. Re-Sure softens over time, detaches, and is sloughed off in tears and by movement of the eyelid over the material. The volume of a single application of Re-Sure Sealant is approximately 2.1 µL (or 2.1 mg), with up to two applications available per device, resulting in a maximum potential dose of 4.2 µL per device.

The requester comments that, while CMS ordinarily would not issue a HCPCS code for this surgical supply, as it is part of the cataract surgical package, the FDA's requirement that the manufacturer submit ongoing information should warrant a code to facilitates the research.

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, which is included in the procedure.

Medicare Payment:

Included in procedure.

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with CMS' preliminary decision stating that the ReSure Sealant is the first and currently the only ocular sealant approved by FDA. According to the speaker, the Device Exposure Registry is a prospective, multicenter, observational, single arm study intended to enroll at least 4,857 patients treated with ReSure Sealant. For Medicare reimbursement purposes, ReSure Sealant is currently considered surgical supply and not likely to receive separate reimbursement from cataract surgery bundle. The speaker stated that Ocular Therapeutix has been working in collaboration with FDA and CMS to explore different approaches to initiate Device Exposure Registry. The speaker reiterated the request for a code for tracking or research, and to accommodate the FDA post market condition for Device Exposure Registry.

Final Decision:

The CMS HCPCS Workgroup reconvened to consider all input provided and upheld its decision not to establish a code. The following modification has been made to the HCPCS Level II standard, national code set:

This request to establish a Level II HCPCS code to separately identify ReSure Sealant has not been approved, because this product is an integral part of a surgical procedure and payment for that service includes payment for ReSure Sealant if it is used.

HCPCS Public Meeting Agenda Item #6

May 22, 2015

Attachment #s: 15.087, 15.088 and 15.089

Topic/Issue:

Three separate, related requests, each to establish a unique Level II HCPCS code to identify one of the 3 components of the Spiration® (IBV) Valve System Reloadable Deployment Catheter System and Extended Shelf-Life for Airway Sizing Kit, marketed under the Trade Name Spiration®: (1) Valve System Airway Sizing Kit; (2) Spiration Valve, Umbrella; and (3) Deployment Catheter and Loader.

Applicant's suggested language:

15.087 XXXX1 Airway sizing kit for umbrella bronchial valve, including 500µL syringe and calibrator.

15.088 XXXX2 Bronchial Valve, Umbrella

15.089 XXXX3 Deployment Catheter and Loader System, for Placement of Umbrella Bronchial Valve

Background/Discussion:

Spiration Inc./Olympus Respiratory America submitted 3 separate, related requests, each to establish a HCPCS code to identify one of the 3 components of the Spiration® Valve System: (1) Airway Sizing Kit; (2) Bronchial Valve, Umbrella; and (3) Deployment Catheter and Loader. The Spiration Valve system is indicated to control prolonged air leaks following lobectomy, segmentectomy, or Lung Volume Reduction Surgery (LVRS). An air leak present on post-operative day 7 is considered prolonged unless present only during force exhalation or cough. An air leak present on day 5 should be considered for treatment if it is: 12) continuous, 2) present during normal inhalation phase of inspiration, or 3) present upon normal expiration and accompanied by subcutaneous emphysema or respiratory compromise. The Valve Systems' use is limited to 6 weeks per prolonged air leak. According to the requester, the system is a minimally invasive technology that consists of a proprietary intra-bronchial valve and deployment catheter. The umbrella-shaped valve is a one-way valve, designed to be placed in selected regions of the bronchial tree using flexible bronchoscope procedure in hospital in- and out-patient hospital settings. The valve is deployed using the deployment catheter, which is passed through the working channel of a flexible bronchoscope into segmental or sub-segmental airways leading to the areas with air leaks. The valve limits airflow to the portions of the lungs distal to an airway with a valve, while still allowing mucus and air movement in the proximal direction. The valve is removed using a flexible bronchoscope and standard bronchoscopy tools.

Each Valve system includes 1 valve contained inside a loading tool, which is attached to one deployment catheter. This assembly is packaged in a sterile tray for single patient use.

The airway sizing kit is an accessory used with a commercially available balloon catheter to determine which airway(s) lead to an air leak and to measure target airway diameters for valve sizing. Once calibrated, the sizing balloon catheter is used to isolate air leaks and size airways for placement of the Spiration Valve. The Airway Sizing Kit includes one 500µL calibration syringe with a plunger and sizing gauge. These components are packaged in a sterile tray for single patient use. The balloon catheters are not included and must be separately purchased.

The requester comments that no existing codes describe the Spiration Valve System or its individual components, and codes are needed in order for hospitals to bill and accurately track costs associated with the use of this device.

Preliminary Decision:

A national program operating need was not identified by Medicare, Medicaid or the Private Insurance sector to establish a code(s) to identify the Spiration Valve System or its component parts or accessories: the Bronchial Valve, Umbrella; Deployment Catheter and Loader; or the Airway Sizing Kit; all of which are included in the procedure.

Medicare Payment:

Included in procedure.

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with CMS' preliminary decision, stating that creating a HCPCS code for the Spiratin Valve separately from the CPT code would allow payers, physicians and hospitals to better understand the association between valve usage and clinical outcomes. The Spiration Valve System has is a designated Humanitarian Use Device (HUD) indicated to control prolonged air leaks of the lung, or significant leaks that are likely to become prolonged following lobectomy, segmentectomy or lung volume reduction surgeries. The speaker also stated that, despite the payment methodology due to the variation in number of valves used per patient case, a unique HCPCS code is required to understand the cost, treatment patterns and outcomes of Spiration Valve System procedures.

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Final Decision:

The CMS HCPCS Workgroup reconvened to consider all input provided, and upheld its decision not to establish a code:

This request to establish a Level II HCPCS code to separately identify Spiration Valve System Airway Sizing Kit has not been approved, because bronchial valve sizing is an integral part of a

surgical procedure and payments for that service includes payment for Airway Sizing Kit if it is used.

HCPCS Public Meeting Agenda Item #7

May 22, 2015

Attachment# 15.096
Topic/Issue:

Request to establish a unique Level II HCPCS code to identify a reusable (rechargeable) cooling bandage, Trade Name: Physicool.

Background/Discussion:

Physicool Ltd. submitted a request to establish a HCPCS code to identify Physicool bandages that use a reusable coolant that does not require refrigeration. The coolant consists of purified water, ethanol, glycerine, menthol, oleyl alcohol, methyl paraben, propyl paraben, imidazolidyl urea and patent blue V. According to the requester, Physicool bandages provide cooling, compression and support. Physicool works by drawing heat out through rapid evaporation, (in contrast to cryotherapy driving cool in, using products that require refrigeration). Physicool bandages are indicated for use by anyone suffering with inflammation and swelling, such as strain, or post-surgery or arthritis. Physicool is supplied as a 4 in. x 4 foot cotton bandage; a 6 in. x 5 foot cotton bandage; 500 mL bottles of Phsicool Coolant; 150mL bottles of Physicool Coolant; and in a combination pack that includes a 4 in. x 4 foot cotton bandage plus a 150ml bottle of coolant, (enough for two recharges). Each bandage recharge requires 75mL of coolant. The bandage can either be reactivated in the foil pack, or while it is on a limb for continuous application. The requester claims a significant therapeutic distinction, specifically, 50% better pain relief and ease of movement for the 1st and 2nd days post knee replacement surgery, when Physicool is used, compared with the use of cryotherapy.

The requester comments that a new HCPCS code to describe Physicool is warranted because it is not described by existing codes; and because Physicool should be distinguished, via coding, from cooling products that do not provide a totally reusable system using the evaporative process.

Preliminary Decision:

Existing code A9273 “Hot water bottle, ice cap or collar, heat and/or cold wrap, any type”, 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 primary speaker described how the Physicool product operates, and communicated that, while the code assignment is appreciated; the fee associated with the code is insufficient, particularly in reimbursement for the combination pack version of the product.

Final Decision:

The CMS HCPCS Workgroup reconvened to consider input provided at the public meeting. CMS upheld its decision:

Existing code A9273 “Hot water bottle, ice cap or collar, heat and/or cold wrap, any type”, adequately describes the product that is subject of this request.

HCPCS Public Meeting Agenda Item #8

May 22, 2015

Attachment# 15.101
Topic/Issue:

Request to establish a unique Level II HCPCS code to identify reusable, waterproof, leak and stain resistant panties, Trade Name: Vv SkiVvys.

Background/Discussion:

Vv Apparel LLC submitted a request to establish a HCPCS code to identify Vv SkiVvys, an eco-friendly, waterproof, leak and stain resistant panty for girls and women that suffer from incontinence, menorrhagia or any physical condition that requires a waterproof, leak and stain resistant panty to protect from bodily fluids secreted from the urethra, vagina or rectum. According to the requester, Vv SkiVvys have a leak resistant leg to restrict leaking of any fluids to outer clothing or furniture. Vv SkiVvys come in 5 sizes: x-small, small, medium, large and x-large; and in three styles: Sporty (bikini), Vintage (full coverage), and Vintage Plus. Vv SkiVvys are sold in individual packages containing one panty.

The requester comments that a unique code to identify Vv SkiVvys is warranted because existing codes do not describe reusable underwear for girls and women that offer complete protection (waterproof, leak and stain resistance) with a waterproof, leak resistant leg area.

Preliminary Decision:

Existing code T4536 "Incontinence product, protective underwear/pull-on, reusable, any size, each", adequately describes the product that is subject of this request.

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, stating that Vv SkiVvys are an all-over waterproof panty; not just a section of the panty. Vv SkiVvys are designed to have a leak resistant leg opening and wicking fabric inside to pull moisture away from the body. Vv SkiVvys are washable and dryable, eco-friendly, so they have a positive impact on our environment. The speaker stated that the panties are unique and satisfy a need for women who suffer from a broad range of afflictions and conditions. Three years ago, the applicant indicated that United States patent was awarded. The primary speaker also indicated that the descriptor of existing code T4536 does not adequately describe Vv SkiVvys, and that there are disparities

between Vv SkiVvys and other products in code category T4536; primarily, that Vv SkiVvys are waterproof.

Final Decision:

The CMS HCPCS Workgroup reconvened to consider input provided at the public meeting. CMS upheld its decision:

Existing code T4536 “Incontinence product, protective underwear/pull-on, reusable, any size, each”, adequately describes the product that is subject of this request.

HCPCS Public Meeting Agenda Item #9

May 22, 2015

Attachment# 15.098

Topic/Issue:

Request to establish a unique Level II HCPCS code to identify the CardioMEMS™ Patient Electronic System (a component of the CardioMEMS™ Heart Failure System (HF system)).

Applicant's suggested language: LXXXX - Patient electronics system (external) for use with implanted pulmonary artery pressure and heart rate sensor, replacement only.

Background/Discussion:

St. Jude Medical, Inc. submitted a request to establish a new HCPCS code to identify the CardioMEMS™ Patient Electronic System (PES), a component of the CardioMEMS Heart Failure System (HF System). The CardiMEMS HF System is comprised of 3 components: an implantable wireless pressure sensor; the PES; and access to a secure database. The HF system provides pulmonary artery hemodynamic data used for monitoring and management of heart failure patients. The PES is an integral part of this system and is necessary to power the implanted sensor with radiofrequency energy; receive and convert information from the sensor into pressure waveforms, PA pressure values and heart rate measurements; and transmit these hemodynamic data to the secure database. The HF is indicated for patients who have been hospitalized for HF in the previous year.

The requester comments that all components are included with the HF system at the time of initial implant, however; a new HCPCS code is needed to identify a replacement PES.

Preliminary Decision:

A national program operating need to was not identified by Medicare, Medicaid or the Private Insurance sector to establish a code to separately report an item or replacement item that is included in the practice expense.

Medicare Payment:

Coverage and payment based on contractor discretion.

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with CMS' preliminary decision. The speaker stated that a significant programmatic need exists for replacement Patient Electronics System (PES) to enable ongoing utility of the CardioMEMS HF System for patients suffering with NYHA Class III heart failure. The PES is not reflected in any current CPT-4 or HCPCS code. The system is not functional without PES. According to the speaker, the system has been determined to provide a substantial clinical improvement over existing therapies based on reduction in HF hospitalizations. The speaker requests a unique code be established for the PES replacement.

Final Decision:

The CMS HCPCS Workgroup reconvened to consider all input provided and upheld its decision not to establish a code, citing insufficient sales volume, as follows:

The reported sales volume is insufficient to support a request for a revision to the National code set. In accordance with HCPCS coding criteria as published on CMS' HCPCS website, there must be sufficient claims activity or volume, as evidence by three months of marketing activity, so that adding a new code enhances the efficiency of this system and justifies the administrative burden of adding a code. CMS' will be happy to consider an application in a subsequent coding cycle if sales volume increase substantially in the meantime, for coding guidance, contact the insurer in whose jurisdiction a claim will be filed.

HCPCS Public Meeting Agenda Item #10

May 22, 2015

Attachment# 15.093
Topic/Issue:

Request to establish a unique Level II HCPCS code to identify the Intra-oral tactile biofeedback device, Trade Name: Speech Buddies®, and to consider the device Durable Medical Equipment.

Applicant's suggested language: EXXXX - Intra-oral tactile biofeedback systems and devices to teach proper tongue placement and coordination for speech training.

Background/Discussion:

Articulate Technologies, Inc. submitted a request to establish a HCPCS code to identify Speech Buddies® handheld intra-oral tactile biofeedback devices. These are tools that appear similar to dental pick or toothbrush handles that have on the tip a specific lingual target and dental stop that enables a client to feel correct tongue placement and movement in order to refine motor speech behaviors to achieve the correct target sound. It is an aid in the remediation of speech disorders. Each device is designed to help with a specific phoneme, or sound ("s", "r", "sh", "ch", "l"). The tip of Speech Buddy is temporarily placed in the client's mouth to train specific tongue placement during speech or sound production. The lingual targets on each device teach exact placement of the tip of the tongue in order to pronounce a certain sound. Speech Buddies is supplied in a professional set of 5 different devices for "s", "r", "sh", "ch", and "l" sounds; and also as individual devices for one specific sound.

The requester comments that existing codes do not adequately describe Speech Buddies.

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, which is included in CPT for professional services.

Medicare Payment:

Included in procedure.

Summary of Primary Speaker Comments at the Public Meeting:

The applicant provided written comments disagreeing with our preliminary decision, commenting that " Medicaid and Private Insurers who bear much of the financial responsibility for covering the remediation of speech disorders" have a need for a code to identify the subject

product; and that you anticipate publication of several peer-reviewed studies which you feel "will improve a future application." You also requested clarification that the Speech Buddies® can be bundled into CPT codes such as 92507.

Final Decision:

The CMS HCPCS Workgroup reconvened to consider all input provided and upheld its decision not to establish a Level II HCPCS code.

This request to establish a Level II HCPCS code to identify an Intra-Oral Biofeedback device has not been approved, because the device is not appropriate for inclusion in the HCPCS Level II code set.

HCPCS Public Meeting Agenda Item #11

May 22, 2015

Attachment# 15.097

Topic/Issue:

Request to establish a unique Level II HCPCS code to identify the "CBT4CBT" web-based training program for Cognitive Behavioral Therapy.

Applicant's suggested language: Use of CBT4CBT for treatment of patients with substance use disorders (SUDs).

Background/Discussion:

CBT4CBT submitted a request to establish a HCPCS code to identify the CBT4CBT web-based training program for cognitive behavioral therapy. This program teaches cognitive and behavioral skills demonstrated to reduce substance use in patients diagnosed with Substance Abuse Disorders (SUDs). The program is self-guided, web-based software that uses narratives, videos and exercises to teach and reinforce a variety of cognitive and behavioral skills that are specific for helping people to reduce substance abuse. CBT teaches skills and strategies to help people understand patterns of use; recognize and deal with craving; address thoughts about substance use that can lead to relapse; effectively refuse offers of alcohol or drugs; change patterns of thinking and decision making that can lead to relapse; problem-solving; and HIV risk reduction. The goal is to break old patterns of response and replace them with new ways of responding. The typical patient has one or more substance abuse problems and will have expressed desire to address their substance use. The program consists of 7 modules, each taking about 1 hour to complete. Modules can be repeated as desired or recommended. CBT4CBT is used as part of an overall treatment program, but a clinician is not involved in the direct use of the program.

The requester comments that a new code is warranted because no existing codes describe computer-based treatment of substance abuse disorders.

Preliminary Decision:

A national program operating need was not identified by Medicare, Medicaid or the Private Insurance sector to establish a HCPCS code to identify CBT4CBT.

Medicare Payment:

Coverage and payment based on contractor discretion.

Summary of Primary Speaker Comments at the Public Meeting:

The applicant provided written comments provided indicate that Computer Based Training (CBT) is based on a broadly accepted empirically validated treatment method and is more efficacious than treatments that are reimbursed; and clinicians have not been able to use the CBT4CBT program" because there is no HCPCS code for reimbursement."

Final Decision:

The CMS HCPCS Workgroup reconvened to consider all input provided and upheld its decision not to establish a code. This request to establish a Level II HCPCS codes to identify CBT4CBT computer based training has not been approved, because this product is not primarily medical in nature.

HCPCS Public Meeting Agenda Item #12

May 22, 2015

Attachment# 15.094
Topic/Issue:

Request to establish a unique Level II HCPCS code to identify a salivary phosphate binder, Trade Name: RenaGum.

Applicant's suggested language: AXXXX - Salivary phosphate binder, 50 mg.

Background/Discussion:

Mastix Medica submitted a request to establish a HCPCS code to identify RenaGum. According to the requester, RenaGum is a medical food indicated for the clinical dietary management of the metabolic imbalance associated with hypophosphatemia, an electrolyte disturbance in which there is an unusually high level of phosphate in the blood, commonly found in persons with chronic kidney disease (CKD) and end-stage renal disease (ESRD). RenaGum is indicated for persons with CKD/ESRD to help maintain normal phosphate levels. Each RenaGum chewing gum tablet contains 50mg chitosan, a naturally occurring polysaccharide which binds with the high levels of phosphorus in the person's saliva. The usual dose is to chew one piece of RenaGum for 15 minutes after a meal (not on an empty stomach), and then discard when done. RenaGum offers a different mechanism of action to bind phosphate than phosphate-binding drugs, and is used in conjunction with the drugs, not as a replacement.

Preliminary Decision:

Existing code A9152 "Single vitamin/mineral/trace element, 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:

There was no primary speaker for this item.

Final Decision:

CMS upheld its decision that existing code A9152 "Single vitamin/mineral/trace element, oral, per dose, not otherwise specified", adequately describes the product that is subject of this request.

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.