Draft

Centers for Medicare & Medicaid Services (CMS) Healthcare Common Procedure Coding System (HCPCS) Public Meeting Agenda for Supplies and "Other"
Wednesday, May 29, 2013, 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# 13.010
Request to establish 9 Level II HCPCS codes to identify a heated water vapor humidifier with integrated flow source device, and its accessories and disposable components, for use with humidified nasal high flow (NHF) therapy. Trade Name: myAIRVO.

AGENDA ITEM #2
Attachment# 13.068
Third request to establish a new Level II HCPCS code to identify a nasal respiratory positive airway pressure device, Trade Name: Provent® Sleep Apnea Therapy.

AGENDA ITEM #3
Attachment# 13.072
Request to establish a new Level II HCPCS code to identify a portable liquid oxygen unit stand which holds a portable liquid oxygen unit in place to make it easier for a patient to complete the refill process. Trade Name: EZ-ASSIST-FILL.

AGENDA ITEM #4
Attachment# 13.009
Request to establish a new code to identify a single-use, disposable NPWT system.

AGENDA ITEM #5
Attachment# 13.056
Request to establish a new Level II HCPCS code to identify a single-use, disposable air delivery system for use with the Air Barrier System™.

AGENDA ITEM #6
Attachment# 13.070
Request to establish a new Level II HCPCS code to identify a miniaturized device designed to administer auricular point stimulation treatment over several days. Trade name: P-STIM.

AGENDA ITEM #7
Attachment# 13.057
Request to establish a new Level II HCPCS code to identify an external electromagnetic transponder used with the Calypso® system, placed on the skin to monitor respiratory and other patient motion during radiation therapy, Trade Name: Surface Beacon® Transponder.

AGENDA ITEM #8
Attachment# 13.069 A and B
Request to establish two new Level II HCPCS codes: one code (Request #13.069A) - to identify a Tumor Treating Fields (TTFields) Electronic Field Generator and System Components, trade name: NovoTTF-100A; and one code (Request #13.069B) to identify the Insulated Transducer Array for use with the TTFields device.

AGENDA ITEM #9
Attachment# 13.081
Request to establish a new Level II HCPCS code to identify a remote blood glucose monitoring device that communicates with an external insulin pump, Trade Name: mySentry™ Remote Glucose Monitor.

AGENDA ITEM #10
Attachment# 13.065
Request to establish a new Level II HCPCS code to identify a voice monitoring system that provides auditory and/or vibratory feedback (cueing) and monitoring (data collection) for persons who are cognitively unaware of their vocal loudness. Trade Name: VocaLog® Vocal Activity Monitor

AGENDA ITEM #11
Attachment# 13.051
Request to establish a new Level II HCPCS code to identify an internet cloud-based personal health record and storage and retrieval system. Trade Name: WellCase Emergency™.

AGENDA ITEM #12
Attachment# 13.075
Request to establish a new Level II HCPCS code to identify customized, off-loading diabetic shoe inserts. Trade Name: TrueContour®

AGENDA ITEM #13
Attachment# 13.066
Request to establish a new Level II HCPCS "E" code to identify the Flexible Foot Lift (FFL) as DME. Trade Name: KX2 Foot Lift Device.

AGENDA ITEM #14
Attachment# 13.016
Request to establish new level II HCPCS code to identify a brush system used in the shower to clean, soothe, stimulate and massage feet without having to bend. Trade Name: FootMate™.

AGENDA ITEM #15
Attachment# 13.061
Request to establish a single new Level II HCPCS code for a standing platform that transmits high-frequency, low-intensity stimulation through a person's feet and up through the skeleton. Trade Name: Juvent 1000N.

AGENDA ITEM #16
Attachment# 13.078
Request to establish a new Level II HCPCS code to identify an elastic band with a plastic connector for attachment to the Ponto sound processor, Trade Name: Ponto Soft Band.

AGENDA ITEM #17
Attachment# 13.050
Request to establish 4 new Level II HCPCS codes to identify 4 separate kits of materials and supplies compatible for use with the CASTBUSTER™ cast removal system.

AGENDA ITEM #18
Attachment# 13.001
Request to establish a code for adult protective underwear in a size that fits up to 80", trade name Sure Care™ Protective Underwear.

AGENDA ITEM #19
Attachment# 13.062
Fifth request since 2009 for CMS to establish new Level II HCPCS codes to identify a liquid medication dispenser, trade names: Medibottle and the Medibottle+acc21000.

AGENDA ITEM #20
Attachment# 13.030
Request to establish a new Level II HCPCS code to identify a bioadherent oral gel, Trade Name: GELCLAIR®.

AGENDA ITEM #21
Attachment# 13.067
Request to establish 2 new Level II HCPCS code to identify the Madison Oral Strengthening Therapeutic (MOST) device.

AGENDA ITEM #22
Attachment# 13.080
Request to establish a new Level II HCPCS code to identify a fiber mattress overlay, Trade Name Aiartex® Mattress Overlay.

AGENDA ITEM #23
Attachment# 13.058
Request to establish 4 new Level II HCPCS codes to identify bedding products made of silk-like fabrics that provide "a generally cleaner, drier, smoother surface than the traditional cotton-blend fabrics, thus minimizing friction between the skin and fabric". Trade Name: DermaTherapy® Bedding.

AGENDA ITEM #24
Attachment# 13.019
Request to establish a new Level II HCPCS "Q" code to identify a bovine collagen gel wound filler. Trade Name: "Excellagen".

AGENDA ITEM #25
Attachment# 13.063
Request to establish a new Level II HCPCS code to identify eye tracking technology that enables a patient to use their eye movement to control a computer as if they were using a mouse. Trade Names: CEye.

Attachment# 13.064
Request to establish a new Level II HCPCS code to identify eye tracking technology that enables a patient to use their eye movement to control a computer as if they were using a mouse. Trade Names: PCEye.

AGENDA ITEM #26
Attachment# 13.007
Request to establish a Level II HCPCS code to identify a single-use, disposable weighted Speculum holder for use in gynecological procedures.

AGENDA ITEM #27
Attachment# 13.052
Request to establish a Level II HCPCS code to identify individualized lactation assessment and management services provided by International Board Certified Lactation Consultants (IBCLCs).

AGENDA ITEM #28
Attachment# 13.055
Request to establish a new Level II HCPCS code to identify magnetic resonance image guided robotic acoustic surgery.

AGENDA ITEM #29
Attachment# 13.053
Request to establish a Level II HCPCS code to identify a corneal endothelium delivery instrument.

HCPCS Public Meeting Agenda Item #1
May 29, 2013

Attachment# 13.010
Topic/Issue:

Request to establish 9 Level II HCPCS codes to identify a heated water vapor humidifier with integrated flow source device, and its accessories and disposable components, for use with humidified nasal high flow (NHF) therapy. Trade Name: myAIRVO. Applicant's suggested language:

XXX1 Heated water vapor humidifier with integrated flow source and alarms

XXX2 Bedside support stand for 'heated water vapor humidifier with integrated flow source and alarms'

XXX3 Heated breathing tube with internal heater wire and integrated temperature sensor for 'heated water vapor humidifier with integrated flow source and alarms'

XXX4 Heated breathing tube with internal heater wire and integrated temperature sensor kitted with Auto-fill water chamber for 'heated water vapor humidifier with integrated flow source and alarms'

XXX5 Auto-fill water chamber for 'heated water vapor humidifier with integrated flow source and alarms'

XXX6 Refill-able water bag for 'auto-fill water chamber'

XXX7 Nasal cannula interface for 'heated breathing tube with internal heater wire and integrated temperature sensor'

XXX8 Tracheostomy interfaces for 'heated breathing tube with internal heater wire and integrated temperature sensor'

XXX9 Mask adapter interface for 'heated breathing tube with internal heater wire and integrated temperature sensor'

Background/Discussion:

According to the requester, the heated water vapor humidifier with integrated flow source device and its accessories and disposable components is a system designed to deliver 15 to 45 L/min of respiratory gas humidified to close to 100% relative humidity at body temperature, via a range of nasal, tracheostomy or mask interfaces. The system is indicated to provide airway hydration and

respiratory support for persons who are spontaneously breathing AND EITHER: suffer from COPD and/or Bronchiectasis and have copious secretions and have had more than one exacerbation in the previous 12 months; OR have a bypassed upper airway such as a tracheostomy or laryngectomy and are required to receive humidification and/or respiratory therapy with or without supplementary oxygen. The requestor claims that there are significant therapeutic distinctions between the myAIRVO device and Nebulizers used with water or saline, and CPAP machines with humidifiers; and therefore that existing HCPCS codes do not describe the myAIRVO device, citing the following reasons: 1) existing codes for oscillation and cough stimulation devices do not identify the dual mechanisms (humidification and respiratory support provided by myAIRVO; 2) existing codes for humidifiers and respiratory assist devices with bi-level pressure capability (and related accessories) describe devices that provide humidification for comfort and compliance, but they do not describe devices that provide 100% relative humidity at body temperature; 3) existing nebulizer codes describe devices/accessories related to the delivery of aerosolized water particles, but none of these deliver water in vapor form and/or high relative humidity; 4) existing codes for oxygen and water vapor enrighing system describe devices used primarily for oxygen therapy, and not devices intended for use with or without supplementary oxygen and that the primary benefits are independent of supplemental oxygen delivery; 5) the existing code for heat and moisture exchange (HME) systems is for passive systems and only for patients who have a bypassed upper airway, and is not intended for long-term use and there is no evidence that it could produce airway hydration and respiratory support benefits.

Preliminary Decision:

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

Medicare Payment:

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

HCPCS Public Meeting Agenda Item #2
May 29, 2013

Attachment# 13.068
Topic/Issue:

Third request to establish a new Level II HCPCS code to identify a nasal respiratory positive airway pressure device, Trade Name: Provent® Sleep Apnea Therapy. Applicant's suggested language: AXXXX or LXXXX "Nasal Expiratory Positive Airway Pressure (EPAP) Device, per box of 30 pairs."

Background/Discussion:

The Provent® Sleep Apnea Therapy device consists of a small adhesive patch that surrounds a one-way valve. Each night, the patient sticks a device on each nostril. The devices are for use during sleep, and are discarded after single use. According to the requester, the Provent® Sleep Apnea Device is engineered to utilize the patient's own airway to keep the airway open during sleep. The valve acts as a one-way resistor, permitting nearly unobstructed inspiration. During expiration, the airflow is directed through small air channels (one-way valves), increasing resistance and creating Expiratory Positive Airway Pressure (EPAP). Use of the nasal EPAP decreases the Apnea Hypopnea Index (AHI), improving sleep quality and decreasing sleepiness. The Provent is indicated for the treatment of mild, moderate and severe Obstructive Sleep Apnea (OSA), and is an alternative for treating patients who refuse, reject or are intolerant of Continuous Positive Airway Pressure (CPAP) therapy. The applicant comments that the "Provent passes all of Medicare's tests for appropriate classification as a prosthetic device". It corrects the dysfunctional oropharynx through dilation by generating pressure during expiration with carryover of this dilation into inspiration; and expansion of lung volume, which increases traction on the trachea and upper airway, increasing tone in the oropharynx, which opens the airway. According to the requester, there is no existing HCPCS category to describe this device.

Preliminary Decision:

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

Medicare Payment:

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

HCPCS Public Meeting Agenda Item #3
May 29, 2013

Attachment# 13.072
Topic/Issue:

Request to establish a new Level II HCPCS code to identify a portable liquid oxygen unit stand which holds a portable liquid oxygen unit in place to make it easier for a patient to complete the refill process. Trade Name: EZ-ASSIST-FILL.

Background/Discussion:

According to the requester, the EZ-ASSIST-FILL consists of a telescoping tension arm mounted on a fiberglass base with a pivot feature. The tension arm slides over the portable reservoir and holds the unit in place, leaving the patient hands-free to hold down the refill lever. The entire unit is held in place by the weight of the reservoir which rests on the base plate. There is no need to remove the reservoir from the EZ-ASSIST-FILL between uses. The device is height adjustable to accommodate all portable units that fill from the top of the stationary reservoir. The EZ-ASSIST-FILL is indicated for use by persons who are prescribed liquid oxygen and who also are unable (e.g., lack the strength) to apply the necessary downward pressure to effect the transfer connection while at the same time, holding the portable tank in place. According to the requester, this is a unique device not described by any existing HCPCS code.

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. Existing code A9900 "Miscellaneous dme supply, accessory, and/or service component of another hcpcs code" is available for assignment by insurers if they deem appropriate.

Medicare Payment:

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

HCPCS Public Meeting Agenda Item #4
May 29, 2013

Attachment# 13.009
Topic/Issue:

Request to establish a new code to identify a single-use, disposable NPWT system. Trade Name: PICO. Applicant's suggested language: Axxx ELECTICAL WOUND SUCTION PUMP DELIVERING NEGATIVE PRESSURE, DISPOSABLE, INCLUDES EXUDATE MANAGEMENT COLLECTION DRESSING, ALL ACCESSORIES AND COMPONENTS, EACH

Background/Discussion:

According to the requester, the PICO is a pocket-sized, electrical (DC) disposable, single-use NPWT system. The system removes low to moderate levels of exudate and infectious materials from acute and chronic wounds, high-risk surgical incisions and flaps and grafts by pulling air out of the dressing, creating negative pressure and drawing excess fluid from the wound into the dressing. Each PICO system can be worn for up to 7 days and delivers continuous sub atmospheric pressure of 80mm Hg to the wound surface. PICO is distinctive in its function from other NPWT systems in that it operates with an advanced proprietary exudate management collection dressing. By including a special air-flow layer designed to allow wound fluid to pass into the upper layer, moisture vapor evaporates from the special top film, thus not allowing fluid to pass into the tubing that connects to the pump.

PICO is battery operated and has a continuous mode of operation. It is supplied with two AA lithium 3 volt DC batteries. The system consist of the following: one pocket sized disposable single use pump, two exudate management collection dressings and secondary fixation strips. There is also PHMB gauze filler and foam filler available for clinicians to order if necessary.

Preliminary Decision:

Revise A9272 to read: WOUND SUCTION, DISPOSABLE, INCLUDES DRESSING, ALL ACCESSORIES AND COMPONENTS, ANY TYPE, EACH.

Code A9272, as revised, adequately describes the product that is the subject of this request.

Medicare Payment:

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

HCPCS Public Meeting Agenda Item #5
May 29, 2013

Attachment# 13.056

Topic/Issue:

Request to establish a new Level II HCPCS code to identify a single-use, disposable air delivery system for use with the Air Barrier System™.

Background/Discussion:

According to the requester, this single-use, disposable Air Delivery System includes a sterile nozzle and sterile flexible hose. The nozzle is applied on top of the incision drape, 5 cm from the incision site. The end of the air supply hose is plugged into the heap filter/blower's air exit port. Sterile air flows through the hose, through the nozzle, and directly to the incision site. This disposable unit is used with a new medical device called the Air Barrier System. The Air Barrier System (ABS) is a portable device for use during procedures in a surgical operating room that produces a directed, non-turbulent flow of air to the surgical site. Used with the Air Delivery System, it creates a high-purity zone of protective air over a surgical site to prevent infection-causing bacteria from entering a patient's body. The ABS consists of a permanent reusable filter unit and a disposable Air Delivery System. The Air Delivery System (single-use nozzle and flexible hose) is the subject of this request.

Preliminary Decision:

The single use, disposable air delivery system is institutional equipment and as such, it is not appropriate for separate billing or coding in HCPCS Level II.

Medicare Payment:

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

HCPCS Public Meeting Agenda Item #6
May 29, 2013

Attachment# 13.070
Topic/Issue:

Request to establish a new Level II HCPCS code to identify a miniaturized device designed to administer auricular point stimulation treatment over several days. Trade name: P-STIM. Applicant's suggested language: "P-STIM: percutaneous auricular neurostimulator with 3 needles; used for before and after measurements of sympathovagal balance".

Background/Discussion:

According to the requester, the P-STIM is a miniaturized device designed to administer auricular point stimulation treatment over several days. Point stimulation by the P-STIM is mainly used to treat pain. The P-STIM is a wearable device this is designed to administer continuous pulses of a low-level electrical current at the ear over several days. Electrical pulses are emitted though three selectively positioned acupunctures needles. The P-STIM is worn for four days on and three days off and is removed by the patient on the fourth day. The average patient usually requires 1-12 weeks of treatment. According to the requester, the patient population for which the device is clinically indicated is patients who suffer from diagnosis as: migraine, chronic pain (lower back or otherwise), shingles, fibromyalgia, refractory neuropathy, central sensitization disorders and PTSD.

Preliminary Decision:

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

Medicare Payment:

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

HCPCS Public Meeting Agenda Item #7
May 29, 2013

Attachment# 13.057

Topic/Issue:

Request to establish a new Level II HCPCS code to identify an external electromagnetic transponder used with the Calypso® system, placed on the skin to monitor respiratory and other patient motion during radiation therapy, Trade Name: Surface Beacon® Transponder. Applicant's suggested language: "AXXXX Electromagnetic Tissue Marker Surface, Any Type, Each".

Background/Discussion:

According to the requester, the Calypso® System Surface Beacon® Transponder is comprised of two transponder units held together with an "elbow" connector, encased in PET tubing. The two transponders are small, passive, electrical components which emit unique frequency signals. The signals determine the transponder location relative to the patient's planned treatment isocenter. The Surface Beacon® transponder is specifically developed for use with the Calypso system, which works in tandem with the transponders to continuously report the current position relative to the machine isocenter. The Surface Beacon Transponder is a disposable, multi-use device intended for single-patient use during the entire course of treatment. The requester states that existing HCPCS codes do not adequately describe the Surface Beacon® transponder because there are no codes that describe the external placement of an electromagnetic tissue marker.

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. CMS' HCPCS workgroup refers the applicant to CMS' Pass-Through application process for coding guidance for use of this device when used in HOPPS.

Medicare Payment:

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

HCPCS Public Meeting Agenda Item #8
May 29, 2013

Attachment# 13.069 A and B
Topic/Issue:

Request to establish two new Level II HCPCS codes: one code (Request #13.069A) - to identify a Tumor Treating Fields (TTFields) Electronic Field Generator and System Components, trade name: NovoTTF-100A; and one code (Request #13.069B) to identify the Insulated Transducer Array for use with the TTFields device. Applicants suggested language:

EXXXX "Tumor Treating Fields (TTFields) Electric Field Generator and System Components"; and

AXXXX "Insulated Transducer Array for use with Tumor Treating Fields (TTFields) Device".

Background/Discussion:

According to the requester, the NovoTTF-100A System is a portable, wearable, battery (or power supply) operated device which delivers TTFields therapy to a targeted tumor by means of surface transducer arrays placed on the patient's scalp. TTFields disrupt the rapid cell division exhibited by cancer cells without damaging normal brain cells. This therapy is indicated as a treatment for adult patients (22 years of age or older) with histologically-confirmed recurring Glioblastoma (GBM) in the supra-tentorial region of the brain after initial treatment of surgery, radiation and chemotherapy. The system can only be prescribed by providers who have received training and certification by the manufacturer. Treatment is initiated after the provider determines the appropriate placement of the insulated transducer array, using a current MRI. The Electric Field Generator is connected to two pairs of insulated transducer arrays (a total of 4 arrays), which are operated sequentially. The intensity of the field, the frequency of the waves, and the temperature of the transducer arrays are pre-set. This is a non-invasive treatment intended for continuous use for a minimum of 18 hours per day while the patient maintains normal daily activities. After the appropriate training, the arrays are removed by the patient, the scalp re-shaved, and new arrays are placed as hair grows back, typically two to three times per week. The typical patient will require 40 transducer arrays per month. The transducer arrays are sterile, disposable items approved for single-use only. They have a 6-month shelf life. The durable components of the NovoTTF-100A System include the Electric Field Generator, Lithium Ion Battery Pack, Battery Rack, Battery Charger, Connection Cable and Carrying Case for the device and battery (which weigh about 6 pounds together).

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 devices that are the subject of this request.

Medicare Payment:

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

HCPCS Public Meeting Agenda Item #9
May 29, 2013

Attachment# 13.081

Topic/Issue:

Request to establish a new Level II HCPCS code to identify a remote blood glucose monitoring device that communicates with an external insulin pump, Trade Name: mySentry™ Remote Glucose Monitor. Applicant's suggested language: "Wireless Remote Display Monitor, for External Sensor Augmented Insulin Infusion Pump, Includes all Accessories".

Background/Discussion:

According to the requester, the mySentry™ remote glucose monitor includes a wall unit, a power cord and a display monitor. The wall unit component stays in the child's room and is plugged into an electrical outlet. It receives data from the sensor-augmented pump at a distance of up to 6 feet. Simultaneously, the wall unit transmits the data wirelessly to the display monitor that stays with the parent (caregiver). The wall unit (in the child's room) must be within 50 feet of the display monitor (in the parent's room) in order to transmit properly. The display monitor displays is about the size of an alarm clock. It displays glucose levels and insulin delivery status. When the pump produces an alarm, the remote monitor does, too, "alerting the parent and allowing the parent to intervene." The requester states that the remote monitor is prescribed separately for use to wirelessly monitor a sensor-augmented insulin pump that has an integrated continuous glucose monitor which provides alarms when the patient's glucose level rises or drops to hyper- or hypo-glycemic range, (the MiniMed Paradigm REAL-Time Revel pump). While adult patients can take action to restore glycemic control based in the information provided by the glucose monitor, "the mySentry is a distinct device that responds to the unique clinical challenges presented, particularly at night, in patients who are children" who may experience nighttime "hypoglycemic unawareness", and who, because they are asleep, do not provide verbal or behavioral cues of hypoglycemia to parents. According to the requester, there are no other products that provide remote monitoring of a sensor augmented insulin pump. Providing information and alerts enables improved glycemic control. Multiple payers have covered this device using miscellaneous DME code E1399. "This has been an administrative burden which a new HCPCS II code would relieve".

Preliminary Decision:

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

Medicare Payment:

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

HCPCS Public Meeting Agenda Item #10
May 29, 2013

Attachment# 13.065
Topic/Issue:

Request to establish a new Level II HCPCS code to identify a voice monitoring system that provides auditory and/or vibratory feedback (cueing) and monitoring (data collection) for persons who are cognitively unaware of their vocal loudness. Trade Name: VocaLog® Vocal Activity Monitor

Background/Discussion:

According to the requester, the VocaLog® consists of a sensor which detects when and how loud a person is "voicing". The sensor is calibrated by a Speech Language Pathologist to a targeted volume for the particular patient. The device cues the person to either speak louder or less loud. The cue can either be vibration and/or an in-ear auditory alert, such as a beep. The VocaLog® has a built-in rechargeable battery and vocal recording/monitoring capabilities (of decibel levels) of up to 21 days. The recording provides quantitative data to the clinician, to identify trends and improvement in vocal intensity outside the voice therapy session (CPT 92507), and as a means of continuing voice therapy outside the clinic. The VocaLog is "specifically designed for persons with Parkinson's disease who develop hypophonia (soft voice)".

Preliminary Decision:

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

Medicare Payment:

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

HCPCS Public Meeting Agenda Item #11
May 29, 2013

Attachment# 13.051
Topic/Issue:

Request to establish a new Level II HCPCS code to identify an internet cloud-based personal health record and storage and retrieval system. Applicant's suggested language: WellCase Emergency™ internet cloud-based Personal Health Record, including medical information, advance directive storage and retrieval, photo identification, and 24-hour emergency support".

Background/Discussion:

According to the requester, WellCase Emergency™ subscription includes: a personalized emergency wallet ID card and key tags; 3 stickers (that could be used to notify medical personnel of the location of the ID card); and online personal health dashboard page including advance directive storage. The intended use is for first responders and emergency medical personnel to have access to a secure personal health profile to view the subscriber's emergency health information. The information can be accessed either by scanning a bar code; entering the URL or clicking on the wellcase.com link; or by phoning the 24-hour emergency support line. Upon approval of a HCPCS code, "WellCase plans to pursue integration with Medicare's Blue Button." According to the requester, a WellCase dashboard is useful in the absence of an emergency situation to input and update health information, but its intended use is to communicate personal health information during emergency events.

Preliminary Decision:

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

Medicare Payment:

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

HCPCS Public Meeting Agenda Item #12
May 29, 2013

Attachment# 13.075
Topic/Issue:

Request to establish a new Level II HCPCS code to identify customized, off-loading diabetic shoe inserts. Trade name: TrueContour®. Applicant's suggested language: "For diabetics only, multiple density insert, custom molded from a digital image combining the three-dimensional shape of patient's foot with off-loading modifications(s) placed relative to identified contours of measured dynamic plantar pressure distribution of patient's foot, total contact with patient's foot, including arch, base layer minimum of 3/16" material of shore A 35 or higher, includes arch filler and other shaping material, custom fabricated, each".

Background/Discussion:

According to the requester, TrueContour® diabetic shoe inserts are therapeutic insoles designed by combining the patient's unique foot shape with customized off-loading modifications based on the patient's measured plantar pressure. TrueContour® diabetic inserts relieve pressure in the forefoot. The target population is diabetic patients who have been certified by their treating physician to be in need of therapeutic shoes, inserts and/or modifications. According to the requester, inserts coded at A5513 are modeled on the shape of the patients' foot and reduce pressure at high pressure areas only by supporting the full foot surface equally. TrueContour® inserts, on the other hand, are designed with customized surface modifications to additionally transfer pressure away from regions of the forefoot which are susceptible to plantar ulcer development.

Preliminary Decision:

Existing code A5513 "For Diabetics Only, Multiple Density Insert, Custom Molded From Model of Patient's Foot, Total Contact With Patient's Foot, Including Arch, Base Layer Minimum of 3/16 Inch Material of Shore A 35 Durometer (or Higher), Includes a Minimum of 3/16 Inch Material of Shore A 35 Durometer or Higher), Includes Arch Filler and Other Shaping Material, Custom Fabricated, Each", adequately describes the product that is the subject of this request.

Medicare Payment:

The payment rules associated with the existing code apply to this product if covered.
Pricing = 38

HCPCS Public Meeting Agenda Item #13
May 29, 2013

Attachment# 13.066

Topic/Issue:

Request to establish a new Level II HCPCS "E" code to identify the Fexible Foot Lift (FFL) as DME. Trade name: KX2 Flexible Foot Lift (FFL) device. Applicant's suggested language: Exxxx Dynamic, Angle/Tension Adjustable, Dorsiflexion/eversion Assist Device for the Foot.

Background/Discussion:

According to the requester, the Flexible Foot Lift (FFL) is a lightweight dorsiflexion assistance device for persons with foot drop; eversion of the foot and extension of the toes; and plantar fasciitis. The FFL consists of an ankle cuff made of heavy material with a "stiffener to prevent collapse;" two triangle buckles and springs attached to the outside of the cuff; and 2 straps that connect between the springs and the person's shoe, sandal or bare foot. According to the requester, the FFL has the ability to straighten the angle of the foot by applying different tensions on the spring straps. According to the requester, there are no other similar products to the KX2. There are rigid AFO inserts that can be used for foot drop, but they do not provide a lift to the foot. They only hold the foot at a 90 degree angle. Existing code categories describe orthotic braces that are used to hold the ankle joint at 90 degrees in a supported position. These codes also do not describe a dynamic device that provides ambulatory assistance through lifting the foot.

Preliminary Decision:

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

Medicare Payment:

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

HCPCS Public Meeting Agenda Item #14
May 29, 2013

Attachment# 13.016
Topic/Issue:

Request to establish a new Level II HCPCS code to identify a brush system for use in the shower to clean, soothe, stimulate and massage feet; without having to bend. Trade Name: FootMate™.

Background/Discussion:

According to the requester, the FootMate® System is a complete foot care system for cleaning, soothing, stimulating, and massaging your feet every time you shower. The FootMate's wide, gentle inner brush massages soles, while stiffer outer bristles smooth rough skin and calluses, and stimulates circulation. It comes with a wall mount caddy that adheres to the shower wall and an anti-mildew retrieval rope allowing for easy use without having to bend over. It also comes with 8 ounces of foaming Rejuvenating Gel™. The patient places the product in the shower or tub, stands on one foot, places the other foot in the cradle of the brush, applies Rejuvenating Gel, and then moves the foot back and forth to clean and massage.

Preliminary Decision:

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

Medicare Payment:

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

HCPCS Public Meeting Agenda Item #15
May 29, 2013

Attachment# 13.061
Topic/Issue:

Request to establish a single new Level II HCPCS code for a standing platform that transmits high-frequency, low-intensity stimulation through a person's feet and up through the skeleton. Trade Name: Juvent 1000N. Applicant's suggested language: EXXXX "High frequency, low intensity mechanical stimulation device with automatic, active feedback and control".

Background/Discussion:

According to the requester, the Juvent 1000N is a vibrating platform, slightly larger than a typical bathroom scale that uses Juvent's patented "Dynamic Motion Therapy®" to deliver patient-specific high-frequency (32 – 37 Hz), low-intensity (0.3g signal) biomechanical stimulation through person's feet and up through the skeleton. The unit has an internal computer that uses an accelerometer to ensure and control treatment dosage and compliance. This "Smart Technology" or "Smart Sensor" automatically calibrates and adjusts the optimum frequency and power for each user, based on the person's body mass and movements. It safely accommodates persons weighing up to 250 pounds. The person stands on the platform for a 10- to 20-minutes per day for 12 to 20 weeks. According to the requester, patients with osteoporosis or sarcopenia would use the Juvent 1000N to help stimulate bone growth and muscle strength. The exogenously induced, low-intensity mechanical stimulus transmitted by the device acts as a surrogate for the muscle-derived, normal endogenous mechanical impulses that diminish due to aging or disease, which may be the cause of loss of bone mass and muscle strength. There are currently no HCPCS E codes that describe this device.

Preliminary Decision:

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

Medicare Payment:

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

HCPCS Public Meeting Agenda Item #16
May 29, 2013

Attachment# 13.078

Topic/Issue:

Request to establish a new Level II HCPCS code to identify an elastic band with a plastic connector for attachment to the Ponto sound processor, Trade Name: Ponto Soft Band. Applicant's suggested language: "Soft Band or Head Band for use with an External Sound Processor".

Background/Discussion:

According to the requester, the soft band consists of a latex-free, adjustable elastic band with a plastic connector disc for coupling to the Ponto sound processors. A sound processor attached to a soft band is used for children or other patients have conductive or mixed hearing loss and who either choose not to have a bone-anchored implant, or who are not candidates for an abutment surgically implanted in the skull, because they are under 5 years of age or have poor bone quality. It is also intended as a treatment for patients who have profound sensorineural hearing loss in one ear and normal hearing in the other ear. Physicians and audiologists prefer to provide a new soft band on a yearly basis. While existing code L8692 "Auditory Osseointegrated Device, External Sound Processor, Used Without Osseointegration, Body Worn, Includes Headband or Other Means of External Attachment" describes an osseointegrated device that includes the headband; however a code does not exist to identify the soft band alone, or replacement soft bands.

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. Existing code L7510 "Repair of Prosthetic Device, Repair or Replace Minor Parts" is available for assignment by insurers to identify a replacement head band.

Medicare Payment:

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

HCPCS Public Meeting Agenda Item #17
May 29, 2013

Attachment# 13.050
Topic/Issue:

Request to establish 4 new Level II HCPCS codes to identify 4 separate kits of materials and supplies compatible for use with the CASTBUSTER™ cast removal system. Specifically: one code for the CASTBUSTER liner for application to a forearm or wrist during cast application; one code for the CASTBUSTER liner for application to a leg or ankle during cast application; one code for the CASTBUSTER wire and handles used for removal of a forearm cast (when the CASTBUSTER liner was used); and one code for the CASTBUSTER wire and handles used for removal of a leg or ankle cast (when the CASTBUSTER liner was used).

Background/Discussion:

According to the applicant, the CASTBUSTER™ has two components: the liner, made of non-latex silicone tubing, positioned at the time of cast application, serves as a "channel" for the second component, the wire. The wire component includes an abrasive wire (currently used by orthopedic surgeons during other surgical procedures) and a pair of handles. The wire is fed through the channel, connected to the handles and, when pulled along the length of the cast, cuts through it. According to the applicant, the handles used to pull the wire can be used repeatedly (not further specified), but other components (the liners and the abrasive wires) are single use. The applicant is seeking HCPCS Level II codes to identify the CASTBUSTER components that would be billed in conjunction with CPT codes that identify the service of cast application or removal.

Preliminary Decision:

A national program operating need was not identified by Medicare, Medicaid, or the private insurance sector to establish codes to identify these devices, which are included in the cast removal procedure.

Medicare Payment:

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

HCPCS Public Meeting Agenda Item #18
May 29, 2013

Attachment# 13.001

Topic/Issue:

Request to establish a code for adult protective underwear in a size that fits up to 80", trade name Sure Care™ Protective Underwear. Applicant's suggested language: "Adult-sized disposable incontinence product, protective underwear/pull-on, extra-extra-large, each".

Background/Discussion:

According to the applicant, this protective underwear/pull-on contains paper pulp and super absorbent polymer that absorbs fluid, locks it away and helps control odors by neutralizing urine pH. It has a soft, cloth-like outer covering for comfort and dignity. This product is intended for management of moderate to heavy incontinence of urine or stool for mobile individuals who are able to change their own product and who have a waist size of 60" to 80". It is intended to be worn like regular underwear. The existing code series T4525, T4526, T4527 and T4528 describe underwear/pull-ons, however this series does not include a code for size "XXL"

Preliminary Decision:

Establish 2 codes:

TXXX1, Adult Sized Disposable Incontinence Product, Protective Brief/Diaper, Above Extra Large, Each

TXXX2, Adult Sized Disposable Incontinence Product, Protective Underwear/Pull-On, Above Extra Large, Each

Medicare Payment:

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

HCPCS Public Meeting Agenda Item #19
May 29, 2013

Attachment# 13.062
Topic/Issue:

Fifth request since 2009 for CMS to establish new Level II HCPCS codes to identify a liquid medication dispenser, trade names: Medibottle and the Medibottle+acc21000.

Background/Discussion:

According to the requester, Medibottle is a pediatric medication delivery system designed for the infant population. The Medibottle consists of a baby bottle with a medicine dispenser and a plunger that fits inside the bottle. The dose of liquid medicine is loaded into the dispenser. When the plunger is pressed, a squirt of the medicine is delivered and the baby swallows the medicine along with the familiar liquid in the bottle. It takes 25 to 30 'squirts' and about 1 minute to deliver 5 mL of liquid medication, using this system. The requester comments that use of the Medibottle improves compliance with medication regimes, and that use of the Medibottle is more effective than other methods (spoons, oral dispensers, droppers, oral syringes, medicine cups, dispenser with pacifier…) in successful delivery of the full dose of "unpalatable" medicine. The Medibottle includes a bottle for hospital and clinic use. The Medibottle+acc21000 includes the bottle, 2 oral dispensers, UBA, user instructions. The requester is asking that a "program operating need" be established for the Medibottle on the basis of its contribution to higher quality and safer care, and superior clinical outcomes, so that the Medibottle can be coded (and reimbursed) by third party payers.

Preliminary Decision:

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

Medicare Payment:

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

HCPCS Public Meeting Agenda Item #20
May 29, 2013

Attachment# 13.030
Topic/Issue:

Request to establish a new Level II HCPCS code to identify a bioadherent oral gel, Trade Name: GELCLAIR®.

Background/Discussion:

According to the requester, GELCLAIR is a viscous, concentrated oral gel, the key components of which include sodium hyaluronate, (which has unique lubricating properties); polyvinylpyrrolidone, (a water soluble polymer that forms films that can provide a protective barrier); and glycerrhetinic acid, (known to have anti-inflammatory properties). GELCLAIR's mode of action is to form a topical, adherent, protective barrier. It is indicated for the management of pain and relief of pain by adhering to the mucosal surface of the mouth, soothing oral lesions of various etiologies, including oral mucositis/stomatitis (may be caused by chemotherapy or radiation therapy), irritation due to oral surgery, traumatic ulcers caused by braces or ill-fitting dentures, or disease. It is also indicted for diffuse aphthous ulcers. The contents of one GELCLAIR packet are dissolved in 1 tablespoon of water. Three times per day the patient rinses their mouth with GELCLAIR for 1 minute or longer to coat oral tissues, gargles, and spits it out. GELCLAIR is supplied in 15 (15ml) sachets per box.

Preliminary Decision:

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

Medicare Payment:

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

HCPCS Public Meeting Agenda Item #21
May 29, 2013

Attachment# 13.067
Topic/Issue:

Request to establish 2 new Level II HCPCS code to identify the Madison Oral Strengthening Therapeutic (MOST) device.

Background/Discussion:

According to the requester, the MOST includes a custom-fit, pliable, single-patient-use mouthpiece; and a portable, reusable computer and transducer. The computer is DC battery powered. The transducer is powered via USB connection. The transducer and computer components may be purchased new or refurbished. The mouthpiece incorporates 4 or 5 bulb sensors placed at locations aligned with the key muscle groups that control swallowing. The mouthpiece connects to the transducer. The MOST provides a graphical readout of the spatial orientation and pressure exerted by the patient's tongue against the hard palate. It is used to screen and evaluate swallowing abnormalities, and also to provide a therapeutic regimen (lingual press treatment training) aimed at improving swallowing abnormalities. It is indicated for persons diagnosed with dysphagia and age-related changes in swallowing in the absence of disease. Use of the MOST requires the patient to meet with their Speech Language Pathologist for proper fitting of the oral component within the oral cavity. Once a patient has learned the routine, lingual press therapy is repeated 3 time per day, 3 days per week for 8 weeks. Follow-up may be done in the clinician's office. If the patient is not capable of doing treatment independent of a healthcare provider's assistance, MOST facilitated Isometric Progressive Resistance Oropharyngeal (I-PRO) therapy will be performed under the direct supervision of a healthcare provider specifically trained in the use of the MOST. According to the requester, there are four CPT-4 codes related to swallowing evaluation, however; these codes do not explain the fitting of the MOST to the patient's hard palate, the evaluation of the measures of the pressure sensor, nor the patient evaluation and development of the treatment regimen. No CPT codes describe or were intended for the technology or evaluation of the MOST patient information. There are no codes that describe the single-patient-use mouthpiece or the transducer and computer which are integral components of delivering clinical information used to aid treatment. There are no codes that can be used to longitudinally screen for swallowing function. There are no codes to report the portable "durable medical equipment" that can use lingual pressure measures to develop a lingual press treatment regimen, or the "durable medical equipment" used in the patient's home to evaluate and treat dysphagia or diminished swallowing function.

Preliminary Decision:

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

Medicare Payment:

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

HCPCS Public Meeting Agenda Item #22
May 29, 2013

Attachment# 13.080
Topic/Issue:

Request to establish a new Level II HCPCS code to identify a fiber mattress overlay, Trade Name Aiartex® Mattress Overlay. Applicant's suggested language: "Mono- and Multi-Filament, Porous Tridimensional Fiber Pad for Mattress"

Background/Discussion:

According to the requester, the Aiartex Overlay is composed of mono- and multi-filament fibers forming two parallel layers connected via suspensory filaments across an inner air chamber. The top porous multifilament layer maximizes skin ventilation and exudate drainage through a combination of capillary and gravity action, thereby minimizing ischemic risk to tissues and associated infections cause by skin maceration. The fiber layers allow for differing levels of skin transpiration and elastic deformity to suit a variety of body types. This malleable quality optimizes patient load distribution while providing micro-ventilation to vulnerable skin surfaces. The materials and structure of the Aiartex Overlay distinguish it from existing products and contribute to its clinical performance. This product does not meet the criteria for any existing codes currently covering Group I support surfaces. HCPCS codes for overlays (E0185, E0188, E0189 and E0199) contemplate foam, air, gel, water or sheepskin, but not the multi-layered and waterproof filament structure used in the Aiartex Overlay. The applicant claims a significant therapeutic distinction when the Aiartex is used compared with competitor's overlays. A new HCPCS code is warranted to describe this innovative new mattress overlay design.

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 item.

Medicare Payment:

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

HCPCS Public Meeting Agenda Item #23
May 29, 2013

Attachment# 13.058
Topic/Issue:

Request to establish 4 new Level II HCPCS codes to identify bedding products made of silk-like fabrics that provide "a generally cleaner, drier, smoother surface than the traditional cotton-blend fabrics, thus minimizing friction between the skin and fabric". Trade Name: DermaTherapy® Bedding. Applicant's suggested language:

AXXX1 Therapeutic linen constructed with silk-like fabric technology, polyester/nylon blend that provides a smooth support surface, free of broken or discontinuous fibers, treated with a durable antimicrobial agent, for patients with eczema and mild atopic dermatitis. Twin bed set (pillow case, flat sheet, and fitted sheet)".

AXXX2 Therapeutic linen constructed with silk-like fabric technology, polyester/nylon blend that provides a smooth support surface, free of broken or discontinuous fibers, treated with a durable antimicrobial agent, for patients with eczema and mild atopic dermatitis. Twin XL bed set (pillow case, flat sheet, and fitted sheet)".

AXXX3 Therapeutic linen constructed with silk-like fabric technology, (50% polyester, 49% nylon, 1% conductive yarns), that provides a smooth support surface, free of broken or discontinuous fibers, treated with a durable antimicrobial agent, for patients at risk for pressure ulcers and related skin break down. Twin size (pillow case, flat sheet, fitted sheet and underpad)".

AXXX4 Therapeutic linen constructed with silk-like fabric technology, (50% polyester, 49% nylon, 1% conductive yarns), that provides a smooth support surface, free of broken or discontinuous fibers, treated with a durable antimicrobial agent, for patients at risk for pressure ulcers and related skin break down. Twin-XL/hospital bed size (pillow case, flat sheet, fitted sheet and underpad)".

Background/Discussion:

According to the requester, DermaTherapy® fabrics are woven of fibers which create micro-channels that draw moisture away and dry the skin more quickly than cotton bedding. These fabrics are also designed to be smooth, minimizing friction with the skin, whether they're damp or dry. The fabrics are free of broken or discontinuous fibers, and this helps to minimize the potential for itching, irritation and abrasion of sensitive skin. DermaTherapy® fabrics are treated with a durable antimicrobial to maintain their freshness by eliminating odor-causing bacteria and fungi. They also carry a soil release finish that aids in removal of medical stains and oily stains commonly associated with skin contact. The requester claims that DermaTherapy has significant value in the home setting for beneficiaries who are afflicted with itching, skin breakdown, and skin irritation associated with eczema and mild to moderate atopic dermatitis;

and who have multiple comorbidities that may be malnourished, or have limited mobility and are high risk to develop pressure ulcers. The requester makes a claim of significant therapeutic distinction in that DermaTherapy technology 1) helps reduce the incidence of pressure ulcers in patients at risk for development for them; and 2) helps reduce the impact on persons with eczema and mild atopic dermatitis and improve their quality of life.

Preliminary Decision:

This product is not primarily medical in nature and therefore it is not appropriate for coding in HCPCS Level II.

Medicare Payment:

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

HCPCS Public Meeting Agenda Item #24
May 29, 2013

Attachment# 13.019
Topic/Issue:

Request to establish a new Level II HCPCS "Q" code to identify a bovine collagen gel wound filler, trade name: Excellagen®. Applicant's suggested language: "Excellagen Formulated Bovine Collagen Topical Gel (2.6%), per 0.5 cc".

Background/Discussion:

According to the requester, Excellagen® (formulated bovine full length fibrillin collagen gel 2.6%) is indicated for the management of wounds including: partial and full thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds (donor sites/graft, post-Moh's surgery, post laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, second degree burns and skin tears) and draining wounds. It is an acellular biological modulator designed for platelet activation (when applied to debrided wounds and in the presence of a small influx of blood), resulting in the localized release of platelet-derived growth factors that are essential to wound healing. Excellagen® also provides a substrate and scaffold for cellular adhesion, migration, and proliferation to promote granulation tissue growth. Excellagen® is supplied as a sterile gel in a package of 4 ready-to-use 1 mL glass syringes with fill volume of 0.5cc. According to the requester, a unique "Q" code is warranted because Excellagen is a "single source" product.

Preliminary Decision:

Existing code A6011, "Collagen based wound filler, gel/paste, per gram of collagen", adequately describes the product that is the subject of this request.

Medicare Payment:

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

HCPCS Public Meeting Agenda Item #25
May 29, 2013

Attachment# 13.063
Topic/Issue:

Request to establish a new Level II HCPCS code to identify eye tracking technology that enables a patient to use their eye movement to control a computer as if they were using a mouse. Trade Names: CEye. Applicant's suggested language: EXXXX "Eye Tracking Device Used In Conjunction With a Speech Generating Device That Permits Manipulation And Control of a Computer".

Background/Discussion:

According to the requester, the Tobii CEye Control Module is a clip-on eye control unit for alternative computer access. It consists of a eye tracker device that interfaces with either the Tobii C12 or C15 Augmentive and Alternative Communication (AAC) devices, (which the applicant claims are coded at E2510 "Speech Generating Device, Synthesized Speech, Permitting Multiple Methods of Message Formulation and Multiple Methods of Device Access"). There will be routine software updates to the module but these are not patient-specific. The CEye mounts under the communication device which allows patients to use their eyes to manipulate a computer with their eyes instead of their hands. It is indicated for individuals who have higher cognitive abilities, but who cannot speak and need an alternative method, like eye movement, to control a computer as if they were using a mouse, in order to communicate and/or work. The requester claims that there is no existing code that describes eye tracking devices, and [private] payers and state Medicaid programs have requested codes.

Preliminary Decision:

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

Medicare Payment:

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

HCPCS Public Meeting Agenda Item #25
May 29, 2013

Attachment# 13.064

Topic/Issue:

Request to establish a new Level II HCPCS code to identify eye tracking technology that enables a patient to use their eye movement to control a computer as if they were using a mouse. Trade Names: PCEye. Applicant's suggested language: EXXXX "Eye Tracking Device Permitting Manipulation and Control of a Computer".

Background/Discussion:

According to the requester, the Tobii PCEye Module is a clip-on eye control unit for alternative computer access. It consists of an eye tracker device that uses a standard USB port and plugs into a PC. It can be used with any PC and does not utilize the Tobii C12 or C15 Alternative Augmented Communication (AAC) devices. The PCEye docks under a PC, and provides individuals a hands-free way of controlling their computer's mouse and keyboard. It can be removed and mounted on other PCs. "There will be routine software updates to the module, but these are not patient-specific". It is indicated for individuals who have higher cognitive abilities who cannot manipulate a mouse or keyboard, but need to do so in order to communicate and/or work. According to the requester, there are no existing HCPCS codes that describe eye tracking devices, and [private] payers and state Medicaid programs have requested codes to identify these devices.

Preliminary Decision:

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

Medicare Payment:

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

HCPCS Public Meeting Agenda Item #26
May 29, 2013

Attachment# 13.007

Topic/Issue:

Request to establish a Level II HCPCS code to identify a single-use, disposable weighted Speculum holder for use in gynecological procedures.

Background/Discussion:

According to the requester, SpecSecure is a single-use disposable gynecological device consisting of a plastic body and cotton straps. The device is placed on the female patient's perineum. The straps are secured around the patient's legs, and the plastic body positively locks the weighted speculum in place during the physician's entire procedure. This relieves the physician of worrying about the speculum moving or being dislodged allowing the physician to concentrate on the procedure.

Preliminary Decision:

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

Medicare Payment:

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

HCPCS Public Meeting Agenda Item #27
May 29, 2013

Attachment# 13.052

Topic/Issue:

Request to establish a Level II HCPCS code to identify individualized lactation assessment and management services provided by International Board Certified Lactation Consultants (IBCLCs). Applicant's suggested language: "individualized lactation assessment and intervention visit furnished by an International Board Certified Lactation Consultant; each 15 minutes".

Background/Discussion:

According to the applicant, several evaluation and management CPT codes describe general services similar in structure to individualized IBCLC services, but are not specific to lactation and do not describe higher intensity individualized services including evaluation and intervention components (e.g., that a lactation "class" would lack). This is an existing service not adequately described by current HCPCS codes. A HCPCS code is needed to enable IBCLCs to bill for the service and to facilitate coverage and reimbursement of the service. IBCLCs are the only health professionals certified in lactation management.

Preliminary Decision:

A national program operating need was not identified by Medicare, Medicaid or the private insurance sector to establish a Level II HCPCS code to identify this professional service. CMS refers the applicant to the American Medical Association (AMA) editorial process for establishing Current Procedural Terminology (CPT) codes.

Medicare Payment:

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

HCPCS Public Meeting Agenda Item #28
May 29, 2013

Attachment# 13.055

Topic/Issue:

Request to establish a new Level II HCPCS code to identify magnetic resonance image guided robotic acoustic surgery. Applicant's suggested language: "Magnetic resonance image guided robotic acoustic surgery, bone metastases pain".

Background/Discussion:

According to the requester, image-guided acoustic surgery is a non-invasive surgical procedure that, based on 3-D planning, combines continuous magnetic resonance (MR) imaging with high-power acoustic energy (non-ionizing radiation) to achieve palliation of pain caused by bone metastases. The procedure is performed under anesthesia or deep sedation in one session. Image-guided acoustic surgery is a new procedure that offers patients with bone metastases an alternative treatment option (e.g., to radiation therapy) to significantly reduce pain and lessen the need for pain medication. It is performed using theExAblate® System, a device used for pain palliation of metastatic bone cancer in patients 18 years of age or older who are suffering from bone pain due to metastatic disease and who have failed standard radiation therapy, or are not candidates for, or who have refused radiation therapy. According to the requester, this new procedure is not adequately described by any existing HCPCS codes, and a HCPCS code is needed to enable proper billing. The applicant expects to "pursue a CPT code, but does not expect a code for at least a few more years, and therefore believes a HCPCS Level II code is warranted.

Preliminary Decision:

A national program operating need was not identified by Medicare, Medicaid or the private insurance sector to establish a HCPCS Level II code to identify image guided robotic surgery. CMS refers the applicant to CMS' Pass-Through process; and/or the American Medical Association's (AMA) process for establishing Current Procedural Terminology (CPT) codes.

Medicare Payment:

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

HCPCS Public Meeting Agenda Item #29
May 29, 2013

Attachment# 13.053
Topic/Issue:

Request to establish a Level II HCPCS code to identify a corneal endothelium delivery instrument, trade name: EndoSerter®. Applicant's suggested language: "VXX- DSEK/DSAEK Corneal Endothelium Delivery Instrument".

Background/Discussion:

According to the requester the EndoSerter® corneal Endothelium Delivery Instrument is a device used for delivering a corneal endothelial allograft into the eye to replace diseased corneal tissue. The EndoSerter® inserts corneal endothelial allograft tissue measuring less than or equal to 8.5mm in diameter and 175 micron in central thickness into the anterior chamber through a minimum 4mm incision during endothelial keratoplasty procedures. Its advantages include the minimal or no use of sutures (hence no suture-related complications), faster visual rehabilitation, less surgically induced astigmatism and ametropia, less long-term risk of wound dehiscence and a reduced risk of intraoperative expulsive hemorrhage. The EndoSerter® protects the tissue by gently rolling the allograft as it is retracted into a protective sheath with minimal manipulation while it is easily inserted into the eye for precise placement.

The device is a single-use, disposable medical device supplied with instructions.

Preliminary Decision:

A national program operating need was not identified by Medicare, Medicaid, or the private insurance sector to establish a code to separately report this surgical instrument that is included in the facility fee.

Medicare Payment:

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

PAYMENT FOR DMEPOS

DMEPOS

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

- DME – equipment used in the home which can withstand repeated use, is primarily and customarily used to serve a medical purpose, 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 is still made on a reasonable charge basis for IOLs inserted in a physician's office. Payment for most of the other DMEPOS items and services is based on the lower of the actual charge for the item or a fee schedule amount. The Part B deductible and 20 percent coinsurance both apply to the DMEPOS items and services described above.

The Social Security Act requires that the DMEPOS fee schedule amounts be established based on average reasonable charges made during a base period (e.g., July 1, 1986 thru June 30, 1987 for prosthetic devices, prosthetics and orthotics). The fee schedule amounts are increased by annual update factors. Because the reasonable charge data required by the law in establishing fee schedule amounts does not exist for new DMEPOS items, the fee schedule amounts for new DMEPOS items are "gap-filled" using fees for comparable items 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.

- **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.