Centers for Medicare & Medicaid Services (CMS)
Healthcare Common Procedure Coding System (HCPCS)
Application Summaries for Durable Medical Equipment, Prosthetics, Orthotics and Medical Supplies (DMEPOS)

Wednesday, June 12, 2019

This HCPCS Code Application Summary document includes a summary of each HCPCS code application discussed at the June 12, 2019 HCPCS Public Meeting for Drugs, Drugs, Biologicals and Radiopharmaceuticals and Radiologic Imaging Agents. 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' 2019-2020 HCPCS coding cycle.

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: https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Alpha-Numeric-HCPCS.html

June 12, 2019

CMS HCPCS Public Meeting

Agenda Item # 1

Application # 19.016

TOPIC

Request to establish a new Level II HCPCS code to identify a single-use vaginal tissue retraction sheath for use with vaginal speculum. Trade name: Nella VuSleeve.

Applicant's suggested language: AXXXX Vaginal speculum retraction sleeve, disposable, each, for the Nella VuSleeve, a vaginal speculum accessory.

BACKGROUND

According to the applicant, the Nella VuSleeve is a single-use Vaginal Tissue Retraction sheath for use with most common vaginal speculum sizes and styles. It is designed to facilitate a gynecological examination for women with vaginal laxity, obesity, or other conditions that hinder the access and visualization of the cervix. The VuSleeve increases visibility and access to the cervix by retracting encroaching vaginal sidewall tissue, allowing healthcare professionals to obtain a full, unobstructed view of and access to the cervix. The Nella VuSleeve is used for cervical cancer screening. According to the applicant, "there is no other FDA approved medical device that is specifically designed for this indicated use." No current HCPCS code exists; there is a programmatic need for a new HCPCS code to describe this supply, which facilitates appropriate cervical cancer screening in women.

PRELIMINARY HCPCS CODING RECOMMENDATION

CMS refers the applicant to the American Medical Association (AMA) for coding guidance for reporting a VuSleeve, if used during a pelvic exam procedure.

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

No separate Medicare payment.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagreed with CMS preliminary recommendation. The speaker stated that VuSleeve is not used or included in every procedure; the sheath is only used when vaginal laxity is present and it meets CMS' definition of a supply. Furthermore, the value of Vusleeve is not currently captured in any procedure code.

FINAL DECISION

New code not established to specifically identify the Vu Sleeve as it would be an incidental supply that is considered to be included in current coding. For coding guidance, contact insurers in whose jurisdiction claims would be filed.

June 12, 2019

CMS HCPCS Public Meeting

Agenda Item # 2

Application # 19.067

TOPIC

Request to create a coding distinction between parenteral nutrition solution lipid formulations currently included in code category B4185 in a way that would separately code a single, specific fish oil solution by brand name, "Omegaven"; and include all soybean oil- containing lipid solutions, (including those also containing lipids from fish and other sources), in code B4185.

Applicant's suggested language:

Establish new code: "Parenteral nutrition solution, per 5 grams fish oil triglycerides (Omegaven)"

Revise existing code B4185 which currently reads "Parenteral nutrition solution, per 10 grams lipids", to instead read "Parenteral nutrition solution, per 10 grams soybean oil-containing lipids"

BACKGROUND

Fresenius Kabi USA, LLC requested that CMS establish a unique code to specify Omegaven by brand name; modify existing code B4185 to specify any and all soybean oil-containing lipids. According to the requester, Omegaven is a novel intravenous lipid emulsion (ILE), that contains fish oil triglycerides as its only active ingredient and no soybean or other plant-source components. Omegaven is indicated as a source of calories and fatty acids in pediatric patients with parenteral nutrition-associated cholestasis (PNAC). The fish oil in Omegaven is a new molecular entity and distinct from the fish oil contained in other primarily plant-based lipid parenteral nutrition (PN) products. This is because the fish oil in Omegaven is produced by Fresenius Kabi using a novel, multi-step winterization process, which results in an enrichment of Omega-3 fatty acid and a different ratio of eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) when compared to the fish oil in Smoflipid. Because of its unique composition, Omegaven has a distinctly different use, mechanism of action, function/treatment, clinical indication, and clinical outcome than the soybean oil-containing ILEs listed above. Omegaven provides a significantly improved medical outcome for pediatric PNAC patients who are dependent on PN and would otherwise be forced to forgo medically necessary lipid in their PN or be exposed to soybean oil, which could allow further progression of PNAC. Omegaven's significant therapeutic distinction is also evident from the statuses granted by the FDA and comments made during the FDA's review and approval of Omegaven such as Omegaven received Priority Review designation and Fast Track designation. The FDA noted that Omegaven will address the unmet need for an alternative parenteral source of nutrition for pediatric patients with PNAC that is not soybean oil-based; soybean oil-based lipid emulsions

are believed to contribute to progression of the manifestations of PNAC. Omegaven allows pediatric patients with PNAC to continue receiving medically necessary lipid PN and experience improved liver function parameters, including PNAC resolution. Omegaven provides fatty acids for intravenous infusion without exposing patients to soybean oil. This allows vulnerable pediatric PNAC patients to continue receiving lipid PN and experience the key benefits associated with ILEs, including age-appropriate growth and low risk of essential fatty acid deficiency. The recommended, and maximum, dose of Omegaven is 1 g/kg/day, administered via intravenous infusion over 8-24 hours either alone or as part of a PN admixture. The Omegaven is supplied as single-dose bottles containing 5 g fish oil/50 ml and 10 g fish oil/100 ml. No other products contain the same active ingredient (fish oil triglycerides) as Omegaven.

PRELIMINARY HCPCS CODING RECOMMENDATION

Existing code B4185 “Parenteral Nutrition Solution, per 10 grams lipids”, adequately describes lipid parental nutrition solutions. As such this code may be used to identify Omegaven. The clinical evidence submitted with this application is insufficient to support the applicant's claim of significant therapeutic distinction.

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

The Medicare fee schedule amounts for code B4185 for lipid solutions would apply to any codes for any type of lipid solution.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagreed with CMS preliminary recommendation. The speaker stated that based on clinical evidence, and personal experience, the adoption of Omegaven will be the new standard of care for PN-dependent pediatric PNAC patients, and feels Omegaven represents a significant therapeutic distinction from other lipid formulations.

FINAL DECISION

1. Revise B4185 to read "Parenteral nutrition solution, not otherwise specified, 10 grams lipids". Effective. 01/01/2020.

2. Establish new Level II HCPCS code B4187 "Omegaven, 10 grams lipids". Effective. 01/01/2020.

June 12, 2019

CMS HCPCS Public Meeting

Agenda Item # 3

Application # 19.102

TOPIC

Request to establish a new Level II HCPCS code to identify a plastic vessel to regulate the flow of urine. Trade name: BioFlo Auto Valve.

Applicant's suggested language: "Vessel containing an automated release mechanism to regulate the flow of urine"

BACKGROUND

BioFlo, LLC requested a new unique code to identify a plastic vessel to regulate the flow of urine, specifically, used in an aseptic closed system for urinary drainage. According to the applicant, the BioFlo Auto Valve, is designed to regulate the flow of urine between two detachable housings maintaining a closed system and allowing for the cyclical emptying of the bladder. An automated release mechanism consisting of magnetic elements, plunger and spring are used to cycle the flow of liquid through the vessel. The BioFlo Auto Valve is meant to be inserted between any urinary catheter and the drainage bag to maintain a closed urinary system even during cleaning and disconnection of the bag. The closed system is designed to eliminate the spread of bacteria in the urinary tract. The population served by the BioFlo Auto Valve is any person with urinary catheter in any setting from hospital to home. The BioFlo Auto Valve package contains one Tyvek bag, one BioFlo Auto Valve with a clear, polycarbonate housing, 4" x 1", which contains an automatic, fluid pressure controlled magnetic valve and a Luer Lock sampling port. Persons using urinary catheters are susceptible for either acquiring a urinary tract infection (UTI) and/or a catheter-associated urinary tract infection (CAUTI). Information on usage of the BioFlo Auto Valve demonstrates: reduction of CAUTI/UTI's. The BioFlo LLC claims a significant therapeutic distinction when use of the BioFlo Auto Valve is compared to the use of other, similar items that would otherwise share a HCPCS code. According to the BioFlo, LLC, the BioFlo Auto Valve is the only closed urinary management system to maintain a "Closed System" even when bags are detached. It is designed to prohibit urine backflow into indwelling catheter, allows to obtain a urine sample aseptically, and provides the ability to disconnect from urine collection bag to allow for easier patient transfer. BioFlo, LLC claims the BioFlo Auto Valve "Is proven to reduce CAUTI in in-patient facilities. And claims that a new code is needed because no existing code describes the BioFlo Auto Valve's automated release mechanism to regulate the flow of urine.

PRELIMINARY HCPCS CODING RECOMMENDATION

Anti-reflux capability is included in existing code A4357 “Bedside drainage bag, day or night, with or without anti-reflux device, with or without tube, each”. Existing code A9900 ”Miscellaneous dme supply, accessory, and/or service component of another HCPCS code” is also available for assignment by insurers, if they deem appropriate. We do not have information from any insurer that a coding distinction to specify “auto-release” release feature is needed.

The Level II HCPCS codes describe categories of similar items. The code set is not intended to be an exhaustive listing of all products on the market. While CMS believes that existing codes, as indicated above, describe the products that are the subject of this request, as a general rule, CMS does not assign individual products to existing codes on behalf of any insurer. Individual insurers have the necessary flexibility to assign individual products to existing codes in the manner consistent with their individual policies and programmatic needs. For coding guidance, please refer to the insurer(s) in whose jurisdiction(s) claim would be filed. For Medicaid, contact the Medicaid Agency in the state in which the claims would be filed. For private insurance, contact the individual private insurance entity.

Under contract to CMS, the Pricing, Data Analysis and Coding (PDAC) provides coding verifications for the purpose of billing Medicare. For confirmation of appropriate code assignment for Medicare billing, you may contact the PDAC Contact Center toll free at 877-735-1326. For your convenience, the PDAC has compiled a product classification system called DMECS that lists individual products by brand name under code categories. This system is available at: http://www.dmepdac.com. If you do not find your product listed by the PDAC matrix, you may request a coding verification for your product by contacting the PDAC at the toll free telephone number listed above.

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

The payment rules associated with the existing code apply to this product if covered. Pricing=37.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagreed with CMS preliminary recommendation. The speaker stated that no existing codes adequately describe BioFlo form and function, and BioFlo AutoValve provides a significant therapeutic distinction and cost effective clinical outcomes. Anti-Reflux capability is not a part of BioFlo AutoValve, rather it is part of the bag.

FINAL DECISION

Anti-reflux capability is included in existing code A4357 "Bedside drainage bag, day or night, with or without anti-reflux device, with or without tube, each". Existing code A9900 "Miscellaneous dme supply, accessory, and/or service component of another hcpcs code" is also available for assignment by insurers, if they deem appropriate. We do not have information from any insurer that a coding distinction to specify "auto-release" release feature is needed.

June 12, 2019

CMS HCPCS Public Meeting

Agenda Item # 4

Application # 19.118

TOPIC

Request to establish a new Levell II HCPCS code to identify sleep position therapy device, Trade Name: Lunoa system.

Applicant's suggested language: EXXXX "Sleep position therapy device, electronic senor with adjustable vibrotactile feedback, includes all components."

BACKGROUND

Respironics, Inc. submitted a request to establish a new Level II HCPCS code to identify the Lunoa system.

According to the applicant, the Lunoa system has three components operated as one system to provide treatment for positional obstructive sleep apnea (POSA). It has a sensor, chest strap, docking station, power adapter, travel case, and portal. The sensor is battery-operated, rechargeable, worn around the chest. The sensor contains a digital accelerometer that continually monitors a patient's sleep position. By emitting the vibro-tactile feedback during sleep, the sensor has been proven to keep patients with positional obstructive sleep apnea (POSA) from sleeping in the supine position. When using the device, if the patient turns to a supine position, the device vibrates until the patient moves to a non-supine position.

According to the applicant, the patient can review the data on the sensor device. When placed in the docking station, the sensor encrypts and transmits the data to the cloud. The data are rendered into readable format and displayed on a portal for the user. The portal allows users, such as the patient and the physician to view the data. Prior to use the each patient completes the adaptation program to ensure that the Lunoa system functions as well as possible.

The applicant claims, "Significant therapeutic distinction when compared to traditional treatments for POSA, as demonstrated by published, peer reviewed evidence. The Lunoa system has been demonstrated in multiple randomized, controlled trials (RCTs) to deliver better outcomes to those historical treatments for POSA, and to deliver equivalent therapeutic effects as other Medicare-recognized treatments for OSA, including positive airway pressure (PAP) devices and customized oral appliances, that are identified by different HCPCS codes." According to the applicant, currently, there are no other similar items that would share a code with Lunoa system.

PRELIMINARY HCPCS CODING RECOMMENDATION

Existing Level II HCPCS code A9279 "Monitoring feature/device, stand-alone or integrated, any type, includes all accessories, components and electronics, not otherwise classified", describes the monitoring features of the Lunoa system sleep position training, monitoring sensing system, and is available for assignment by insurers if they deem appropriate. Existing code A9280 "Alert or alarm device, not otherwise classified" is available for assignment by insurers if they deem appropriate to describe the "vibrational feedback" provided by the Lunoa system.

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

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

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagreed with CMS' preliminary recommendation. The speaker commented that "A" codes are not appropriate for a therapeutic device. The speaker states that there are no existing codes that describe the Lunoa System, nor similar items demonstrated to have a similar clinical benefit.

FINAL DECISION

Establish a new Level II HCPCS code K1001 "Electronic positional obstructive sleep apnea treatment, with sensor, includes all components and accessories, any type". Effective 01/01/2020.

June 12, 2019

CMS HCPCS Public Meeting

Agenda Item # 5

Application # 19.119

TOPIC

Request to establish a new Level II HCPCS code to identify the Precice External Remote Controller for patient use as part of their post-operative limb-lengthening protocol.

BACKGROUND

NuVasive Specialized Orthopedics, Inc. submitted a request to establish a new Level II HCPCS code to identify the Precice External Remote control (ERC).

According to the applicant, Precice external remote control is the non-invasive hand-held device for patient use to control the magnetic intramedullary device surgically placed in the affected limb. The orthopedic surgeon programs the patient's external remote control with a customized adjustment protocol. The magnet in the implant turns when the patient places the ERC on the affected limb for a few minutes every day for approximately six months. It is indicated for limb length discrepancies, fractures, pseudoarthrosis, malunions and transport of long bones.

According to the applicant, there is no similar item and there is available HCPCS Level II code for a hand-held "intramedullary external remote control".

PRELIMINARY HCPCS CODING RECOMMENDATION

The ERC Controller is initially issued post-surgery prior to patient discharge. As such, it is included in the hospital payment. If used during a specific HOPD or ASC procedure/service, payment would be included in the CPT code that is reported. Separate billing would be redundant.

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

No separate Medicare payment.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

We received no comments at CMS' HCPCS Public Meeting regarding this application.

FINAL DECISION

The ERC Controller is initially issued post surgery prior to patient discharge. As such, it is included in the hospital payment. If used during a specific HOPD or ASC procedure/service, payment would be included in the CPT code that is reported. Separate billing would be redundant.

June 12, 2019

CMS HCPCS Public Meeting

Agenda Item # 6

Application # 19.120

TOPIC

Request to establish a new Level II HCPCS code to identify Wheelchair Accessory, Trade Name: Sunrise Medical Dynamic Seating Component.

Applicant suggested language: EXXX1 "wheelchair accessory, dynamic seating (seat to back or pelvis) component."

BACKGROUND

Sunrise Medical US LLC, submitted a request to establish a new Level II HCPCS code to identify Sunrise medical dynamic seating component.

According to applicant, the mechanism consists of dynamic components, joints, linkages and elastomers, and is designed to be attached to a wheelchair frame. The system is designed to accommodate the wheelchair user's flexion and extension with minimal displacement at the pelvis during movement, and the variable spring resistance returns the individual back to their initial posture. The Sunrise dynamic back component allows a person seated in a wheelchair to independently extend at the hips for postural relief or abnormal tone or uncontrollable movement. Static wheelchair frame components do not allow for an individual's abnormal and uncontrolled movement within the system and cannot withstand the high level of repeated force these individuals can exert. This device is designed to move with the patient. As the person extends, flexes stretches and shifts his or her weight due to high tone, uncontrolled movement, or relieve discomfort or pressure, the dynamic component responds to the forces that movement produces. According to applicant, the dynamic seating components are recommended for people with permanent disabilities, who require the use of manual or power mobility and who exhibit atypical muscle tone, diminished muscle strength and abnormal movement patterns spastic, athetoid, ataxia, hypotonic, mixed a typical muscle tone and a typical movement pattern. The dynamic seating component is significantly different because it provides pressure relief; reinforces functional movement patterns (spasticity), allows strengthening and encourages active communication by accommodating forward flexion. Spasticity requiring treatments most commonly seen in conditions such as stroke, multiple sclerosis, and celebral palsy. Clinical studies have shown benefits that include increased social interaction, increased strength and range of motion, and development of motor skills.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish EXXXX: "Wheelchair accessory, dynamic positioning hardware for back"

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

We believe that the item would be paid in accordance with the payment rules that apply to capped rental items if covered.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker agreed with CMS' preliminary coding recommendation, but argued against Capped Rental for disabled individuals and other potential patients with permanent disabilities.

FINAL DECISION

Establish a new Level II HCPCS code E2398 "Wheelchair accessory, dynamic positioning hardware for back" Effective 1/1/2020.

June 12, 2019

CMS HCPCS Public Meeting

Agenda Item # 7

Application # 19.123

TOPIC

Request to establish a new Level II HCPCS code to identify a self-guided exercising device of the hand, including wrist and fingers, Trade Name: RAPAEL Smart Glove for Home.

Applicant's suggested language: EXXXX "Self-guided exercising device of the hand, including wrist and fingers, using hand mounted device with software contents enabling real-time measurement and monitoring of hand movements."

BACKGROUND

Request submitted on behalf of NEOFECT USA, to establish a new level II HCPCS code to identify RAPAEL Smart Glove for Home.

According to applicant, the device is a hand-mounted glove-shaped wearable device used by patients requiring forearm, hand, wrist, and finger exercises as part of their neuromuscular rehabilitation. It is intended to improve range of motion, coordination and timing of functional arm and hand movements by engaging the patient in training exercises, using the patient's hand as a controller. The RAPAEL Smart Glove software directs the patients to properly perform repetitive task-oriented exercises that improve patients ability to properly perform activities of daily living. The system includes the smart glove device, charger, tablet, software, instructions for use and warranty. The virtual reality environment helps to motivate patients to complete more repetitions during exercise session. The software adjusts the difficulty of the exercises in real time to further encourage completion. The population that benefits clinically from the this device are people with stroke, traumatic brain injury, multiple sclerosis, arthritis, fracture and post skin graft, with some degree of active motion. Typical treatment protocol entails eight exercises during 25-30 minute sessions. Before each exercise, the system measures the patient's range of motion threshold and set the appropriate level of exercise difficulty. The RAPAEL Smart Glove is the only home-based medical device for arm and hand exercise, using hand-mounted glove with embedded sensors to monitor real time movements. No existing HCPCS code adequately describe the device.

PRELIMINARY HCPCS CODING RECOMMENDATION

Existing code A9300 "Exercise Equipment", adequately describes the RAPAEL Smart Glove and is available for assignment by insurers if they deem appropriate.

The Level II HCPCS codes describe categories of similar items. The code set is not intended to be an exhaustive listing of all products on the market. While CMS believes that an existing code, as indicated above, describes the product that is the subject of this request, as a general rule, CMS does not assign individual products to existing codes on behalf of any insurer. Individual insurers have the necessary flexibility to assign individual products to existing codes in the manner consistent with their individual policies and programmatic needs. For coding guidance, please refer to the insurer(s) in whose jurisdiction(s) claim would be filed. For Medicaid, contact the Medicaid Agency in the state in which the claims would be filed. For private insurance, contact the individual private insurance entity.

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PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

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

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

We received no comments at CMS' HCPCS Public Meeting regarding this application, or in response to our published preliminary recommendation.

FINAL DECISION

Existing code A9300 "Exercise Equipment", adequately describes the RAPAEL Smart Glove and is available for assignment by insurers if they deem appropriate.

June 12, 2019

CMS HCPCS Public Meeting

Agenda Item # 8

Application # 19.124

TOPIC

Request to establish a Level II HCPCS code to identify suspension and vibration reduction propulsion wheels, Trade Name: Loopwheels.

Applicant's suggested language: "Manual wheelchair accessory, vibration reducing and suspension propulsion wheel, excludes tire, any size, each."

BACKGROUND

Jelly Products Ltd. submitted a request to establish a new Level II HCPCS code to identify Loopwheels.

According to applicant, Loopwheels are a propulsion wheels technology with an integral carbon composite spring system comprised of six flexible springs in place of rigid spokes thus incorporating the shock-absorption system within the wheel. In addition to propulsion of the wheelchair, it reduces vibration of the body, makes it easier to pass over uneven surfaces, reduce pain and increase sitting tolerance in the wheelchair. Loopwheels are available in 24' and 25' diameter and may be used with all manual wheelchairs. The Loopwheel is clinically beneficial for manual wheelchair users with spasms, chronic pain, fatigue, pressure sores, and poor bladder control. Recommended weight limits are greater than 50 kg and up to 120 kg. Loopwheels propulsion wheels on average reduce vibration by up to 70 percent compared to spoked wheel. It requires the least force needed to initiate movement and maintain motion to minimize wear and tear of the shoulders. The current code E1015 is inappropriate due to technology, functional and cost differences. The caster fork and propulsion wheels have different technologies

PRELIMINARY HCPCS CODING RECOMMENDATION

The suspension and vibration reduction propulsion wheels that are the subject of this request are included in the wheelchair base code on initial issue. Existing code E2224 “Manual wheelchair accessory, propulsion wheel excludes tire, any size, replacement only, each” adequately describes replacement propulsion wheels, and is available for assignment by insurers if they deem appropriate.

The Level II HCPCS codes describe categories of similar items. The code set is not intended to be an exhaustive listing of all products on the market. While CMS believes that existing codes, as indicated above, describe the product that is the subject of this request, as a general rule, CMS does not assign individual products to existing codes on behalf of any insurer. Individual insurers

have the necessary flexibility to assign individual products to existing codes in the manner consistent with their individual policies and programmatic needs. For coding guidance, please refer to the insurer(s) in whose jurisdiction(s) claim would be filed. For Medicaid, contact the Medicaid Agency in the state in which the claims would be filed. For private insurance, contact the individual private insurance entity.

Under contract to CMS, the Pricing, Data Analysis and Coding (PDAC) provides coding verifications for the purpose of billing Medicare. For confirmation of appropriate code assignment for Medicare billing, you may contact the PDAC Contact Center toll free at 877-735-1326. For your convenience, the PDAC has compiled a product classification system called DMECS that lists individual products by brand name under code categories. This system is available at: http://www.dmepdac.com. If you do not find your product listed by the PDAC matrix, you may request a coding verification for your product by contacting the PDAC at the toll free telephone number listed above.

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

This is a component of the wheelchair, so separate payment on initial issue is not allowed. On replacement, the payment rules associated with existing code E2224 applies to this product if covered. Pricing=32.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagreed with CMS preliminary recommendation. The speaker stated that whole body vibrations can be very damaging and can contribute to lower back pain, spasms, fatigue, poor bladder control, presence of pressure sores and limited rehabilitation, due to low confidence and worry about pressure sores. Existing products do not adequately address the problems, and a unique HCPCS code is needed to identify integrated shock absorbing wheel systems.

FINAL DECISION

The suspension and vibration reduction propulsion wheels that are the subject of this request are included in the wheelchair base code on initial issue. Existing code E2224 "Manual wheelchair accessory, propulsion wheel excludes tire, any size, replacement only, each" adequately describes replacement propulsion wheels, and is available for assignment by insurers if they deem appropriate.

June 12, 2019

CMS HCPCS Public Meeting

Agenda Item # 9

Application # 19.125

TOPIC

Request to establish a new Level II HCPCS code to identify Surface Acoustic Waves 90KHz Pain Management Ultra Sound, Trade Name: The PainShield MD.

BACKGROUND

Nano Vibronix Ltd. submitted a request to establish a new Level II HCPCS code to identify the PainShield MD and its associated disposable components.

According to the applicant, the PainShield MD is an ultrasound device used to apply heat to the tissues in the body with a transducer/applicator that is incorporated into a patch that adheres to the skin, as does a bandage. The PainShield MD is used to generate continuous surface acoustic waves ultrasound at 90KHZ, through a reusable applicator/transducer that covers an area of about 6 cm^2. The small applicator allows treatment of less accessible body parts such as the heel and wrist. The device include a transducer/applicator, rechargeable battery powered driver unit and a cable that connects the driver to the transducer.

According to the applicant, "the PainShield MD is indicated for the treatment of selected medical conditions such as pain relief, muscle spasm and joint contractures. The package contains the pain shield MD device, one small patch, one large patch, charger, quick reference guide, and user manual.

According to the applicant, existing CPT code 97024 covers performance of therapy by a professional therapist and not the device. The existing payment model does not address FDA approved indication for pain management, nor does it facilitate home use of the equipment. While CPT code 97024 is applicable for use in facility settings, the PainShield MD is prescribed by a licensed provider as a DME product to be self-administered outside of any facility setting, and without any procedure being performed.

PRELIMINARY HCPCS CODING RECOMMENDATION

CMS refers the applicant to the American Medical Association (AMA) for coding guidance for diathermy treatment performed incident to a physician’s service. CMS is not aware of a claims processing need on the part of any insurance sector to report self-administered diathermy by patients in their home.

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

No separate Medicare payment.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagreed with CMS' preliminary recommendation. The speaker asked for reconsideration on the basis that CPT code 97042 is used for warmer devices. According to the speaker, the PainShield MD only rises 2 degrees above the body temperature, which means the device is not diathermy and as such, code 97024 is not applicable. And a Level II HCPCS code to identify the device for self-administration at home is warranted.

FINAL DECISION

Establish new Level II HCPCS code K1004 "Low frequency ultrasonic diathermy treatment device for home use, includes all components and accessories". Effective 01/01/2020.

June 12, 2019

CMS HCPCS Public Meeting

Agenda Item # 10

Application # 19.139

TOPIC

Request to establish a new Level II HCPCS code to identify C-Brace Microprocessor Stance and Swing phase Knee-Ankle-Foot-Orthosis, Trade Name: C-Brace.

Applicant's suggested language: L2XXX "Microprocessor controlled knee-ankle-foot-orthosis."

BACKGROUND

Ottobock submitted a request a new Level II HCPCS code to identify C-Brace. According to the applicant, the C-Brace is a microprocessor controlled hydraulic knee joint unit and custom-fabricated thigh, calf, and foot component. The C-Brace provides stability for the foot, ankle, and the knee, and replace the eccentric muscle contraction of the quadriceps and hamstring muscles. The C-Brace assists the patient when descending stairs, slopes, and negotiating uneven terrain, mimicking the eccentric contraction of the quadriceps. The knee joint contains a knee angle sensor and a hydraulic pressure sensor to measure joint angle and hydraulic force, an inertial motion unit (IMU) with 3-axis accelerometer and 3-axis gyroscope, a real time chronometer, a dual Bluetooth module for data exchange and a rechargeable battery. A fully charged battery provides 18 hours of power. The Bluetooth links to an external PC for data acquisition and patient specific control parameters. The microprocessor of the C-Brace receives input from the sensors and the IMU and performs real time gait analysis. Acceleration and rotation rates in all movement of the orthosis in space. The C-Brace then uses this information to control the flexion and extension valves of the hydraulic unit that provides varying levels of resistance to knee flexion (bending), mimicking eccentric contraction of the quadriceps, and to the knee extension, mimicking eccentric contraction of the hamstrings. The C-Brace is used for ambulatory patients with peripheral or central neurologic conditions that results in weakness or paresis of the quadriceps and or other knee extensor muscles such as lesions of the femoral nerve, lumber disk herniation, poliomyelitis /post –polio syndrome, Charcot-Marie-Tooth (CMT), and incomplete spinal cord injury. It is also used for persons with orthopedic conditions that result in uncontrolled knee flexion including chronic patella tendon rupture, failed knee joint replacement, and knee joint derangement that cause pain when the quadriceps fail to keep the knee extended during stance phase. Patients with weakness or paresis of the quadriceps are not able to stabilize their knees from collapsing. The applicant stated they are not making a claim of significant therapeutic distinction. Existing codes are inadequate to describe the product because it does not describe the new technology, advanced microprocessor controlled orthotic knee joint, microprocessor stance and swing control.

PRELIMINARY HCPCS CODING RECOMMENDATION

The CMS needs additional time to fully consider this request. We would appreciate input from the applicant and others pertaining to the following questions:

Does the C-Brace, in any way, assist in movement or have an active drive function?

What is the average length of time the device is used by a typical patient?

Is the microprocessor control (powered unit) feature necessary for the bracing function?

How is this feature necessary for the effective use of the brace in restricting or eliminating motion in a diseased or injured leg?

Is the device attached to the leg capable of functioning as a brace in the absence of input from the powered unit?

If the powered device fails to function, what is its default state?

What muscle and muscle function does the powered unit replace?

What percentage of the patient’s native muscle strength is the device capable of providing?

What degree of precision can the device provide in functional motion, or is that native muscle dependent?

What are the maximum flexion/extension forces that can be provided by the device?

How does the device compare and differ from the E-MAG and Sensor Walk?

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The comments provided on Ottobock's behalf at CMS' HCPCS Public Meeting in response to our questions, included product description, demonstration and an update on sales data for the C-Brace. The speaker reiterated request for a new code and specifically requested Pricing = 38.The speaker also stated that the C-Brace operates differently from all other KAFOs. The C-Brace offers stumble recovery, shock absorption for level walking, reciprocal slope and stair decent, swing control, and activity specific mode.

FINAL DECISION

Establish a new Level II HCPCS code L2006 "Knee ankle foot device, any material, single or double upright, swing and/or stance phase microprocessor control with adjustability, includes all components (e.g., sensors, batteries, charger), any type activation, with or without ankle joint(s), custom fabricated". Effective 1/1/2020.

June 12, 2019

CMS HCPCS Public Meeting

Agenda Item # 11

Application # 19.140

TOPIC

Request to establish two new Level II HCPCS codes to identify BrainPort Vision Pro and training services.

Applicants suggested language:

LXXX1 "Vision aid prosthetic system, including intro-oral simulation device, headset with integrated digital video camera, and patient controls"

LXXX2 "Vision aid prosthetic system, training services, and individual, up to 10 hours."

BACKGROUND

Wicab, Inc. submitted a request to establish two new Level II HCPCS codes for BrainPort Vision Pro and training services.

According to applicant, the BrainPort vision pro is an oral electronic vision aid device consisting of intra-oral device, headset with integrated digital camera and two patient control buttons. The device provides electro-tactile stimulation to assist profoundly blind persons in task of orientation, mobility and object of recognition. "It serves as an adjunctive device to other assistive methods such as the white cane or a guide dog." The BrainPort translates information from the headset's video camera into a gentle electrical stimulation patterns presented on the surface of the tongue. The user will interpret the patterns as the shape, size, location, and motion of objects in their environment. Good candidates for using the BrainPort Vision Pro are people that have completed conventional blind rehabilitation training are comfortable using conventional assistive tools and technology.

According to the applicant, this product is for persons with blindness regardless of the cause of blindness, duration, age or gender. BrainPort Vision Pro use requires supervised one-on-one training for 10 hours over three-day period, including customized training content for the individual user. A new code is needed because there is no code for a prosthetic that is not implanted.

PRELIMINARY HCPCS CODING RECOMMENDATION

CMS is not aware of a claims processing need on the part of any insurance sector to establish code to report the BrainPort Vision Pro adjunctive device to other assistive methods. CMS refers

the applicant to the American Medical Association (AMA) for coding guidance for reporting individual training services.

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

Medicare payment determination is not applicable based on the preliminary recommendation to not establish a code.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

No comments were at CMS' HCPCS Public Meeting regarding this application or in response to our published preliminary recommendation.

FINAL DECISION

CMS is not aware of a claims processing need on the part of any insurance sector to establish code to report the BrainPort Vision Pro adjunctive device to other assistive methods. CMS refers the applicant to the American Medical Association (AMA) for coding guidance for reporting individual training services.

June 12, 2019

CMS HCPCS Public Meeting

Agenda Item # 12

Application # 19.148

TOPIC

Request to establish a "not otherwise classified" Level II HCPS code for blood products.

BACKGROUND

AABB (formerly known as the American Association of Blood Banks), America's Blood Centers and the American Red Cross submitted a request to establish a Level II HCPCS code to identify blood products. The applicant also claims, "The group of HCPCS codes for blood products (i.e., P-codes) does not currently have a not otherwise classified code". According to the applicant, since there are "no miscellaneous/not otherwise classified HCPCS codes for use by hospitals to bill third party payers during the interim period between FDA approval and the establishment of a specific HCPCS Level II code, hospitals would find themselves unable to immediately bill third party payers for any of these currently investigational blood products in the event that one or more of them – or other future new blood products not adequately described any existing P-code – receives FDA approval".

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish new code PXXXX "Blood component or product not otherwise classified"

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The written comments provided on behalf of AABB, American Red Cross and American Blood Center supporting the establishment of a new code to facilitate timely adopting new products.

FINAL DECISION

Establish new Level II HCPCS code P9099 "Blood component or product not otherwise classified". Effective 1/1/2020.

June 12, 2019

CMS HCPCS Public Meeting

Agenda Item # 13

Application # 19.149

TOPIC

Request to revise 46 existing Level II HCPCS procedure codes.

Applicant's suggested language: add the phrase "via in-person or via telemedicine" to each of the 46 existing Level II HCPCS procedure codes listed below.

BACKGROUND

The Los Angeles Police Protection League submitted 46 applications; one each to revise 46 existing Level II HCPCS codes that describe professional services. The revision request is uniform across all 46 applications, asking CMS to add the following language: "via in-person or vi telemedicine" to each of the 46 listed existing codes. The applicant comments that the proposed changes to code descriptions are intended to both expand on specific locations and to increase patient access to items and services.

Number	Requested Additional Language	Existing Language
1	Request to revise G0108 to include "via inperson or via telemedicine" end of the existing present nomenclature	Diabetes outpatient self-management training services, individual, per 30 minutes
2	Request to revise G0109 to include "via inperson or via telemedicine" end of the existing present nomenclature	Diabetes outpatient self-management training services, group session (2 or more), per 30 minutes
3	Request to revise G0296 to include "via inperson or via telemedicine" end of the existing present nomenclature	Counseling visit to discuss need for lung cancer screening using low dose ct scan (ldct) (service is for eligibility determination and shared decision making)
4	Request to revise G0436 to include "via inperson or via telemedicine" end of the existing present nomenclature	Smoking and tobacco cessation counseling visit for the asymptomatic patient; intermediate, greater than 3 minutes, up to 10 minutes
5	Request to revise G0437 to include "via inperson or via telemedicine" end of the existing present nomenclature	Smoking and tobacco cessation counseling visit for the asymptomatic patient; intensive, greater than 10 minutes

6	Request to revise G0442 to include "via inperson or via telemedicine" end of the existing present nomenclature	Annual alcohol misuse screening, 15 minutes
7	Request to revise G0443 to include "via inperson or via telemedicine" end of the existing present nomenclature	Brief face-to-face behavioral counseling for alcohol misuse, 15 minutes
8	Request to revise G0444 to include "via inperson or via telemedicine" end of the existing present nomenclature	Annual depression screening, 15 minutes
9	Request to revise G0447 to include "via inperson or via telemedicine" end of the existing present nomenclature	Face-to-face behavioral counseling for obesity, 15 minutes
10	Request to revise G0506 to include "via inperson or via telemedicine" end of the existing present nomenclature	Comprehensive assessment of and care planning for patients requiring chronic care management services (list separately in addition to primary monthly care management service)
11	Request to revise G0513 to include "via inperson or via telemedicine" end of the existing present nomenclature	Prolonged preventive service(s) (beyond the typical service time of the primary procedure), in the office or other outpatient setting requiring direct patient contact beyond the usual service; first 30 minutes (list separately in addition to code for preventive service)
12	Request to revise G0514 to include "via in-person or via telemedicine" at the end of the existing present nomenclature	Prolonged preventive service(s) (beyond the typical service time of the primary procedure), in the office or other outpatient setting requiring direct patient contact beyond the usual service; each additional 30 minutes (list separately in addition to code g0513 for additional 30 minutes of preventive service)
13	Request to revise G8432 to include "via in-person or via telemedicine" at the end of the existing present nomenclature	Depression screening not documented, reason not given
14	Request to revise G8932 to include "via in-person or via telemedicine" at the end of the existing present nomenclature	Suicide risk assessed at the initial evaluation
15	Request to revise G8780 to include "via in-person or via telemedicine" at the end of the existing present nomenclature	Counseling for diet and physical activity performed
16	Request to revise G9357 to include "via in-person or via telemedicine" at the end of the existing present nomenclature	Post-partum screenings, evaluations and education performed

17	Request to revise H0025 to include "via in-person or via telemedicine" at the end of the existing present nomenclature	Behavioral health prevention education service (delivery of services with target population to affect knowledge, attitude and/or behavior)
18	Request to revise S0342 to include "via in-person or via telemedicine" at the end of the existing present nomenclature	Lifestyle modification program for management of coronary artery disease, including all supportive services; fourth quarter / stage
19	Request to revise S0315 to include "via in-person or via telemedicine" at the end of the existing present nomenclature	Disease management program; initial assessment and initiation of the program
20	Request to revise S0316 to include "via in-person or via telemedicine" at the end of the existing present nomenclature	Disease management program, follow-up/reassessment
21	Request to revise S0317 to include "via in-person or via telemedicine" at the end of the existing present nomenclature	Disease management program; per diem
22	Request to revise S0340 to include "via in-person or via telemedicine" at the end of the existing present nomenclature	Lifestyle modification program for management of coronary artery disease, including all supportive services; first quarter / stage
23	Request to revise S0341 to include "via in-person or via telemedicine" at the end of the existing present nomenclature	Lifestyle modification program for management of coronary artery disease, including all supportive services; second or third quarter / stage
24	Request to revise S9140 to include "via in-person or via telemedicine" at the end of the existing present nomenclature	Diabetic management program, follow-up visit to non-md provider
25	Request to revise S9141 to include "via in-person or via telemedicine" at the end of the existing present nomenclature	Diabetic management program, follow-up visit to md provider
26	Request to revise S9436 to include "via in-person or via telemedicine" at the end of the existing present nomenclature	Childbirth preparation/lamaze classes, non-physician provider, per session
27	Request to revise S9437 to include "via in-person or via telemedicine" at the end of the existing present nomenclature	Childbirth refresher classes, non-physician provider, per session
28	Request to revise S9438 to include "via in-person or via telemedicine" at the end of the existing present nomenclature	Cesarean birth classes, non-physician provider, per session
29	Request to revise S9439 to include "via in-person or via telemedicine" at the end of the existing present nomenclature	Vbac (vaginal birth after cesarean) classes, non-physician provider, per session

30	Request to revise S9441 to include "via in-person or via telemedicine" at the end of the existing present nomenclature	Asthma education, non-physician provider, per session
31	Request to revise S9442 to include "via in-person or via telemedicine" at the end of the existing present nomenclature	Birthing classes, non-physician provider, per session
32	Request to revise S9443 to include "via in-person or via telemedicine" at the end of the existing present nomenclature	Lactation classes, non-physician provider, per session
33	Request to revise S9444 to include "via in-person or via telemedicine" at the end of the existing present nomenclature	Parenting classes, non-physician provider, per session
34	Request to revise S9445 to include "via in-person or via telemedicine" at the end of the existing present nomenclature	Patient education, not otherwise classified, non-physician provider, individual, per session
35	Request to revise S9447 to include "via in-person or via telemedicine" at the end of the existing present nomenclature	Infant safety (including cpr) classes, non-physician provider, per session
36	Request to revise S9449 to include "via in-person or via telemedicine" at the end of the existing present nomenclature	Weight management classes, non-physician provider, per session
37	Request to revise S9451 to include "via in-person or via telemedicine" at the end of the existing present nomenclature	Exercise classes, non-physician provider, per session
38	Request to revise S9452 to include "via in-person or via telemedicine" at the end of the existing present nomenclature	Nutrition classes, non-physician provider, per session
39	Request to revise S9453 to include "via in-person or via telemedicine" at the end of the existing present nomenclature	Smoking cessation classes, non-physician provider, per session
40	Request to revise S9454 to include "via in-person or via telemedicine" at the end of the existing present nomenclature	Stress management classes, non-physician provider, per session
41	Request to revise S9460 to include "via in-person or via telemedicine" at the end of the existing present nomenclature	Diabetic management program, nurse visit
42	Request to revise S9465 to include "via in-person or via telemedicine" at the end of the existing present nomenclature	Diabetic management program, dietitian visit
43	Request to revise S9470 to include "via in-person or via telemedicine" at the end of the existing present nomenclature	Nutritional counseling, dietitian visit

44	Request to revise S9472 to include "via in-person or via telemedicine" at the end of the existing present nomenclature	Cardiac rehabilitation program, non-physician provider, per diem
45	Request to revise S9473 to include "via in-person or via telemedicine" at the end of the existing present nomenclature	Pulmonary rehabilitation program, non-physician provider, per diem
46	Request to revise S5190 to include "via in-person or via telemedicine" at the end of the existing present nomenclature	Wellness assessment, performed by non-physician

PRELIMINARY HCPCS CODING RECOMMENDATION

CMS would like to thank the applicant; the LAPPL; its membership; and all first responders, for their commitment and service in protecting American Citizens. We appreciate your interest in and efforts in improving health care, and access to care, and in engaging CMS via your applications and additional, follow up communications with CMS staff.

Regarding identification of location of service, we would like to call your attention to a place of service (POS) code #02, newly published in 2017, “Telehealth”: "The location where health services and health related services are provided or received, through a telecommunication system”. Place of service codes are for use by health care providers on professional claims to specify the entity where service(s) were rendered. The entire POS code set can be found at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Downloads/Website-POS-database.pdf.

For payment and policy information pertaining to the telehealth POS code, we refer the applicant to the insurers in whose jurisdictions claims would be filed. For example: the individual private insurance entity, the Medicaid Agency in the state in which a claim would filed, the Medicare contractor, VA or DOD.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The speakers reiterated the incoming request to revising 46 existing HCPCS codes to add the language “in person or via telemedicine”. The speakers commented that this coding action would grant first responders access to needed help and training previously unavailable due to their work nature and schedule. The speakers further requested clarification in writing of telemedicine as the originating site that would allow firefighters to receive and be properly reimbursed, and providers to be compensated for their time.

FINAL DECISION

Regarding identification of location of service, we believe that the use of currently available, national Place Of Service (POS) codes developed by CMS and available for assignment by any

insurer to identify and report site of service on claims forms submitted to insurers, communicate the information necessary for insurers to identify and adjudicate claims for telehealth and alternative sites of service, in accordance with their individual policies and programs. Place of service codes are reported by health care providers, together with service or procedure codes, on professional claims to specify the entity where service(s) were rendered. In particular, we would like to call your attention to a place of service (POS) code #02, newly published in 2017, "Telehealth": "The location where health services and health related services are provided or received, through a telecommunication system".

We would also like to call to your attention two other POS codes that might be particularly useful in reporting care to first responders as you described to CMS: POS code # 11 “Office”, “Location, other than a hospital, skilled nursing facility (SNF), military treatment facility, community health center, State or local public health clinic, or intermediate care facility (ICF), where the health professional routinely provides health examinations, diagnosis, and treatment of illness or injury on an ambulatory basis; and POS code #12 “Home”, “ Location, other than a hospital or other facility, where the patient receives care in a private residence. The entire POS code set can be found at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Downloads/Website-POS-database.pdf. For payment and policy information and coding guidance pertaining to the telehealth and/or use of POS codes, we refer you to the insurers in whose jurisdictions claims would be filed. For example: the individual private insurance entity, the Medicaid Agency in the state in which a claim would filed, the Medicare contractor, VA or DOD.