Centers for Medicare & Medicaid Services (CMS)
Healthcare Common Procedure Coding System (HCPCS)
Application Summaries for DME and Accessories; O & P; Supplies and Other

June 7, 2017

This HCPCS Code Application Summary document includes a summary of each HCPCS code application discussed at the June 7, 2017 HCPCS Public Meeting for DME and Accessories; O & P; Supplies and Others HCPCS code applications are presented within the summary document in the same sequence as the Agenda for this Public Meeting. Each individual summary includes: the application number, topic; background/discussion of the applicant's request; CMS' published preliminary HCPCS coding recommendation; CMS' published preliminary Medicare payment recommendation; a summary of comments offered on behalf of each applicant at CMS' HCPCS public meeting in response to our preliminary recommendations; and CMS' final HCPCS coding decision. We publish a separate HCPCS Code Application Summary document for each HCPCS Public Meeting held. This is one of a series of five HCPCS Code Application Summaries for CMS' 2017-2018 HCPCS coding cycle.

Introduction and Overview

Approximately 69 people attended. The agenda included 17 items.

Cindy Hake, Director, CMS National Level II HCPCS Coding Program and Deputy Director, Division of DMEPOS Policy, provided an overview of the HCPCS public meeting procedures as it relates to the overall HCPCS coding process.

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

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

Information provided at the CMS HCPCS Public Meetings is considered by the CMS HCPCS Coding Workgroup at a subsequent workgroup meeting. The Workgroup reconvenes after the public meetings, and reconsiders its preliminary coding recommendations in light of any new information provided, and formulates its final coding decisions.

CMS maintains the permanent HCPCS Level II codes, and reserves final decision making authority concerning requests for permanent HCPCS codes. Final decisions regarding Medicare payment are made by CMS and must comply with the Statute and Regulations. Payment determinations for non-Medicare insurers, (e.g., state Medicaid Agencies or Private Insurers) are made by the individual state or insurer.

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

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

June 7, 2017

Agenda Item # 1 (a)

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."

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 humility 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

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

There was no primary speaker for this item. No comments were offered at CMS' HCPCS Public Meeting in response to our preliminary decision.

FINAL DECISION

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.

Agenda Item # 1 (b)

June 7, 2017

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

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagreed with CMS' preliminary recommendation on the basis that A9280 is a non-classified code. You stated that other alarms such as for cardiac, diabetic and sleep issues have been granted a specific code. You commented that the OSTOM-i Alert Sensor is an alarm that not only advises the patient when it is time to empty or change their pouch but the device is also part of a system that captures data on the volume and timing when the body is eliminating waste such as solids, liquid and gas. And you reiterated the original request for a HCPCS code specific to the ostomy-I Alert Sensor device.

FINAL DECISION

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.

June 7, 2017

Agenda Item # 1 c

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

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The applicant submitted written comments written comments in response to CMS' published preliminary coding recommendation. Specifically, you disagreed with CMS' preliminary recommendation, stating that the Genteel Lancing device is a breakthrough technology and should be considered Durable Medical Equipment (DME). It is not a supply item. The Genteel device is designed to be a permanent and durable lancing device which can be used for years, as opposed to single or limited number of finger sticks; the genteel device is the only lancer cleared for use for alternative sites as well as fingers; the unique vacuum blood draw assist results in painless blood testing. You commented that painless blood testing leads to improved compliance and more frequent testing which, in turn, results in lower Hemoglobin A1c; fewer emergency room visits and an overall reduction in health care costs. You reiterated your original request for a unique code to distinguish the Genteel lancing device from the other inferior lancing devices; to facilitate data tracking; and because it's the right thing to do.

FINAL DECISION

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.

June 7, 2017

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.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagreed with CMS' preliminary recommendation, restating the original request to either establish a new HCPCS code to describe non-fixed mechanical hinged oral appliances, or assign the Narval CC to existing HCPCS code E0486. The speaker offered the following reasons for these recommendations: 1) Narval CC meets the current E0486 coding description; 2) Local coverage policy article A52512 unnecessarily limits beneficiary access to care and is inconsistently implemented; and 3) patient variability requires a wide range of MRDs to support diverse clinical needs.

FINAL DECISION

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

June 7, 2017

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

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

Written comments were submitted by the applicant describing the Willow Curve's use of dynamic light therapy in conjunction with kinetic heat to treat pain. The commenter stated that there is a need for a new code to describe this low-level laser therapy medical device and to distinguish it from a heating pad.to describe the Willow Curve using dynamic light therapy in conjunction with kinetic heat to treat pain. The applicant stated that "there is a need for a new code to describe this low-level laser therapy medical device with the following language: Low-level light therapy device emitting both red and infrared radiation."

FINAL DECISION

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.

June 7, 2017

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 and 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.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagreed with CMS' preliminary recommendation commenting that the device is not limited to use in facilities; the device has been used successfully in home environments; and the combination of these components into an enhanced integrated system does not change their character as DME. The speaker reiterated the original request to recognize the product as DME and establish two new Level II HCPCS codes. We also appreciated the demonstration of the AgileLife Transfer and Mobility System provided to CMS staff on August 23, 2017.

FINAL DECISION

Existing codes E1035 "Multi-positional patient transfer system, with integrated seat, operated by caregiver, patient weight capacity up to and including 300 lbs" or E1036 "Multi-positional patient transfer system, extra-wide, with integrated seat, operated by caregiver, patient weight capacity greater than 300 lbs" adequately describes the device that is the subject of this request.

June 7, 2017

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.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagreed with CMS' preliminary recommendation commenting that the artificial pancreas device system, single hormonal control, is clinically and functionally different from devices described by E0784 which does not acknowledge the on-going evolution of diabetes technology". The speaker commented that the device meets all criteria to add a permanent Level II HCPCS code; reiterated the original request; and indicated that the decision to use S-codes gives clear evidence that E0784 does not adequately describe this device.

FINAL DECISION

A national program operating need was not identified by Medicare, Medicaid, or the private insurance sector to establish a new Level II HCPCS code to identify 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.

June 7, 2017

Agenda Item # 6

Application# 17.115

TOPIC

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: "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

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The commenter disagreed with CMS' preliminary decision, stating that the specified existing codes do not distinguish between products based on type of FDA clearance (e.g., FDA Class III and FDA Class II 510 K devices); the cost of manufacturing and quality management is higher for class III then class II devices; and as such higher reimbursement, and separate codes to support higher reimbursement, are appropriate.

FINAL DECISION

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.

June 7, 2017

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: "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

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The commenter disagreed with CMS' preliminary decision, stating that the specified existing codes do not distinguish between products based on type of FDA clearance, (e.g., FDA Class III and Class II 510 K devices); the cost of manufacturing and quality management is higher for class III then class II devices; and as such higher reimbursement, and separate codes to support higher reimbursement, are appropriate.

FINAL DECISION

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.

June 7, 2017

Agenda Item # 7 (a)

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.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagreed with CMS' preliminary decision, and reiterated the original code request to separately identify the iUFlow device. You also indicated that when the uroflowmetry

device is used in the patient's home, it is not part of a procedure, and a HCPCS code is needed to report the device on claims.

FINAL DECISION

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.

June 7, 2017

Agenda Item # 7 (b)

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.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagreed with CMS' preliminary coding recommendation, indicating that the sale of more than 30,000 devices constitutes a national program operating need for new codes; suggested that the adaptive eating utensil should be considered Durable Medical Equipment; and reiterated the original code request to establish new codes.

FINAL DECISION

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.

June 7, 2017

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. The reporting and use of additional codes could be considered duplicative.

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

No separate Medicare payment.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The applicant submitted written comments disagreeing with the preliminary recommendation that the SAM device is applied daily in the home by the patient, and not in the medical setting. Therefore, HCPCS coding and billing is appropriate for reporting the home use of the SAM device for medical treatment.

FINAL DECISION

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. This device is FDA cleared for use only when administered and monitored by a healthcare practitioner. The products that are the subject of this application are an integral part of a procedure and payment for that service includes payment for the ultrasound device and coupling patches if used. Reporting using additional codes could be considered duplicative and inappropriate.

June 7, 2017

Agenda Item # 9

Application# 17.094

TOPIC

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

Applicant's suggested language: "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.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The commenter disagreed with CMS' preliminary coding recommendation, stating that the FDA classification of the WalkJoy as a Biofeedback device does not mean the device is used as part of a procedure, and independent use of the device by a patient in their home is not part of a procedure. The device should be considered Durable Medical Equipment and separately billable when used in the home.

FINAL DECISION

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. For Medicare, this product is an integral part of a procedure, and payments for that service includes payment for the WalkJoy device if it is used. Non-Medicare insurers did not identify a national program operating need to establish a new code. For coding guidance for non-Medicare insurers, 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.

June 7, 2017

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 and the Kangaroo ePump, if used in the home, are 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

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The commenter disagreed with CMS' preliminary decision, and reiterated the original request to establish two new HCPCS codes. The commenter stated that existing HCPCS codes do not describe the Kangaroo ePump, or the Kangaroo Joey Pump, or the enteral feeding set supply kits designed; and that the Kangaroo ePump and Joey Pump and enteral feeding sets are designed for both the institutional and home setting.

FINAL DECISION

1) The Kangaroo Joey Enteral Feed and Flush Pump and the Kangaroo ePump Enteral Feeding Pump, if used in the home, are adequately described by the existing code B9002 "Enteral nutrition infusion pump, any type". The code B9002 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.

June 7, 2017

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

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The commenter disagreed with CMS' preliminary recommendation, and suggested that the workgroup reconsider the original request to modify existing code A9277 to add the same unit of service as the matching sensor: 1 unit = 1 day, to allow for consistent, reliable payment for devices which perform a similar medical purpose. The commenter also stated that there is a need for consistency to the billing and payment of CGM supplies, and to standardize billing practices across both current and future transmitters, but that "a consolidated billing code eliminates the flexibility needed in the market".

FINAL DECISION

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, newly code K0553 "Supply allowance for therapeutic continuous glucose monitor (CGM), includes all supplies and accessories, 1 month supply = 1 Unit Of Service", effective 07/01/2017, is available for assignment for insurers if they deem appropriate.

June 7, 2017

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

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The applicant submitted written comments on behalf of QuadshoX, LLC, in reaction to our published preliminary coding recommendation. These comments stated that no existing code

category describes QuadshoX wheelchair suspension kits, and as such categorizing them in existing codes is misleading and inappropriate. The applicant offered examples of the potential benefits for the use of the QuadshoX suspension systems and suggested that the FDA's classification of QuadshoX as wheelchair "accessories" should be interpreted by CMS's contractors as requiring separate coding and payment. The applicant reiterated the original request for a unique HCPCS code.

FINAL DECISION

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.

June 7, 2017

Agenda Item # 13

Application# 17.125

TOPIC

Request to establish a new Level II HCPCS code to identify a hand-held intrapulmonary acoustical airway clearance device. Trade Name: Vibralung Acoustical Percussor.

Applicant's suggested language: "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 a hand-held 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

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

There was no primary speaker for this item. No comments were offered at CMS' HCPCS Public Meeting in response to our preliminary decision.

FINAL DECISION

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.

June 7, 2017

Agenda Item # 14

Application# 17.110

TOPIC

Request to establish a new Level II HCPCS code to identify a robotic manipulator arm which attaches to a wheelchair or tabletop, and is for use by persons with limited upper extremity mobility who also use a power wheelchair: 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.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagreed with CMS' preliminary coding recommendation, commenting that the JACO is similar to a prosthetic arm since it can grab and reach. It serves a significant unmet need to assist with Activities of Daily Living for persons in Group 3 powered wheelchairs. You also indicated that a new code is warranted as CRT Power Group 3 wheelchair users require various levels of care, JACO can self-empower individuals to carry out ADL activities independently, which can reduce care-giver time and empower individual users. In addition, you suggested the following language for a code: "Power wheelchair accessory, robotic arm with three finger hand".

FINAL DECISION

A national program operating need has not been identified by Medicare, Medicare, or Private Insurers. For coding guidance, contact the insurer in whose jurisdiction a claim would be filed.

June 7, 2017

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.

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 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 Ibs.

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

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagreed with CMS' preliminary recommendation, commenting that existing code E2626 does not adequately describe GoWing or its capabilities. The applicant stated that the GoWing differs from the "traditional arm support" in that it is electrically powered by the user's wheelchair battery, can be adjusted by the user, and the up/down tension is fully adjustable. You reiterated the request to establish a new code and recommended the following language: " Wheelchair accessory, arm support, attached to wheelchair, powered, locking, user adjusted."

FINAL DECISION

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.

June 7, 2017

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), ostegogenesis 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.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

Written and oral comments were provided at CMS' HCPCS Public Meeting in reaction to our published, preliminary coding recommendations for application numbers: 17.118, 17.119, and 17.120. Specifically, you expressed agreement with the preliminary decision not to create unique HCPCS codes for all three application requests. You discussed the low utilization of these devices. You suggested alternative coding options to either establish one wheelchair accessory NOC (not Otherwise Classified) code; or two wheelchair accessory NOC codes, one for prefabricated lower extremity positioning devices and the other for custom fabricated lower extremity positioning devices. You also stated that there are no studies about clinical distinctions between “footboxes” and other footrests, and that Sunrise Medical “cannot afford” such studies. You also indicated that the CMS HCPCS workgroup should consider the coding issues associated with the complex rehab products foot box technology.

FINAL DECISION

Establish E0954, "Wheelchair accessory, foot box, any type, includes attachment and mounting hardware, each foot".

June 7, 2017

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), ostegogenesis 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.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker submitted written and oral comments at CMS' HCPCS Public Meeting in reaction to our published, preliminary coding recommendations for application numbers: 17.118, 17.119, and 17.120. Specifically, you expressed agreement with the preliminary decision not to create unique HCPCS codes for all three application requests. You discussed the low utilization of these devices. You suggested alternative coding options to either establish one wheelchair accessory NOC (not Otherwise Classified) code; or two wheelchair accessory NOC codes, one for prefabricated lower extremity positioning devices and the other for custom fabricated lower extremity positioning devices. You also stated that there are no studies about clinical distinctions between “footboxes” and other footrests, and that Sunrise Medical “cannot afford” such studies. You also indicated that the CMS HCPCS workgroup should consider the coding issues associated with the complex rehab products foot box technology.

FINAL DECISION

Establish E0954, "Wheelchair accessory, foot box, any type, includes attachment and mounting hardware, each foot".

June 7, 2017

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, and 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), ostegogenesis 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.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

Written and oral comments were provided at CMS' HCPCS Public Meeting in reaction to our published, preliminary coding recommendations for application numbers: 17.118, 17.119, and 17.120. Specifically, you expressed agreement with the preliminary decision not to create unique HCPCS codes for all three application requests. You discussed the low utilization of these devices. You suggested alternative coding options to either establish one wheelchair accessory NOC (not Otherwise Classified) code; or two wheelchair accessory NOC codes, one for prefabricated lower extremity positioning devices and the other for custom fabricated lower extremity positioning devices. You also stated that there are no studies about clinical distinctions between “footboxes” and other footrests, and that Sunrise Medical “cannot afford” such studies. You also indicated that the CMS HCPCS workgroup should consider the coding issues associated with the complex rehab products foot box technology.

FINAL DECISION

Establish E0954, "Wheelchair accessory, foot box, any type, includes attachment and mounting hardware, each foot".

June 7, 2017

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 relsient 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.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

No comments were offered on behalf of Adaptive Engineering Lab in reaction to CMS' published preliminary coding recommendations.

FINAL DECISION

Establish E0954, "Wheelchair accessory, foot box, any type, includes attachment and mounting hardware, each foot".

June 7, 2017

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.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

No comments were offered on behalf of Adaptive Engineering Lab in reaction to CMS' published preliminary coding recommendations.

FINAL DECISION

Establish E0954, "Wheelchair accessory, foot box, any type, includes attachment and mounting hardware, each foot".

June 7, 2017

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

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker provided comments at CMS' HCPCS Public Meeting in reaction to our published preliminary coding recommendation. Specifically, the commenter offered technical specifications and a detailed description of the device that is the subject of this HCPCS code application.

FINAL DECISION

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.

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.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker provided comments at CMS' HCPCS Public Meeting in reaction to our published preliminary coding recommendation. Specifically, the commenter offered technical specifications and a detailed description of the device that is the subject of this HCPCS code application.

FINAL DECISION

1) Establish L3761, "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 L3761 or revised code L3760 adequately describes the product that is the subject of this application, depending on whether it is custom fit.

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.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker provided comments at CMS' HCPCS Public Meeting in reaction to our published preliminary coding recommendation. Specifically, the commenter offered technical specifications and a detailed description of the device that is the subject of this HCPCS code application.

FINAL DECISION

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.

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 code 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 describes 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

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The commenter offered technical specifications and a detailed product description of the ErgoBrace Post-Op Knee Brace.

FINAL DECISION

This request to establish a new Level II HCPCS code to separately identify the ErgoBrace Post-Op Knee Brace has not been approved. Existing code 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 describes product and is available for assignment by insurers if they deem appropriate.

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.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker offered technical specifications and a detailed product description of the Level-Up device.

FINAL DECISION

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.

June 7, 2017

Agenda # 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 excerpted 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.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker offered technical specifications and a detailed product description of the ErgoBaum Royal and ErgoBaum Prince devices.

FINAL DECISION

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.

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.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker offered technical specifications and a detailed product description of the Mobile Commode Chair.

FINAL DECISION

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.

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.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker provided handouts for each of the workgroup members that included technical specifications pertaining to the applications inclusive of detailed product descriptions.

FINAL DECISION

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.