

**Centers for Medicare & Medicaid Services (CMS)
Healthcare Common Procedure Coding System (HCPCS)
Public Meeting Agenda
DME and Accessories; O & P; Supplies and Other
June 7, 2017 9:00 am – 5:00 pm
CMS Auditorium
7500 Security Boulevard
Baltimore (Woodlawn), Maryland 21244-1850**

8:15 -9:00 a.m. Arrival and sign-in

9:00 a.m. Background and purpose of meeting
Meeting Format and Ground Rules

For each agenda item, a written overview of the request and CMS' preliminary coding decision is provided. 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(a)

APPLICATION# 17.005

Request to revise existing Level II HCPCS Code A4604, which currently reads, "Tubing with integrated heating element for use with Positive Airway Pressure Device", to remove the phrase "heating element" and replace it with "low condensation, high humidity PAP tubing or high performance PAP tubing."

Applicant's suggested language: A4604 "Tubing with integrated low condensation, high humidity PAP tubing for use with Positive Airway Pressure Device".

No Primary Speaker

Agenda Item # 1(b)

APPLICATION# 17.081

Repeat request to establish a new Level II HCPCS code to identify an ostomy pouch fill alert sensor. Trade name: OSTOM-i Alert Sensor.

Applicant's suggested language: AXXXX "OSTOM-i Alert Sensor for electronically monitoring pressure within ostomy/stoma bags. One unit per 3 months".

Primary Speaker: Mr. John Aforismo

Agenda Item # 1(c)

APPLICATION# 17.085

Request to establish a new Level II HCPCS code to identify a mechanical reusable lancing device. Trade name: the Genteel Lancing Device.

Applicant's suggested language: "A reusable vacuum assisted lancing device with depth control".

No Primary Speaker

Agenda Item # 2

APPLICATION# 17.006

Request to establish a new Level II HCPCS code to identify a mandibular repositioning device, Trade Name: Narval CC.

Applicant's suggested language: EXXXX "Oral device/appliance with non-fixed hinges used to reduce upper airway collapsibility, adjustable or non-adjustable, custom fabricated, includes fitting and adjustments".

Primary Speaker: Mr. Christopher Salmen

Agenda Item # 3

APPLICATION# 17.008

Request to establish a new Level II HCPCS code to identify a non-invasive neurovascular stimulation operating system, Trade Name: the Willow Curve.

Applicant's suggested language: EXXXX "Willow Curve, Low Level Light Therapy Device Emitting Both Red and Infrared Radiation".

No Primary Speaker

Agenda Item # 4

APPLICATION# 17.078

Request to establish two new Level II HCPCS codes to identify a zero-lift transfer and mobility system, differentiated based on patient weight capacity up to, and above 300 lbs. . Trade Name: AgileLife and Mobility System.

Applicant' suggested language for first code: EXXXX "Zero-lift patient transfer and mobility system, integrated electric bed, pressurized mattress, wheelchair, commode and docking station for bedridden patients, operated by caregiver with a touchscreen pad, patient weight capacity up to 300 lbs".

Applicant's suggested language for second code: EXXXX "zero-lift patient transfer and mobility system, integrated electric bed, GRZ air pressure distribution mattress, wheelchair, commode and docking station for bedridden patients, operated by caregiver with a touchscreen pad, patient weight capacity greater than 300 lbs"

Primary Speaker: Mr. James A. Boiani

Agenda Item # 5

APPLICATION# 17.086

Request to establish a new Level II HCPCS code to identify an automated external basal insulin delivery system. Trade Name: MiniMed 670G.

Applicant's suggested language: "automated basal insulin delivery system, external, insulin".

Primary Speaker: Dr. Francine Kaufman

Agenda Item # 6

APPLICATION# 17.115

TOPIC

Repeat request to establish a new Level II HCPCS code to identify test strips for Artificial Pancreas Device System Integrated Blood Glucose Meter, Trade Name: CONTOUR NEXT test strips.

Applicant's suggested language: HXXXX: "Blood glucose meter strips, PMA approved, for blood glucose meters wirelessly integrated with Artificial Pancreas Device Systems (APDS)".

APPLICATION# 17.116

Request to establish a new Level II HCPCS code to identify an artificial pancreas device system integrated blood glucose meter. Trade Name: CONTOUR NEXT LINK 2.4 Blood Glucose Monitoring System.

Applicant's suggested language: HXXXX "Blood glucose meter, PMA-approved and wirelessly integrated with Artificial Pancreas Device Systems (APDS)".

Primary Speaker: Mr. Robert Schumm

Agenda Item # 7 (a)

APPLICATION# 17.082

Request to establish a new Level II HCPCS code to identify an automated uroflowmetry device, trade name: iUFlow device.

Applicant's suggested language: AXXXX "Automated uroflowmetry device, includes software and accessories".

Primary Speaker: Ms. Patty Telgener

Agenda Item # 7 (b)

APPLICATION# 17.089

Request to establish two new Level II HCPCS codes to identify a tremor-cancelling, micro-controlled motion stabilization device and starter kit, trade name: Liftware.

Applicant's suggested language:

- 1) EXXXX "Movement Stabilizing Adaptive Utensil Starter Kit (includes base, charger and utensil)".
- 2) EXXXX "Movement Stabilizing Adaptive Utensil, each additional".

Primary Speaker: Mrs. Patty Telgener

Agenda Item # 8

APPLICATION# 17.090

Request to establish two new Level II HCPCS to identify: 1) a multi-hour long-duration therapeutic ultrasound device; and 2) a supply of single-use coupling patches. Trade names: Sustained Acoustic Medicine (SAM), SAM Sport, SAM Professional.

Applicant did not suggest coding language.

No Primary Speaker

Agenda Item # 9

APPLICATION# 17.094

Repeat request to establish a new Level II HCPCS code to identify a Functional Vibrotactile Stimulation Device System, Trade Name: WalkJoy.

Applicant's suggested language: EXXXX "Functional Stimulation Device System".

Primary Speaker: Mr. Blain Tomlinson

Agenda Item # 10

APPLICATION# 17.109

Request to establish two new Level II HCPCS codes to identify: 1) the Kangaroo ePump Enteral Feeding Pump and Enteral Feeding sets; and 2) the Kangaroo Joey Enteral Feed and Flush Pump and Enteral Feeding sets.

Applicant's suggested language:

BXXXX: "Enteral nutrition infusion pump - nutrition, hydration, and flushing".

BXXXX: "Enteral feeding supply kit; pump fed, per day, includes but not limited to feeding/flushing, hydration, administration tubing, dressing, tape."

Primary Speaker: Mr. William Nadeau

Agenda Item # 11

APPLICATION# 17.121

Request to revise existing Level II HCPCS code A9277, adding the language "1 unit = 1 day", and to assign the revised code to identify a transmitter for use with Dexcom G5 Mobile Continuous Glucose Monitoring System and G4 PLATINUM Continuous Monitoring System (both adult and pediatric models).

Applicant's suggested language: Revise A9277, which currently reads, "Transmitter; external, for use with interstitial continuous glucose monitoring system", to instead read, "Transmitter; external, for use with interstitial continuous glucose monitoring system, 1 unit = 1 day".

Primary Speaker: Ms. Beth Keyt

Agenda Item # 12

APPLICATION# 17.122

Request to establish a new Level II HCPCS code to identify retrofit rear wheel suspension kits for tilt-in-space wheelchairs. Trade Name: QuadshoX Wheelchair Suspension Kit.

Applicant's suggested language: "retrofit suspension kits, wheelchairs".

No Primary Speaker

Agenda Item # 13

APPLICATION# 17.125

Repeat request to establish a new Level II HCPCS code to identify an intrapulmonary acoustical airway clearance device. Trade Name: Vibralung Acoustical Percussor.

Applicant's suggested language: EXXXX "Intrapulmonary Acoustical Airway Clearance".

No Primary Speaker

Agenda Item # 14

APPLICATION# 17.110

Request to establish a new Level II HCPCS code to identify a robotic manipulator arm. Trade name: JACO.

Applicant does not suggest coding language.

APPLICATION# 17.111

Request to establish a new Level II HCPCS code to identify a powered arm support. Trade Name: GoWing.

Applicant does not suggest coding language.

Primary Speaker: Mr. Ron Borgschulte

Agenda Item # 15

APPLICATION# 17.118

Request to establish a new HCPCS Level II code to identify a foot box that is "prefabricated, full, with or without divider with fixed attaching hardware". Trade Name: Sunrise Medical's Jay Full Foot Box with or without divider.

Applicant's suggested language: EXXXX - "Wheelchair positioning accessory, foot box, prefabricated, full, with or without divider with fixed attaching hardware".

APPLICATION# 17.119

Request to establish a new HCPCS Level II code to identify single (individual) foot box technology. Trade Name: Sunrise Medical's Jay Single Foot Box.

Applicant's suggested language: EXXXX - "Wheelchair positioning accessory, foot box, prefabricated, single, with fixed attaching hardware, each".

APPLICATION# 17.120

Request to establish a new HCPCS Level II code to identify custom-fabricated foot box technology. Trade Name: Jay Your Way custom foot box technology.

Applicant's suggested language: EXXXX - "Wheelchair positioning accessory, foot box, custom fabricated with fixed attaching hardware".

Primary Speaker: Mrs. Rita Stanley

Agenda Item # 16

APPLICATION# 17.123

Request to establish a new HCPCS Level II code to identify a foot box that is "prefabricated, full, with or without divider with fixed attaching hardware". Trade Name: Adaptive Engineering Lab Foot Box.

Applicant's suggested language: "Wheelchair positioning accessory, foot box, prefabricated, full, with or without divider with fixed attaching hardware".

APPLICATION# 17.124

Request to establish a new HCPCS Level II code to identify a foot box that is "prefabricated, single, with fixed attaching hardware". Trade Name: Adaptive Engineering Lab Foot Box.

Applicant's suggested language: "Wheelchair positioning accessory, foot box, prefabricated, single, with fixed attaching hardware, each".

No Primary Speaker

Agenda Item # 17

APPLICATION# 17.065

Request to establish a new Level II HCPCS code to identify an external foot brace and to consider the device an orthotic. Trade name: Shoebaum Short.

Applicant did not suggest coding language.

APPLICATION# 17.071

Request to establish a new Level II HCPCS code to identify an external elbow brace, and to consider the device as an orthotic. Trade Name: ErgoBrace G1 EPA Post-op Elbow Brace Over Motion.

Applicant does not suggest coding language.

APPLICATION# 17.072

Request to establish a new Level II HCPCS code to identify a foldable under-arm crutch with patented shock absorbers and telescopic tubing, and to consider the device an orthotic. Trade Name: ErgoBaum Dual.

Applicant does not suggest coding language.

APPLICATION# 17.073

Request to establish a new Level II HCPCS code to identify an external knee brace and to consider the device an orthotic. Trade Name: ErgoBrace Post-Op Knee Brace.

Applicant does not suggest coding language.

APPLICATION# 17.074

Request to establish a new Level II HCPCS code to identify an over-the-shoe universal height compensator and balancer, and to consider the device an orthotic. Trade Name: Level-Up, orthosis, corrective shoe.

Applicant does not suggest coding language.

Agenda Item # 17 (continued)

APPLICATION# 17.075

Request to revise existing Level II HCPCS code E0111 "Crutch forearm, includes crutches of various materials, adjustable or fixed, each, with tip and handgrips" to identify an ergonomic crutch with patented shock absorbers and telescopic tubing, and to consider the device an orthotic. Trade Name: ErgoBaum Royal and ErgoBaum Prince.

Applicant does not suggest coding language.

APPLICATION# 17.076

Request to establish a new Level II HCPCS code to identify a commode chair, and to consider the device an orthotic Trade Name: Mobile Commode Chair.

Applicant does not suggest coding language.

APPLICATION# 17.098

Request to establish a new Level II HCPCS code to identify a fully-adjustable ergonomic cane, and to consider it an orthotic. Trade Name: Ergocane.

Applicant does not suggest coding language.

Primary Speaker: Mr. Alan Fisboin

HCPCS Public Meeting Agenda Item # 1

Application# 17.005

TOPIC

Request to revise existing Level II HCPCS Code A4604, which currently reads, "Tubing with integrated heating element for use with Positive Airway Pressure Device", to remove the phrase "heating element" and replace it with "low condensation, high humidity PAP tubing or high performance PAP tubing."

Applicant's suggested language: A4604 "Tubing with integrated low condensation, high humidity PAP tubing for use with Positive Airway Pressure Device".

BACKGROUND

Exceleron Medical, Inc. submitted a request to revise existing Level II HCPCS Code A4604, which currently reads, "Tubing with integrated heating element for use with Positive Airway Pressure Device", to instead read, "Tubing with integrated low condensation, high humidity PAP tubing for use with Positive Airway Pressure Device". According to the applicant, traditional heated PAP tubing is designed to reduce condensation (rain-out) during therapy by keeping the temperature constant the entire length of the tubing. In turn, this enables higher humidity levels to be achieved, thereby creating more comfort for the patient. The Exceleron Rainout Guard (ROG) Tubing achieves the same thing without a heating element, by passing all flow and moisture through the ROG module at the end of the tube.

ROG is a 6 ft. PAP tube with an inbuilt ROG module at the patient end of the tube. Excess moisture that reaches the ROG module passes through a set of blades configured in a tortuous path that turns water droplets into water vapor. In turn, this minimizes condensation and increases the humidity level at the patient level. ROG increases humidity levels while minimizing condensation in PAP therapy applications. The ROG can be used when patients are utilizing heated humidification in PAP therapy. This ROG module is used in PAP therapy applications to include both CPAP and RAD therapies.

The applicant comments that a revision to the existing code A4604 is warranted because A4604 currently has the term "heating element" in the descriptor. The ROG Tube is equivalent in performance to heated tubing and should carry the A4604 code with a slight modification in the code description. The ROG module is newer technology that achieves the same result without the use of electrical power in the patient breathing circuit.

PRELIMINARY HCPCS CODING RECOMMENDATION

This request to revise existing Level II HCPCS code A4604 "Tubing with integrated heating element for use with positive airway pressure device" has not been approved. The code A4604 was established to identify a heating tube. The device that is the subject of this request is not a heating tube. Existing code A7037 "Tubing used with positive airway pressure device" adequately describes the product that is the subject of this request and is available for assignment by insurers if they deem appropriate.

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

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

HCPCS Public Meeting Agenda Item # 1 (continued)

Application# 17.081

TOPIC

Repeat request to establish a new Level II HCPCS code to identify an ostomy pouch fill alert sensor. Trade name: OSTOM-i Alert Sensor.

Applicant's suggested language: AXXXX "OSTOM-i Alert Sensor for electronically monitoring pressure within ostomy/stoma bags. One unit per 3 months".

BACKGROUND

Drug Knowledge, LLC submitted a request to establish a new Level II HCPCS code to identify the OSTOM-i Alert Sensor. According to the applicant, the OSTOM-i Alert Sensor is a discrete device that clips onto the outside of the patient's ostomy pouch, monitoring the filling of the pouch. It captures the volume and timing of output for each patient in order to allow for timely emptying of the ostomy bag, preventing complications. It improves the functionality of the ostomy bag.

The OSTOM-i Alert Sensor sends a Bluetooth alert to an app on the patient's mobile device (either a phone or tablet), notifying the patient that the ostomy bag is filling up. This information provides the patient the opportunity to change the ostomy bag more timely. The OSTOM-i Alert Sensor also captures guidance information about volume of output over a time period, allowing the information to be e-mailed to physicians and other healthcare professionals to monitor the condition. Each OSTOM-i Alert System can be used for no longer than three months.

The applicant comments that no current HCPCS codes accurately describe this unique product and its functionality. The existing code A9280 "Alert or alarm device, not otherwise classified" has to do with a negative response when lying on a mattress, whereas the OSTOM-i Alert Sensor is for day or night use.

PRELIMINARY HCPCS CODING RECOMMENDATION

This request to establish a new Level II HCPCS code to separately identify Ostom-i Alert Sensor has not been approved. Existing code A9280 "Alert or alarm device, not otherwise classified" adequately describes this product and is available for assignment by insurers if they deem appropriate.

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

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

HCPCS Public Meeting Agenda Item # 1 (continued)

Application# 17.085

TOPIC

Request to establish a new Level II HCPCS code to identify a mechanical reusable lancing device. Trade name: the Genteel Lancing Device.

Applicant's suggested language: "A reusable vacuum assisted lancing device with depth control".

BACKGROUND

Genteel, LLC submitted a request to establish a new HCPCS Level code to identify the Genteel Lancing Device. According to the applicant, Genteel is a painless, hand held, durable, reusable, vacuum-assisted lancing device. Genteel is used with disposable sterile lancets to draw capillary blood from the fingertip or alternate sites for blood glucose testing or other testing using small amounts of blood. Genteel uses calibrated depth control, designed to ensure the needle reaches only the capillaries, not the deeper pain nerves. It may be used up to 10,000 cycles over several years.

Genteel is commonly used by those with diabetes who need to repeatedly draw a drop of test blood for glucose monitoring.

The applicant comments that there are currently no existing HCPCS codes that are specific to non-disposable, long-term, durable medical equipment lancing devices, and "the only available code for this durable, reusable lancing device is E1399 "Durable medical equipment, miscellaneous".

PRELIMINARY HCPCS CODING RECOMMENDATION

This request to establish a new Level II HCPCS code to separately identify the Genteel Lancing Device has not been approved. Existing code A4258 "Spring-powered device for lancet, each" adequately describes this product and is available for assignment by insurers if they deem appropriate.

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

The payment rules associated with the existing code apply to this product if covered. Pricing = 34

HCPCS Public Meeting Agenda Item # 2

Application# 17.006

TOPIC

Request to establish a new Level II HCPCS code to identify a mandibular repositioning device, Trade Name: Narval CC.

Applicant's suggested language: EXXXX "Oral device/appliance with non-fixed hinges used to reduce upper airway collapsibility, adjustable or non-adjustable, custom fabricated, includes fitting and adjustments".

BACKGROUND

ResMed Corp submitted a request to establish a new Level II HCPCS code to identify the Narval CC. According to the applicant, Narval CC is a removable, mandibular repositioning device that is intended to reduce or alleviate snoring and mild-to-moderate obstructive sleep apnea (OSA).

Narval functions by mechanically repositioning the lower jaw in a forward position to increase the patient's oropharyngeal space during sleep to reduce airway collapsibility, and treat OSA. It includes two custom-fabricated splints that fit over the upper and lower teeth and are connected by variable-sized rods.

The applicant comments that establishing a new code to identify "non-fixed hinge" devices would facilitate claims processing and ensure that patients have access to innovative OSA treatments such as Narval CC.

PRELIMINARY HCPCS CODING RECOMMENDATION

A national program operating need was not identified by Medicare, Medicaid or the Private Insurance sector to establish a new Level II HCPCS code to identify the product that is the subject of this request. For coding guidance, contact the insurer in whose jurisdiction a claim would be filed. For Medicaid, contact the Medicaid Agency in the state in which a claim would be filed. For private insurance, contact the individual private insurance entity. For Medicare, contact the Medicare contractor.

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

Based on the preliminary coding recommendation, a Medicare payment determination would not apply.

HCPCS Public Meeting Agenda Item # 3

Application# 17.008

TOPIC

Request to establish a new Level II HCPCS code to identify a non-invasive neurovascular stimulation operating system, Trade Name: the Willow Curve.

Applicant's suggested language: EXXXX "Willow Curve, Low Level Light Therapy Device Emitting Both Red and Infrared Radiation".

BACKGROUND

Physician's Technology, LLC submitted a request to establish a new Level II HCPCS code to identify the Willow Curve. According to the applicant, the Willow Curve uses a non-invasive neurovascular stimulation (NINS) operating system which is housed in the product as a type of biomedical computer. The Willow Curve is indicated for temporary relief of minor muscle and joint pain. The device emits dynamic particles of light (photons or photonic energy) and heat (thermal kinetic energy) to a treatment area of the body of the user.

The patient applies the Willow Curve to the appropriate area, turns the unit on, and selects the proper mode of treatment for the condition. The Willow Curve offers three different modules for treatment: sensory, analytic and formulary, and therapeutic. At the conclusion of the treatment (approximately 25 minutes), the Willow Curve is removed, and the patient's joint is re-assessed. The patient may self-perform multiple treatments on the pain area per day, as needed.

The Willow Curve is prescribed in a clinic to address pain caused by various diagnoses, including osteoarthritis, rheumatoid arthritis, and rotator cuff injuries. The Willow Curve is often employed in situations where the patient is unable to take NSAIDS or oral medications, ineligible for surgery, and/or current pain therapy is inadequate.

The applicant comments that a new code is warranted because existing codes do not describe this product as they are very generalized and vague. Existing CPT code 99070 is considered to be a very non-specific "catch-all" code. Furthermore, the applicant believes that the Willow Curve should have a unique code that is specific to this type of technology.

PRELIMINARY HCPCS CODING RECOMMENDATION

This request to establish a new Level II HCPCS code to separately identify the Willow Curve Light Therapy device has not been approved. Existing code E0221 "Infrared heating pad system" adequately describes the device that is the subject of this request, and it is available for assignment by insurers if they deem appropriate. In fact, the code E0221 was established for the predicate product to the Willow Curve device.

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

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

HCPCS Public Meeting Agenda Item # 4

Application# 17.078

TOPIC

Request to establish two new Level II HCPCS codes to identify a zero-lift transfer and mobility system, differentiated based on patient weight capacity up to, and above 300 lbs. . Trade Name: AgileLife and Mobility System.

Applicant' suggested language for first code: EXXXX "Zero-lift patient transfer and mobility system, integrated electric bed, pressurized mattress, wheelchair, commode and docking station for bedridden patients, operated by caregiver with a touchscreen pad, patient weight capacity up to 300 lbs".

Applicant's suggested language for second code: EXXXX "zero-lift patient transfer and mobility system, integrated electric bed, GRZ air pressure distribution mattress, wheelchair, commode and docking station for bedridden patients, operated by caregiver with a touchscreen pad, patient weight capacity greater than 300 lbs"

BACKGROUND

On behalf of Next Health, LLC, a request was submitted to establish two new Level II HCPCS codes to identify the AgileLife Transfer and Mobility System, differentiated based on patient weight capacity. According to the applicant, the system offers safe, zero-lift patient transfers to and from bed-to-chair for physically-challenged patients.

The AgileLife Transfer and Mobility System is comprised of a fully-powered hospital bed, transfer system, control pad, patient pendant, wheelchair and dock. The wheelchair docks at the foot of the bed, the "transfer to bed" icon is pressing on the control panel, and the bed and chair meet each other to gently transfer the patient into the bed. The reverse transfer is initiated by pressing the "transfer to chair" icon. There are multiple other options on the control panel to assist the caregiver. The wheelchair can convert into a commode, making it a "zero lift" option. In addition, the system includes an in-bed scale, therapeutic pressure redistribution surfaces for the bed and chair, as well as other accessories that address therapeutic and comfort needs of bedbound patients. Finally, the system includes an optional integrated bed exit alarm and a wider tilt-in-space wheelchair

The applicant comments that new codes are needed because the current codes do not adequately describe this next-generation product for transfers and mobility.

PRELIMINARY HCPCS CODING RECOMMENDATION

This request to establish two new Level II HCPCS codes to separately identify the AgileLife Transfer and Mobility System has not been approved, because the request is for capital equipment. Capital equipment is not appropriate for inclusion in the HCPCS Level II code set.

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

Based on the preliminary coding recommendation, a Medicare payment determination would not apply.

HCPCS Public Meeting Agenda Item # 5

Application# 17.086

TOPIC

Request to establish a new Level II HCPCS code to identify an automated external basal insulin delivery system. Trade Name: MiniMed 670G.

Applicant's suggested language: "automated basal insulin delivery system, external, insulin".

BACKGROUND

Medtronic Diabetes submitted a request to establish a new Level II HCPCS code to identify the MiniMed 670G. According to the applicant, MiniMed 670G is used for the management of Type 1 diabetes mellitus. In contrast to conventional insulin pumps, MiniMed 670G detects and also predicts glycemic variances that indicate that the patient is at risk of either hypoglycemia or hyperglycemia. MiniMed 670G then automatically responds by continuously increasing, decreasing, suspending, and restarting delivery of basal insulin, based on sensor glucose values and recognizing the amount of insulin already on board for the individual patient. By design, the MiniMed 670G has an algorithm to control glucose levels to a fixed target, thereby continually keeping them within range.

The automated basal insulin delivery system requires the user to deliver an insulin bolus for meals, including performing a fingerstick blood glucose reading. Besides that, the MiniMed 670G does not require input or intervention by the user, automating most routine attention needed for control. By delivering a responsive and variable rate of insulin for twenty-four hours a day, the MiniMed 670G improves glycemic control and prevents episodes of severe hypoglycemia and hyperglycemia.

The applicant comments that existing HCPCS codes for insulin pumps do not recognize the predictive capability, the automatic adjustment of basal insulin delivery, the response to both hypoglycemia and hyperglycemia, and the significantly reduced need for user input of automated basal insulin delivery systems. As underscored by its FDA approval with a new classification as an "Artificial Pancreas Device System, Single Hormonal Control," and not as a pump, the MiniMed 670G is a distinct diabetes technology requiring a new HCPCS code to differentiate it.

PRELIMINARY HCPCS CODING RECOMMENDATION

A national program operating need was not identified by Medicare, Medicaid, or the private insurance sector to establish a new Level II HCPCS code to identify the product that is the subject of this request. Existing codes E0784 "External ambulatory infusion pump, insulin" and S1034 "Artificial pancreas device system (e.g., low glucose suspend (lgs) feature) including continuous glucose monitor, blood glucose device, insulin pump and computer algorithm that communicates with all of the devices", S1035 "Sensor; invasive (e.g., subcutaneous), disposable, for use with artificial pancreas device system", S1036 "Transmitter; external, for use with artificial pancreas device system", and S1037 "Receiver (monitor); external, for use with artificial pancreas device system" are available for assignment by insurers if they deem appropriate to identify this device or its components. For coding guidance, contact the insurer in whose jurisdiction a claim would be filed. For Medicaid, contact the Medicaid Agency in the state in which a claim would be filed. For private insurance, contact the individual private insurance entity. For Medicare, contact the Medicare contractor.

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

The payment rules associated with the existing code apply to this product if covered. Pricing = 36

HCPCS Public Meeting Agenda Item # 6

Application# 17.115

TOPIC

Repeat request to establish a new Level II HCPCS code to identify test strips for Artificial Pancreas Device System Integrated Blood Glucose Meter, Trade Name: CONTOUR NEXT test strips.

Applicant's suggested language: HXXXX: "Blood glucose meter strips, PMA approved, for blood glucose meters wirelessly integrated with Artificial Pancreas Device Systems (APDS)".

BACKGROUND

Ascensia Diabetes Care submitted a request to establish a new Level II HCPCS code to identify CONTOUR NEXT test strips. According to the applicant, CONTOUR NEXT test strips are used with the CONTOUR NEXT LINK 2.4 wireless meter. The CONTOUR NEXT LINK 2.4 wireless meter is used by persons with diabetes to measure blood glucose in whole blood, which wirelessly transmits glucose values to MiniMed 630G/670G insulin pumps and facilitates transfer of information to the Medtronic CareLink Software through use of radio frequency communication.

The patient population using Artificial Pancreas Device Systems (APDS) are type 1 diabetes patients whose pancreas is unable to produce insulin. The CONTOUR NEXT LINK 2.4 blood glucose monitoring system is used four times per day, or more frequently if indicated by symptoms or by information from the APDS continuous glucose monitor. The APDS software uses the digitally transmitted information to calibrate the APDS continuous meter. Then the APDS system provides both patient warnings and automated insulin control to both high and low continuously measured glucose levels.

The applicant comments that unique HCPCS codes for blood glucose monitoring systems that are integrated components of APDS will help segregate meter and test strip supplies for APDS use, reduce patient access barriers, and ensure delivery and proper performance of the APDS therapy.

PRELIMINARY HCPCS CODING RECOMMENDATION

This request to establish a new Level II HCPCS code to separately identify Contour NEXT test strips has not been approved. Existing code A4253 "Blood glucose test or reagent strips for home blood glucose monitor, per 50 strips" adequately describes this product and is available for assignment by insurers if they deem appropriate.

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

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

HCPCS Public Meeting Agenda Item # 6 (continued)

Application# 17.116

TOPIC

Request to establish a new Level II HCPCS code to identify an artificial pancreas device system integrated blood glucose meter. Trade Name: CONTOUR NEXT LINK 2.4 Blood Glucose Monitoring System.

Applicant's suggested language: HXXXX "Blood glucose meter, PMA-approved and wirelessly integrated with Artificial Pancreas Device Systems (APDS)".

BACKGROUND

Ascensia Diabetes Care US, Inc. submitted a request to establish a new Level II HCPCS code to identify the CONTOUR NEXT LINK 2.4 Blood Glucose Monitoring System (BGMS).

According to the applicant, the CONTOUR NEXT LINK 2.4 BGMS is a device used by persons with diabetes to measure blood glucose in whole blood. It wirelessly transmits the glucose values to the MiniMed 630G/670G insulin pumps and facilitates transfer of information to the Medtronic CareLink software through use of radio frequency communication.

The patient population using ADPS are Type 1 Diabetes Patients whose pancreas is unable to produce insulin. The BGMS is used four times per day, or more frequently if indicated by symptoms or by information from the APDS continuous glucose monitor. Fingertip puncture, blood collection, and strip insertion in the meter are conducted as for other CONTOUR NEXT meters.

The applicant comments that "adequate coding should be provided for a new class of PMA-approved, high accuracy, wirelessly integrated blood glucose meters and the corresponding PMA test strips. As a matter of policy, it is not reasonable to expect that extremely low competitive bidding prices for unconnected generic meters and strips would allow the provision of specifically PMA-approved, very-high-accuracy, and wirelessly integrated system meters that are critical to the proper performance, for APDS. The generic meters lack PMA approval, the required accuracy, the required manufacturing and quality controls, and completely lack electronic wireless integration with the APDS systems".

PRELIMINARY HCPCS CODING RECOMMENDATION

This request to establish a new Level II HCPCS code to separately identify the Contour NEXT Link 2.4 blood glucose meter has not been approved. Existing code E0607 "Home blood glucose monitor" adequately describes this product and is available for assignment by insurers if they deem appropriate.

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

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

HCPCS Public Meeting Agenda Item # 7

Application# 17.082

TOPIC

Request to establish a new Level II HCPCS code to identify an automated uroflowmetry device, trade name: iUFlow device.

Applicant's suggested language: AXXXX "Automated uroflowmetry device, includes software and accessories".

BACKGROUND

On behalf of Kesem Health Pty Ltd., a request was submitted to establish a new Level II HCPCS code to identify the iUFlow device. According to the applicant, the iUFlow is a urinary flowmeter with a fully-automated bladder diary for diagnosis and management of lower urinary tract disorders. The iUFlow allows urologists and their patients to automatically capture patient urinary data and assist urologists in diagnosing and monitoring of patient's treatment. It enables patients to perform a uroflowmetric test at home rather than the office.

The iUFlow is comprised of the iUFlow device and the iUFlow application software that receive data from the device and utilizes an algorithm to analyze the data. The iUFlow device is placed on the toilet bowl to measure the urinary volume and flow rate. The device is equipped with a wired connection to allow it to connect to a mobile device.

The applicant comments that no existing HCPCS codes are appropriate for reporting the iUFlow device.

PRELIMINARY HCPCS CODING RECOMMENDATION

This request to establish a new Level II HCPCS code to separately identify the iUFlow device has not been approved, because this product is an integral part of a procedure and payments for that service includes payment for this uroflowmetry device if it is used.

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

No separate Medicare payment.

HCPCS Public Meeting Agenda Item # 7 (continued)

Application# 17.089

TOPIC

Request to establish two new Level II HCPCS codes to identify a tremor-cancelling, micro-controlled motion stabilization device and starter kit, trade name: Liftware.

Applicant's suggested language:

- 1) EXXXX "Movement Stabilizing Adaptive Utensil Starter Kit (includes base, charger and utensil)".
- 2) EXXXX "Movement Stabilizing Adaptive Utensil, each additional".

BACKGROUND

On behalf of Verily Life Sciences, an Alphabet Company, a request was submitted to establish two new Level II HCPCS codes to identify Liftware. According to the applicant, Liftware is a hand-held stabilizing device that works to counteract the user's unintended hand tremor, due to conditions like Essential Tremor and Parkinson's disease. Liftware is intended to assist patients in performing specific eating functions and/or enabling the individual to eat by themselves without assistance. Liftware works most effectively for people with mild-to-moderate hand tremor in which the tremor causes them to regularly spill food while eating.

The Liftware technology contains sensors that detect hand motion and a small onboard micro-controller that distinguishes unwanted hand tremor from the intended movement of the hand. To counteract hand tremor and stabilize the device, the microcontroller directs two motors in the handle in order to move the device attachment in the opposite direction of any detected tremor.

The applicant comments that no existing HCPCS codes appropriately report this micro-controlled assistive device.

PRELIMINARY HCPCS CODING RECOMMENDATION

A national program operating need was not identified by Medicare, Medicaid, or the private insurance sector to establish a new Level II HCPCS codes to identify the movement stabilizing adaptive utensil and starter kit. For coding guidance, contact the insurer in whose jurisdiction a claim would be filed. For Medicaid, contact the Medicaid Agency in the state in which a claim would be filed. For private insurance, contact the individual private insurance entity. For Medicare, contact the Medicare contractor.

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

Based on the preliminary coding recommendation, a Medicare payment determination would not apply.

HCPCS Public Meeting Agenda Item # 8

Application# 17.090

TOPIC

Request to establish two new Level II HCPCS to identify: 1) a multi-hour long-duration therapeutic ultrasound device; and 2) a supply of single-use coupling patches. Trade names: Sustained Acoustic Medicine (SAM), SAM Sport, SAM Professional.

Applicant did not suggest coding language.

BACKGROUND

ZetrOZ Systems, LLC submitted a request to establish two new Level II HCPCS codes, one each to identify the Sustained Acoustic Medicine (SAM) and the coupling patches used with the device. According to the applicant, the SAM device is a wearable, low-intensity, long-duration ultrasound diathermy device used to aid in soft-tissue recovery and treat pain from conditions such as arthritis. It is indicated for the treatment of pain, muscle spasms, joint contracture, and to increase local circulation.

The SAM device is applied to the skin over the treatment site on a daily basis by the patient, and is completely non-invasive. The ultrasound energy produced by the device penetrates approximately 5 cm into the musculoskeletal tissue, thereby reaching deep tissues of the body.

The SAM device is powered by a rechargeable battery and applied with an ultrasonic coupling patch that contains an adhesive bandage, plastic connector ring, and integrated coupling media. The device delivers continuous ultrasound energy at 3 MHz, 0.132 watts per squared centimeter, and 1.3 watts for a total of 18,720 joules of energy per 4-hour treatment.

The applicant comments that the existing codes for low-intensity ultrasound bone stimulators do not adequately describe the SAM device. The device and the patches are currently being billed using existing code E1399 "Durable medical equipment, miscellaneous" and existing code A9901 " DME delivery, set up, and/or dispensing service component of another HCPCS code" is used to bill for the shipping costs.

PRELIMINARY HCPCS CODING RECOMMENDATION

This request to establish two new Level II HCPCS codes to separately identify the SAM multi-hour long-duration therapeutic ultrasound device and a supply of single-use coupling patches has not been approved. These products are an integral part of a procedure and payments for that service includes payment for the ultrasound device and coupling patches if used. Reporting using additional codes could be considered duplicative.

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

No separate Medicare payment.

HCPCS Public Meeting Agenda Item # 9

Application# 17.094

TOPIC

Repeat request to establish a new Level II HCPCS code to identify a Functional Vibrotactile Stimulation Device System, Trade Name: WalkJoy.

Applicant's suggested language: EXXXX "Functional Stimulation Device System".

BACKGROUND

On behalf of WalkJoy, Inc. a repeat request was submitted to establish a new code to identify the WalkJoy device. According to the applicant, the WalkJoy is a vibrotactile stimulation biofeedback device. It is a noninvasive, wearable gait and balance restoration device supplied as a pair of assemblies (left and right), each consisting of a solid state device which attaches to velcro straps and a USB/AC charging unit. The WalkJoy is worn around the lower leg, centered on the front of the tibia, directly below the knee.

Upon heel strike during gait, the device delivers vibrotactile stimulation intended to provide a secondary signal to healthy nerves in the lower leg toward reestablishment of the human sensor-motor loop, thereby aiding in the restoration of gain and balance loss due to any form of neuropathy. The WalkJoy employs technology based on "sensory stimulation," i.e., the ability of the central nervous system to use an alternative sensory stimulation to restore motor function.

The WalkJoy is indicated for patients who have peripheral neuropathy and to prevent fall risks and other walking health problems. Peripheral nerve damage produces loss of sensation and an inability to control muscles, which leads to poor gait, balance, increased falls and foot ulcers.

The applicant commented that a new code is warranted because there are no similar products on the market, and there are no existing HCPCS codes that identify vibrotactile stimulation biological feedback devices, gait resolution, or the use of this technology for proprioceptive gait improvements and fall prevention.

PRELIMINARY HCPCS CODING RECOMMENDATION

This request to establish a new Level II HCPCS code to separately identify the WalkJoy device (functional Vibrotactile Stimulation Device System) has not been approved. This product is an integral part of a procedure, and payments for that service includes payment for the WalkJoy device if it is used.

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

No separate Medicare payment.

HCPCS Public Meeting Agenda Item # 10

Application# 17.109

TOPIC

Request to establish two new Level II HCPCS codes to identify: 1) the Kangaroo ePump Enteral Feeding Pump and Enteral Feeding sets; and 2) the Kangaroo Joey Enteral Feed and Flush Pump and Enteral Feeding sets.

Applicant's suggested language:

BXXXX: "Enteral nutrition infusion pump - nutrition, hydration, and flushing".

BXXXX: "Enteral feeding supply kit; pump fed, per day, includes but not limited to feeding/flushing, hydration, administration tubing, dressing, tape".

BACKGROUND

Medtronic, Inc. submitted a request to establish two new Level II HCPCS codes to identify: 1) the Kangaroo ePump Enteral Feeding Pump and Enteral Feeding sets; and 2) the Kangaroo Joey Enteral Feed and Flush Pump and Enteral Feeding sets. According to the applicant, the Kangaroo ePump and the Kangaroo Joey pump are enteral feeding pumps that deliver formula via rotary peristaltic tension loop pumping to provide nutrition for those patients with a functioning gastrointestinal tract but are unable to meet their complete nutrition and hydration needs with an oral diet.

The Kangaroo ePump and the Kangaroo Joey Pump are comprised of an enteral feeding pump and disposable Enteral Feeding Sets. These enteral feeding pumps are programmed to deliver formula with either continuous or intermittent feeding, and can provide automatic flushing capability when used with Kangaroo feed and flush sets. The ePump is optimized for the institutional setting. The Joey Pump feature set matches the Kangaroo ePump and is ideal for the home setting.

The applicant comments that current HCPCS codes available for reporting the enteral feeding pumps and supplies do not accurately describe the Kangaroo pumps and supplies, which allow for automated feed/flush and hydration programming.

PRELIMINARY HCPCS CODING RECOMMENDATION

- 1) The Kangaroo Joey Enteral Feed and Flush Pump is adequately described by the existing code B9002 "Enteral nutrition infusion pump, any type", which is available for assignment by insurers if they deem appropriate.

2) The supply kit for the Kangaroo Joey Enteral Feed and Flush Pump is adequately described by the existing code B4035 "Enteral feeding supply kit; pump fed, per day, includes but not limited to feeding/flushing syringe, administration set tubing, dressings, tape". The code B4035 is available for assignment by insurers if they deem appropriate. B4035 includes any supplies necessary for flushing if it is done.

3) A national program operating need was not identified by Medicare, Medicaid, or the Private Insurance sector to establish a new HCPCS code to identify the Kangaroo ePump Enteral Feeding Pump, because it is institutional equipment, as reported in the application. As such, it is not eligible for inclusion in the HCPCS Level II code set.

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

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

HCPCS Public Meeting Agenda Item # 11

Application# 17.121

TOPIC

Request to revise existing Level II HCPCS code A9277, adding the language "1 unit = 1 day", and to assign the revised code to identify a transmitter for use with Dexcom G5 Mobile Continuous Glucose Monitoring System and G4 PLATINUM Continuous Monitoring System (both adult and pediatric models).

Applicant's suggested language: Revise A9277, which currently reads, "Transmitter; external, for use with interstitial continuous glucose monitoring system", to instead read, "Transmitter; external, for use with interstitial continuous glucose monitoring system, 1 unit = 1 day".

BACKGROUND

Dexcom, Inc. submitted a request to revise existing Level II HCPCS code A9277, adding the language "1 unit = 1 day". According to the applicant, a Continuous Glucose Monitoring (CGM) system enables people with diabetes to monitor, track, and understand trends in their glucose information in real-time. It alerts the patient to changes in their glucose values, allowing the patient to immediately make appropriate adjustments to avoid adverse events.

The Transmitter (A9277) is one of three components of CGM system, which include CGM systems currently manufactured by Dexcom and Medtronic. The other components are the Sensor and the Receiver. The CGM Transmitter works by sending encrypted data from the Sensor to the Receiver, and the patient responds to the data as needed. The Transmitter is worn outside the body, generally under the patient's clothes, and it is physically connected to the Sensor.

CGM devices have different indications for different age groups. The Dexcom G5 CGM system is indicated for detecting trends and tracking patterns for persons aged 2 years and older; the Dexcom G4 PLATINUM CGM system is for persons aged 18 and older; and the Dexcom G4 PLATINUM (Pediatric) CGM system is for persons aged 2 to 17 years old.

The applicant comments that the current A9277 code is insufficient to describe the multiplicity of Transmitters on the market which have differing battery lives of 90, 180, and 365 days (depending on the manufacturer). Revision of existing code A9277 to add a unit of duration for the Transmitter is necessary in order to improve coding accuracy and describe duration of use.

PRELIMINARY HCPCS CODING RECOMMENDATION

A national program operating need was not identified by Medicare, Medicaid, or the private insurance sector to revise the descriptor of existing code A9277. For therapeutic CGMs, refer to new code K0553.

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

The payment rules associated with the existing code apply to non-therapeutic CGM transmitters classified under A9277. Pricing = 00. The payment rules associated with code K0553 apply to therapeutic CGM transmitters. Pricing = 34

HCPCS Public Meeting Agenda Item # 12

Application# 17.122

TOPIC

Request to establish a new Level II HCPCS code to identify retrofit rear wheel suspension kits for tilt-in-space wheelchairs. Trade Name: QuadshoX Wheelchair Suspension Kit.

Applicant's suggested language: "retrofit suspension kits, wheelchairs".

BACKGROUND

QuadshoX, LLC submitted a request to establish a new Level II HCPCS code to identify the QuadshoX Wheelchair Suspension Kit. According to the applicant, QuadshoX products are retro-fit suspension kits that provide rear wheel suspension for tilt-in-space manual wheelchairs. Tilt-in-space manual wheelchairs chairs do not have suspension mechanisms, and the impact experienced from traversing rough terrain is directly transferred to the person sitting in the chair. The added suspension mechanism mitigates the impact and vibration that occur from going over cracks, bumps, and other impediments.

The suspension kit mounts directly to the frame of the wheelchair and is designed to be integrated with the existing axle. By simply taking off the old mounting bracket and installing the kit, suspension is easily and quickly installed onto the tilt-in-space wheelchair.

The applicant comments that existing HCPCS codes do not adequately describe retrofit suspension kits. "The DME providers do not feel that [code E1015] adequately addresses QuadshoX suspension kits."

PRELIMINARY HCPCS CODING RECOMMENDATION

This request to establish a new Level II HCPCS code to separately identify the QuadshoX Wheelchair Suspension Kit has not been approved. Existing code E1015 "Shock absorber for manual wheelchair, each" adequately describes the function of this product and is available for assignment by insurers if they deem appropriate.

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

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

HCPCS Public Meeting Agenda Item # 13

Application# 17.125

TOPIC

Repeat request to establish a new Level II HCPCS code to identify an intrapulmonary acoustical airway clearance device. Trade Name: Vibralung Acoustical Percussor.

Applicant's suggested language: EXXXX "Intrapulmonary Acoustical Airway Clearance".

BACKGROUND

Westmed, Inc. submitted a request to establish a new Level II HCPCS code to identify the Vibralung Acoustical Percussor. According to the applicant, the Vibralung is unlike other airway clearance devices which require either application of external force or forced ventilation. The Vibralung uses a Treatment Control Unit (TCU) to generate acoustical waves that travel inside a patient's airways through a Hand-Held Transducer (HHT) as patients breathe normally.

The Vibralung uses an electro-mechanical acoustical transducer to generate variable frequency sound waves. These sound waves are transferred directly into a patient's pulmonary airways via a mouthpiece, breathing mask, or tracheal tube, and they become super-imposed over the normal respiratory waves in a patient's pulmonary airways that result from that patient's normal breathing.

The applicant comments that existing codes describe devices that have a different mechanism of action than the Vibralung in that the Vibralung does not require application of external force. For this reason, and because "Vibralung may be used more safely than some other devices," a new code is warranted.

PRELIMINARY HCPCS CODING RECOMMENDATION

This request to establish a new Level II HCPCS code to separately identify the Vibralung Acoustical Percussor has not been approved. Existing code E0480 "Percussor, electric or pneumatic, home model" adequately describes this product, and it is available for assignment by insurers if they deem appropriate.

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

The payment rules associated with the existing code apply this product if covered. Pricing = 36

HCPCS Public Meeting Agenda Item # 14

Application# 17.110

TOPIC

Request to establish a new Level II HCPCS code to identify a robotic manipulator arm. Trade name: JACO.

Applicant does not suggest coding language.

BACKGROUND

Partners in Medicine, LLC submitted a request to establish a new Level II HCPCS code to identify the JACO. According to the applicant, JACO is a durable robotic arm designed for use by individuals with upper extremity mobility limitations who use a power wheelchair. JACO is used to increase mobility and activities of daily living for those who live with upper extremity mobility limitations.

JACO is constructed of carbon fiber, which is light weight and durable. JACO has six articulated joints, which enables the robot to actuate and move the attached gripper (robotic hand) in three dimension. Each joint is an assembled set of gears and motors enclosed in an aluminum casing, allowing the robotic arm to move silently and effortlessly. The gripper itself has three "fingers", constituting two fingers and an opposable thumb. It has a reach of 35 inches, and a payload of 2.8 pounds. The user controls JACO movements by use of the existing wheelchair controller.

JACO draws its power from the wheelchair's batter (24 volts DC). The maximum power consumption is 25 watts and has minimal impact on the chair's battery life. Users can monitor battery levels with the provided software.

The applicant comments that no existing HCPCS code reflects the capabilities, sophistication, and complexity of the JACO arm.

PRELIMINARY HCPCS CODING RECOMMENDATION

A national program operating need was not identified by Medicare, Medicaid, or the private insurance sector to establish a new Level II HCPCS code to identify the JACO robotic arm. For coding guidance, contact the insurer in whose jurisdiction a claim would be filed. For Medicaid, contact the Medicaid Agency in the state in which a claim would be filed. For private insurance, contact the individual private insurance entity. For Medicare, contact the Medicare contractor.

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

Based on the preliminary coding recommendation, a Medicare payment determination would not apply.

HCPCS Public Meeting Agenda Item # 14 (continued)

Application# 17.111

TOPIC

Request to establish a new Level II HCPCS code to identify a powered arm support. Trade Name: GoWing.

Applicant does not suggest coding language.

BACKGROUND

Partners in Medicine, LLC submitted a request to establish a new Level II HCPCS code to identify the GoWing. According to the applicant, the GoWing is a powered arm support designed for individuals with limited arm and shoulder movements who use a power wheelchair. With its user-controlled lifting mechanism, the GoWing provides assistance to the user in lifting their arm. GoWing's multidimensional flexibility and dexterity expands daily activities like eating, drinking, personal care, typing, and reaching objects. By allowing the user to lift their arm, the GoWing allows the user to sit upright in the wheelchair rather than bending over to reach for food and drink. By maintaining an upright position, the user's posture is improved, back and neck pain may be reduced, and aspiration is minimized.

The GoWing attaches to the side of a power wheelchair and it is secured to the seat frame. The GoWing cradles the user's forearm and elbow from below and it does not require any straps or locks. By using a keyboard, the user can adjust the amount of assistance the GoWing provides. The user determines the amount of lift provided, based on their own arm strength, level of fatigue, and weight being lifted.

GoWing operates on the basis of compensation of the weight of the arm. The mechanism in the main body is capable of adjusting the tension applied so as to create "zero gravity" movement of the user's arm. For its power source, the GoWing uses the 24 volt system of the wheelchair. The GoWing is 29" high, 8" deep, and 2.5." wide. The total weight of the GoWing is 15 lbs.

The applicant comments that no existing HCPCS codes reflect the capabilities and sophistication of the GoWing arm support.

PRELIMINARY HCPCS CODING RECOMMENDATION

This request to establish a new Level II HCPCS code to separately identify the Go Wing powered arm support has not been approved. Existing code E2626 "Wheelchair accessory, shoulder elbow, mobile arm support attached to wheelchair, balanced, adjustable" adequately describes this product and is available for assignment by insurers if they deem appropriate.

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

The payment rules associated with the existing codes apply to these products if covered. Pricing
=32

HCPCS Public Meeting Agenda Item # 15

Application# 17.118

TOPIC

Request to establish a new HCPCS Level II code to identify a foot box that is "prefabricated, full, with or without divider with fixed attaching hardware". Trade Name: Sunrise Medical's Jay Full Foot Box with or without divider.

Applicant's suggested language: EXXXX - "Wheelchair positioning accessory, foot box, prefabricated, full, with or without divider with fixed attaching hardware".

BACKGROUND

Sunrise Medical, LLC submitted a request to code a foot box that is "prefabricated, full, with or without divider with fixed attaching hardware". According to the applicant, Sunrise Medical's foot box technology is designed to provide positioning; to maintain or improve alignment; and for skin protection for the legs, ankles and feet. Foot box technology is determined, selected, measured, fitted and configurable. The full foot box is attached to the footplates or platform and secured to the wheelchair frame.

Foot box technology is primarily used with complex rehab wheelchairs due to the diagnosis of those individuals who require both. Foot box technology consists of a back and two sides, a base, foam and a cover; and fixed attaching hardware. A full foot box (with or without a divider) positions both legs within a full-size box. Full foot boxes are attached to the individual's wheelchair. Foot boxes offer calf, ankle, and foot positioning, lower leg support and protection for individuals who use wheelchairs due to mobility limitations and with lower leg deformities, contractures, certain skin wounds/injuries, spasticity (hypertonia, hyperreflexia), osteogenesis imperfecta, osteopenia, or other conditions requiring positioning of the lower extremities. A full foot box is selected when the beneficiary has abduction or other deformity that prevents the separation between the legs needed to use single foot boxes. For individuals with brittle bones, this is important to also help prevent injuries.

The applicant comments that a unique code is needed for the full foot box technology, and to distinguish it from the single foot box; as there are technology, clinical, and cost differences between these two.

PRELIMINARY HCPCS CODING RECOMMENDATION

A national program operating need was not identified by Medicare, Medicaid, or the private insurance sector to establish a new Level II HCPCS code to identify the full foot box. For coding guidance, contact the insurer in whose jurisdiction a claim would be filed. For Medicaid, contact the Medicaid Agency in the state in which a claim would be filed. For private insurance, contact the individual private insurance entity. For Medicare, contact the Medicare contractor.

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

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

HCPCS Public Meeting Agenda Item # 15 (continued)

Application# 17.119

TOPIC

Request to establish a new HCPCS Level II code to identify single (individual) foot box technology. Trade Name: Sunrise Medical's Jay Single Foot Box.

Applicant's suggested language: EXXXX - "Wheelchair positioning accessory, foot box, prefabricated, single, with fixed attaching hardware, each".

BACKGROUND

Sunrise Medical, LLC submitted a request for a new HCPCS Level II code to identify single (individual) foot box technology. According to the applicant, the single foot box is designed to accommodate each leg independently; to provide positioning; to maintain or improve alignment; and for skin protection for the leg, ankle, and foot. Single foot box technology is determined, selected, measured, and fitted.

Single foot box technology is primarily used with complex rehab wheelchairs, due to the diagnosis of those individuals who require both. Single foot box technology consists of a back and two sides, a base, foam, and a cover; and fixed attaching hardware. A single foot box may be ordered for only one leg or as a pair (for both left and right leg). Single foot boxes are attached to the individual's wheelchair footplate or platform and front rigging. Single foot boxes offer calf, ankle, and foot positioning, lower leg support and protection for individuals who use wheelchairs due to mobility limitations and with lower leg deformities, contractures, certain skin wounds/injuries, spasticity (hypertonia, hyperreflexia), osteogenesis imperfecta, osteopenia, or other conditions requiring positioning of the lower extremities.

Single foot box technology is often chosen when only one leg requires positioning, such as in the presence of a venous leg ulcer or skin injury or elephantiasis, lymphedema, or cellulitis only affecting one leg. A single foot box may also be prescribed if one leg requires elevation and the other one does not, or in the case of one leg being amputated.

The applicant comments that single foot box technology should have a unique HCPCS code in order to allow proper coverage and payment policies; and to distinguish it from other footbox configurations.

PRELIMINARY HCPCS CODING RECOMMENDATION

A national program operating need was not identified by Medicare, Medicaid, or the private insurance sector to establish a new Level II HCPCS code to identify the single foot box. For coding guidance, contact the insurer in whose jurisdiction a claim would be filed. For Medicaid, contact the Medicaid Agency in the state in which a claim would be filed. For private insurance, contact the individual private insurance entity. For Medicare, contact the Medicare contractor.

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

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

HCPCS Public Meeting Agenda Item # 15 (continued)

Application# 17.120

TOPIC

Request to establish a new HCPCS Level II code to identify custom-fabricated foot box technology. Trade Name: Jay Your Way custom foot box technology.

Applicant's suggested language: EXXXX - "Wheelchair positioning accessory, foot box, custom fabricated with fixed attaching hardware".

BACKGROUND

Sunrise Medical, LLC submitted a request to establish a new HCPCS Level II code to identify custom foot box technology. According to the applicant, Jay Your Way custom foot box is manufactured based on the unique needs and measurements of the individual when prefabricated technology cannot meet their needs. Customization options include: sizes, shapes, tapers and contours, various foam types cut-outs for off-loading, and inserts of gel or other material to further protect an area from skin injury.

Custom foot box technology, at a minimum, consists of a back with two sides, a base, foam, and a cover; and fixed attaching hardware. Full foot boxes are attached to the individual's wheelchair. Foot boxes offer calf, ankle, and foot positioning, lower leg support and protection for individuals who use wheelchairs due to mobility limitations and with lower leg deformities, contractures, certain skin wounds/injuries, spasticity (hypertonia, hyperreflexia), osteogenesis imperfecta, osteopenia, or other conditions requiring positioning of the lower extremities.

The applicant comments that custom-fabricated foot box technology requires a unique code. Pricing varies and cannot be grouped with prefabricated items because the cost depends on the type and number of customizations required.

PRELIMINARY HCPCS CODING RECOMMENDATION

A national program operating need was not identified by Medicare, Medicaid, or the private insurance sector to establish a new Level II HCPCS code to identify a custom foot box. For coding guidance, contact the insurer in whose jurisdiction a claim would be filed. For Medicaid, contact the Medicaid Agency in the state in which a claim would be filed. For private insurance, contact the individual private insurance entity. For Medicare, contact the Medicare contractor.

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

Payment will be based on the carrier's determination regarding which coverage and payment rules are applicable. To be considered a customized item for payment purposes, a covered item must be uniquely constructed or substantially modified for a specific beneficiary according to

orders of a physician and be so different from another item used for the same purpose that the two items cannot be grouped together for pricing purposes.

HCPCS Public Meeting Agenda Item # 16

Application# 17.123

TOPIC

Request to establish a new HCPCS Level II code to identify a foot box that is "prefabricated, full, with or without divider with fixed attaching hardware". Trade Name: Adaptive Engineering Lab Foot Box.

Applicant's suggested language: "Wheelchair positioning accessory, foot box, prefabricated, full, with or without divider with fixed attaching hardware".

BACKGROUND

Adaptive Engineering Lab submitted a request to establish a new Level II HCPCS code to identify a foot box that is "prefabricated, full, with or without divider with fixed attaching hardware". According to the applicant, foot box technology is designed to provide positioning, to maintain and improve alignment, and to protect the skin of the legs. Foot box technology is part of a wheelchair seating system and is only functional when attached to a wheelchair base. There are no therapeutic distinctions between the AEL and Sunrise Medical Products.

Foot box technology has a wood base that is shaped to provide posterior and lateral support for the calves, ankles, and feet. High resilient foam or other material is added to the base and then covered in vinyl. Foot boxes are attached to the footplate and secured to the wheelchair frame.

The applicant comments that existing code E0995 "Wheelchair accessory, calf rest/pad, replacement only, each" does not adequately describe foot boxes.

PRELIMINARY HCPCS CODING RECOMMENDATION

A national program operating need was not identified by Medicare, Medicaid, or the private insurance sector to establish a new Level II HCPCS code to identify the full foot box that is the subject of this request. For coding guidance, contact the insurer in whose jurisdiction a claim would be filed. For Medicaid, contact the Medicaid Agency in the state in which a claim would be filed. For private insurance, contact the individual private insurance entity. For Medicare, contact the Medicare contractor.

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

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

HCPCS Public Meeting Agenda Item # 16 (continued)

Application# 17.124

TOPIC

Request to establish a new HCPCS Level II code to identify a foot box that is "prefabricated, single, with fixed attaching hardware". Trade Name: Adaptive Engineering Lab Foot Box.

Applicant's suggested language: "Wheelchair positioning accessory, foot box, prefabricated, single, with fixed attaching hardware, each".

BACKGROUND

Adaptive Engineering Lab submitted a request to establish a new Level II HCPCS code to identify a foot box that is "prefabricated, single, with fixed attaching hardware". According to the applicant, foot box technology is designed to provide positioning, to maintain and improve alignment, and to protect the skin of the legs. Foot box technology is part of a wheelchair seating system and is only functional when attached to a wheelchair base. There are no therapeutic distinctions between the AEL and Sunrise Medical Products.

Foot box technology has a wood base that is shaped to provide posterior and lateral support for the calves, ankles, and feet. High resilient foam or other material is added to the base and then covered in vinyl. Foot boxes are attached to the footplate and secured to the wheelchair frame.

The applicant comments that existing code E0995 "Wheelchair accessory, calf rest/pad, replacement only, each" does not adequately describe foot boxes.

PRELIMINARY HCPCS CODING RECOMMENDATION

A national program operating need was not identified by Medicare, Medicaid, or the private insurance sector to establish a new Level II HCPCS code to identify the single foot box that is the subject of this request. For coding guidance, contact the insurer in whose jurisdiction a claim would be filed. For Medicaid, contact the Medicaid Agency in the state in which a claim would be filed. For private insurance, contact the individual private insurance entity. For Medicare, contact the Medicare contractor.

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

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

HCPCS Public Meeting Agenda Item # 17

Application# 17.065

TOPIC

Request to establish a new Level II HCPCS code to identify an external foot brace and to consider the device an orthotic. Trade name: Shoebaum Short.

Applicant did not suggest coding language.

BACKGROUND

Ergoactives, LLC submitted a request to identify the Shoebaum Short foot brace and to consider it an orthotic. According to the applicant, the Shoebaum Short is a walking boot that is worn on the lower extremities to support, correct, or prevent deformities. It is the world's first patented Short Injury Boot/CAM Walker with three independent loaded spring shock absorbers that reduce the impact of the injured leg with the ground as the patient walks. It also includes a multi-angle hinge at the ankle level that may be blocked at certain positions (if needed) and comes in a standard black color with yellow night reflectors across the boot.

The Shoebaum Short comes equipped with a slideable patented spring-loaded sole that also works as a pressure reduction system with three spring shock absorbers for when the user walks with a foot or ankle injury. No other walking boot has a hinge system that allows the patient to walk in a perfect ergonomic manner. The multi-function hinge at the ankle level may be "blocked" or adjusted from 90 degrees to 135 degrees. It locks at 10 degree angle intervals. It features a double lateral shock absorber.

The applicant comments that existing codes do not adequately reflect the technology, features, and material of the Shoebaum Short.

PRELIMINARY HCPCS CODING RECOMMENDATION

This request to establish a new Level II HCPCS code to separately identify the Shoebaum Short has not been approved. Existing codes L4386 "Walking boot, non-pneumatic, with or without joints, with or without interface material, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise" or L4387 "Walking boot, non-pneumatic, with or without joints, with or without interface material, prefabricated, off-the-shelf" adequately describes the product, depending on whether the product is customized to fit or off-the-shelf. L4386 or L4387 are available for assignment by insurers if they deem appropriate.

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

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

HCPCS Public Meeting Agenda Item # 17 (continued)

Application# 17.071

TOPIC

Request to establish a new Level II HCPCS code to identify an external elbow brace, and to consider the device as an orthotic. Trade Name: ErgoBrace G1 EPA Post-op Elbow Brace Over Motion.

Applicant does not suggest coding language.

BACKGROUND

Ergoactives, LLC submitted a request to establish a new Level II HCPCS code to identify the ErgoBrace Post-op Elbow Brace, and to consider it an orthotic. According to the applicant, the ErgoBrace is a light, telescopic over motion post-op elbow brace. It is used following major ligament surgeries, post-op elbow or arm surgery, and post-cast removal. It is also beneficial for ligament strains, tennis elbow bursitis, and supracondylar stable fractures, triceps ligament injuries, and control of motion for pain management.

The ErgoBrace is covered with plastic to eliminate the patient's direct contact with metal, allowing for a more comfortable experience. It has an adjustable hinge equipped with spring-assisted push-buttons. This allows for adjustability from 120 degrees of flexion to 180 degrees of extension, and it can be locked at 0, 15, 30, 45, and 90 degrees.

The applicant comments that there are no existing HCPCS codes to describe this ErgoBrace.

PRELIMINARY HCPCS CODING RECOMMENDATION

- 1) Establish LXXXX, "Elbow Orthosis (EO), with adjustable position locking joint(s), prefabricated, off-the-shelf". Effective 1/1/18.
- 2) Revise L3760, which currently reads, "Elbow orthosis, with adjustable position locking joint(s), prefabricated, includes fitting and adjustments, any type", to instead read, "Elbow Orthosis (EO), with adjustable position locking joint(s), prefabricated, item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise".

New code LXXXX or revised code L3760 adequately describes the product that is the subject of this application, depending on whether it is custom fit.

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

The payment rules associated with the existing code apply to this product if covered. Pricing = 38. The fee schedule amounts for L3760 will be applied to the corresponding new OTS code.

HCPCS Public Meeting Agenda Item # 17 (continued)

Application# 17.072

TOPIC

Request to establish a new Level II HCPCS code to identify a foldable under-arm crutch with patented shock absorbers and telescopic tubing, and to consider the device an orthotic. Trade Name: ErgoBaum Dual.

Applicant does not suggest coding language.

BACKGROUND

Ergoactives, LLC submitted a request to establish a new Level II HCPCS code to identify the ErgoBaum Dual, and to consider it an orthotic. According to the applicant, the ErgoBaum Dual is an underarm crutch with five independent shock absorbers that prevents nerve injury and compression. The ErgoBaum Dual is the only crutch on the market that includes patented variable adjusters, sequential shock absorbers in the under arm region, and shock absorbers in the handgrip.

The applicant comments that existing HCPCS codes do not adequately describe all the features designed in this product. Existing codes describe standard crutches that do not clearly take into consideration the anatomical and ergonomically designed characteristics of the human body and the actual use of the device and the associated potential negative effects.

PRELIMINARY HCPCS CODING RECOMMENDATION

A national program operating need was not identified by Medicare, Medicaid, or the private insurance sector to establish a new HCPCS code to identify the product that is the subject of this request. For coding guidance, contact the individual insurance contractor in whose jurisdiction a claim would be filed. For Medicaid, contact the Medicaid Agency in the state in which a claim would be filed. For private insurance, contact the individual insurance contractor. For Medicare, contact the Medicare contractor.

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

Based on the preliminary coding recommendation, a Medicare payment determination would not apply.

HCPCS Public Meeting Agenda Item # 17 (continued)

Application# 17.073

TOPIC

Request to establish a new Level II HCPCS code to identify an external knee brace and to consider the device an orthotic. Trade Name: ErgoBrace Post-Op Knee Brace.

Applicant does not suggest coding language.

BACKGROUND

Ergoactives, LLC submitted a request to establish a new Level II HCPCS code to identify the ErgoBrace Post-Op Knee Brace. According to the applicant, the ErgoBrace is a light, telescopic over motion post-op knee brace. It is used in major ligament surgeries, meniscal repairs, patella realignment, stable femoral fractures, stable knee plateau fractures, pes anserinus bursitis, tendinitis, and range of motion control.

The ErgoBrace has plastic to cover the metal, so that the patient has a more comfortable experience. It has two adjustable hinges with spring-assisted push buttons for flexion from 120 degrees to 180 degrees of extension. It locks quickly at 10, 20, 30 with a variation of 10 degrees, and from 45, 60, 75 and 90 degrees with a variation of 15 degrees.

The applicant comments that existing HCPCS codes do not describe this product with multiple locking mechanisms and the technology of its design.

PRELIMINARY HCPCS CODING RECOMMENDATION

This request to establish a new Level II HCPCS code to separately identify the ErgoBrace Post-Op Knee Brace has not been approved. Existing codes L1832 "Knee orthosis, adjustable knee joints (unicentric or polycentric), positional orthosis, rigid support, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise" or L1833 "Knee orthosis, adjustable knee joints (unicentric or polycentric), positional orthosis, rigid support, prefabricated, off-the shelf", depending on whether it is custom fit on delivery or off-the-shelf, adequately describe product and is available for assignment by insurers if they deem appropriate.

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

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

HCPCS Public Meeting Agenda Item # 17 (continued)

Application# 17.074

TOPIC

Request to establish a new Level II HCPCS code to identify an over-the-shoe universal height compensator and balancer, and to consider the device an orthotic. Trade Name: Level-Up, orthosis, corrective shoe.

Applicant does not suggest coding language.

BACKGROUND

ErgoActives, LLC submitted a request to establish a new Level II HCPCS code to identify the Level-Up. According to the applicant, the Level-Up is a universal height compensator and adjuster that alleviates the discomfort for those wearing casts or other devices that create height differences while standing, seated, or walking. It was designed specifically for the non-injured foot. It should never be used without wearing a normal shoe.

The Level-Up is used in the non-affected foot by placing the regular size shoe in the base of the device. It is suitable for users who walk with a maximum of angular external rotation of 40+ degrees or 10+ degrees in internal rotation.

The Level-Up matches the height of the ShoeBaum air cast, or any other fracture boot in the market; it is universal. To accommodate the maximum span of shoe sizes, the device is available in three major shoe sizes: small (for girls and women, sizes 5 to 7.5, and boys and men, sizes 5 to 7); medium (for girls and women, sizes 7.5 to 9; and boys and men, sizes 7 to 10); and large (for girls and women, sizes 10 to 11.5; and boys and men, sizes 10.5 to 13.5).

The applicant comments that existing HCPCS codes do not describe a product that compensates the user's height when using a cast or orthotic boot.

PRELIMINARY HCPCS CODING RECOMMENDATION

This request to establish a new Level II HCPCS codes to separately identify the Level-Up has not been approved. The item that is the subject of this request is not primarily medical in nature and, therefore, it is not suitable for coding within HCPCS.

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

Based on the preliminary coding recommendation, a Medicare payment determination would not apply.

HCPCS Public Meeting Agenda Item # 17 (continued)

Application# 17.075

TOPIC

Request to revise existing Level II HCPCS code E0111 "Crutch forearm, includes crutches of various materials, adjustable or fixed, each, with tip and handgrips" to identify an ergonomic crutch with patented shock absorbers and telescopic tubing, and to consider the device an orthotic. Trade Name: ErgoBaum Royal and ErgoBaum Prince.

Applicant does not suggest coding language.

BACKGROUND

Ergoactives, LLC submitted a request to revise existing Level II HCPCS code E0111 "Crutch forearm, includes crutches of various materials, adjustable or fixed, each, with tip and handgrips" to identify the ErgoBaum Royal and ErgoBaum Prince. The product is available in two sizes: the ErgoBaum Royal for adults; the ErgoBaum Prince for children and junior adults. According to the applicant, the ErgoBaum Royal is a forearm crutch designed for continued use, reducing friction and pain through a patented shock absorber in the lower part of the crutch.

The anatomically designed grip reduces the risk of hand slip or slide. This secondary shock absorber reduces the pressure in the palm of the hand and reduces the burden in the medial nerve, reducing the risk of carpal tunnel syndrome as a result of the pressure exerted by traditional crutches. The third shock absorber in the lower part of the crutch rebounds with every step and reduces the impact force being transferred to the patient.

Additional features include a panic button with an audible alarm and a mounted light to facilitate movement in darker places.

The applicant comments that existing HCPCS codes describe a standard, generic crutch, and the proposed revision is necessary in order to represent the technology, design and features provided by the ErgoBaum Royal and ErgoBaum Prince.

PRELIMINARY HCPCS CODING RECOMMENDATION

A national program operating need was not identified by Medicare, Medicaid, or the private insurance sector to revise existing code E0111 to identify the product that is the subject of this request. For coding guidance, contact the individual insurance contractor in whose jurisdiction a claim would be filed. For Medicaid, contact the Medicaid Agency in the state in which a claim would be filed. For private insurance, contact the individual insurance contractor. For Medicare, contact the Medicare contractor.

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

Based on the preliminary coding recommendation, a Medicare payment determination would not apply.

HCPCS Public Meeting Agenda Item # 17 (continued)

Application# 17.076

TOPIC

Request to establish a new Level II HCPCS code to identify a commode chair, and to consider the device an orthotic Trade Name: Mobile Commode Chair.

Applicant does not suggest coding language.

BACKGROUND

Ergoactives, LLC submitted a request to establish a new Level II HCPCS code to identify the Mobile Commode Chair, and to consider it an orthotic. According to the applicant, the Mobile Commode Chair is a multi-function mobile commode chair that supports the patient while defecating or urinating.

The Mobile Commode Chair allows the user to use the integrated commode; or it can be placed over the toilet to provide additional patient support and comfort. It can also be used to transport the patient to the bathroom and shower, since it is water resistant.

The applicant comments that existing HCPCS codes do not adequately describe this device's technology, features, and material.

PRELIMINARY HCPCS CODING RECOMMENDATION

A national program operating need was not identified by Medicare, Medicaid, or the private insurance sector to establish a new HCPCS code to identify the product that is the subject of this request. For coding guidance, contact the individual insurance contractor in whose jurisdiction a claim would be filed. For Medicaid, contact the Medicaid Agency in the state in which a claim would be filed. For private insurance, contact the individual insurance contractor. For Medicare, contact the Medicare contractor.

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

Based on the preliminary coding recommendation, a Medicare payment determination would not apply.

HCPCS Public Meeting Agenda Item # 17 (continued)

Application# 17.098

TOPIC

Request to establish a new Level II HCPCS code to identify a fully-adjustable ergonomic cane, and to consider it an orthotic. Trade Name: Ergocane.

Applicant does not suggest coding language.

BACKGROUND

Ergoactives, LLC submitted a request to establish a new HCPCS Level II code to identify the Ergocane. According to the applicant, the Ergocane is a fully-adjustable ergonomic cane that provides higher levels of comfort and stability. It has an ergonomic grip handle equipped with shock absorbers in the center of the palm of the hand. It provides support for standing and walking with motion-assisted pendulum design, using internal inertia whereby the cane moves alongside the patient while they walk.

The grip handle is equipped with a new anatomical technology that allows for efficient grabbing of the handle that prevents slipping, allowing for a comfortable, safe, anatomic grip. The cane's anatomic design permits the user to put their whole weight on the cane, providing excellent support. At the same time, the Ergocane is designed to reduce callous formation and carpal tunnel compression, which are associated with long-term cane use.

The Ergocane fully adjusts to the user's height with just a push of the button. It does not possess any holes for height adjustment.

The applicant comments that existing HCPCS codes do not adequately describe the Ergocane's technology, features, and material.

PRELIMINARY HCPCS CODING RECOMMENDATION

A national program operating need was not identified by Medicare, Medicaid, or the private insurance sector to establish a new HCPCS code to identify the product that is the subject of this request. For coding guidance, contact the individual insurance contractor in whose jurisdiction a claim would be filed. For Medicaid, contact the Medicaid Agency in the state in which a claim would be filed. For private insurance, contact the individual insurance contractor. For Medicare, contact the Medicare contractor.

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

Based on the preliminary coding recommendation, a Medicare payment determination would not apply.

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. Additionally, the Social Security Act requires adjustments to the fee schedule amounts for certain items furnished on or after January 1, 2016, in areas that are not competitive bid areas, based on information from competitive bidding programs (CBPs) for DME, enteral nutrients, equipment and supplies. For new items where specific reasonable charge data required by the law in establishing fee schedule amounts does not exist, the fee schedule amounts for comparable items are used for the new items or the fee schedule amounts may be "gap-

filled” using 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**

The allowed payment amount for covered items is based on local carrier pricing (e.g., local fee schedule amounts or reasonable charges or other carrier pricing method.