Centers for Medicare & Medicaid Services (CMS) Healthcare Common Procedure Coding System (HCPCS) Public Meeting Agenda for Durable Medical Equipment (DME) and Accessories; Orthotics and Prosthetics (O & P); Supplies and Other

Tuesday, June 5, 2018, 9:00 am – 5:00 pm

CMS Auditorium
7500 Security Boulevard
Baltimore (Woodlawn), Maryland 21244-1850

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

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

For each agenda item, a written overview of the request and CMS's preliminary coding recommendation is provided. An overview of Medicare pricing/payment, methodology is also attached to this agenda. Preliminary recommendations are not final or binding upon any payer, and are subject to change. Meeting participants will hear presentations about each agenda item from the registered primary speaker and other speakers (if any). Presentations will be followed by an opportunity for questions regarding that particular agenda item. The public meetings provide an opportunity for the general public to provide additional input related to requests to modify the HCPCS code set. Final decisions are not made at the public meetings. Applicants will be notified of final decisions in November.

The agenda includes a summary of each HCPCS code application on the agenda. The information provided in each summary reflects claims made by the applicant and should not be construed as a statement of fact or an endorsement by the federal government.

June 5, 2018

HCPCS Public Meeting Agenda Item # 1

Application# 18.111

TOPIC

Repeat request to establish a new Level II HCPCS code to identify a digestive enzyme; (immobilized lipase) packed cartridge, Trade Name: RELiZoRB.

Applicant's suggested language: Applicant's suggested language: BXXXX-"digestive enzyme packed cartridge for hydrolyzing fats in formula prior to ingestion during enteral nutrition feeding, 30 per box".

BACKGROUND

Alcresta Therapeutics, Inc. submitted a repeat request to establish a new HCPCS Level II code to identify RELiZORB, an enzyme packed cartridge indicated for use in adults to hydrolyze fats in entral formula. The cartridge fits in line with enteral feeding systems, and is connected between the infusion pump and the feeding tube. The active ingredient is the digestive enzyme lipase, attached to polymetric carriers together called iLipase. As the formula passes through RELiZORB, it makes contact with the iLipase, and fats in the formula are modified to more absorbable forms prior to ingestion. Fat malabsorption is most common in individuals who cannot produce or secrete adequate amounts of digestive enzymes because of compromised pancreatic function.

According to the applicant, RELiZORB is a first-of-its kind digestive enzyme cartridge designed to mimic normal pancreatic function by breaking down fats in enteral tube feeding formula. The applicant comments that, the last application was submitted, data was published at the most recent North American Cystic Fibrosis Conference. The results of the study demonstrate that RELiZORB is safe and effective in patients with pancreatic enzymatic insufficiency (EPI) that are receiving enteral feeding.

The applicant comments that a new code is needed to facilitate separate billing of the RELiZORB. Unlike supplies which are inert materials used to administer formula during enteral tube feeding, RELiZORB actively modifies the composition of the formula by hydrolyzing fats into an absorbable form. RELiZORB provides proven therapeutic benefit and should not be considered a supply. Currently, providers must utilize HCPCS code B9998 for enteral supplies, resulting in delayed claims processing. New clinical evidence is included in this application since their submission of 17.084 and 16.074.

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PRELIMINARY HCPCS CODING RECOMMENDATION

Newly established code Q9994 “In-line cartridge containing digestive enzyme(s) for enteral feeding, each”, published March 30, 2018 and effective July 1, 2018, is available for assignment by insurers, if they deem appropriate, to report RELiZORB.

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

The payment rules associated with the existing code apply to this product. P=00
Medicare payment for this product is included in existing enteral feeding supply kit code B4035.

June 5, 2018

HCPCS Public Meeting Agenda Item # 2

Application# 18.112

TOPIC

Request to assign existing Level II HCPCS code B4150-"enteral formula, nutritional complete with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories= 1 unit" to identify a new enteral formula for complete meal replacement with intact protein, Trade Name: Ultrient 1.3 RTF (Ready to Feed).

BACKGROUND

Trovita Health Sciences, Inc. submitted a request to assign the existing Level II HCPCS code B4150- "Enteral formula, nutritionally complete with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through a enteral feeding tube, 100 calories = 1 unit" to Ultrient 1.3 RTF.

According to the applicant, this is a new non-soy enteral formula containing an intact whey protein concentrate as a primary protein source. Ultrient 1.3 also includes fats, carbohydrates, a vitamin and mineral blend, with fiber that is administered only through an enteral feeding tube. The product is primarily used as a sole-source meal replacement option for anyone with a medical condition that will require enteral/tube feeding for a prolonged period of time.

The applicant comments that Ultrient 1.3 would be adequately described under existing HCPCS code B4150.

PRELIMINARY HCPCS CODING RECOMMENDATION

Existing code B4150 "Enteral formula, nutritionally complete with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit", is available for assignment by insurers, if they deem appropriate to identify Ultrient 1.3RTF.

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

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

Pricing = 39

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HCPCS Public Meeting Agenda Item # 3

Application# 18.101

TOPIC

Request to establish a new Level II HCPCS code to identify the batteries for use with portable pneumatic total artificial heart, Trade Name: Freedom Onboard Battery

Applicant's suggested language: QXXXX, Battery (Li-Ion) for use with portable pneumatic biventricular driver, total artificial heart, each

BACKGROUND

Syncardia Systems Inc., submitted a request to establish a new Level II HCPCS code to identify the rechargeable lithium-ion Freedom Onboard Battery which powers the Freedom Portable Driver used with the Syncardia TAH-t. According to the applicant, a TAH-t is a biventricular device that replaces the left and right ventricles and 4 valves when implanted into a patient's chest. Patients with TAH-t require six Freedom Onboard Batteries including 2 to power the portable driver and 4 charged batteries for battery rotation. The batteries are intended for repeat use and should be rotated every 2 hours. They have an expected life of 4 years and 3 months. The batteries are charged with the Freedom Home AC Power Supply System, for which there has also been a separate application submission (18.102).

The TAH-t is indicated for those with end-stage biventricular heart failure and/or those who are not eligible for heart transplants.

The applicant comments that a new code is warranted because no other code identifies the Freedom Onboard Batteries only used with the TAH-t Freedom Portable Driver. The applicant adds that the existing codes, Q0508 and Q0509, are not used specifically for the Freedom Onboard Battery.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish LXXXX "Miscellaneous component, supply or accessory for use with total artificial heart system". Effective 1/1/19.

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

If covered, payment will be based on the carrier's consideration of the item.

June 5, 2018

Application# 18.102

TOPIC

Request to establish a new Level II HCPCS code to identify the power supply system for use with pneumatic biventricular total artificial heart, Trade Name: Freedom Home AC Power Supply System

Applicant's suggested language: QXXXX, Power supply system for use with portable pneumatic biventricular total artificial heart

BACKGROUND

SynCardia Systems Inc., submitted a request to establish a new Level II HCPCS code to identify the power supply system for use with the pneumatic biventricular total artificial heart. According to the applicant, the power supply system powers the Freedom Portable Driver and charges the Freedom Onboard Batteries. The driver, batteries, and power supply system work together to power the total artificial heart (TAH-t) which is a pulsating replacement for the left and right ventricles and four values. The AC Power Supply System is comprised of 2 home AC power supplies with an integrated cord, a 4-well battery charger, and an AC power adaptor backup. The product is powered by any external grounded wall power outlet.

The Home AC Power Supply System is indicated for use by persons with a TAH-t, including those with end-stage biventricular failure and those ineligible for heart transplants. The system is intended for repeated use for 3-5 years. The power system is prescribed following a patient's discharge and used in patients' homes.

The applicant comments that a new code is warranted because no current code describes the power supply system used specifically for the TAH-t.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish LXXXX "Miscellaneous component, supply or accessory for use with total artificial heart system". Effective 1/1/19.

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

If covered, payment will be based on the carrier's consideration of the item.

June 5, 2018

Application# 18.103

TOPIC

Request to establish five new Level II HCPCS codes to identify supplies and accessories for the Freedom portable driver system that operates the SynCardia Total Artificial Heart (TAH-t) outside of the hospital, Trade Names: Freedom Shoulder Bag, Freedom Backpack, Freedom Accessory Bag, Freedom Car Charger, Freedom Filter Pack, Freedom Miscellaneous Supplies including the Freedom Patient Tool Kit, and the handles and straps for the backpack, shoulder bag, Freedom Driver, and the accessory bag.

Applicant's suggested language:

QXXX1 Miscellaneous supply or accessory for use with an implanted total artificial heart

QXXX2 Miscellaneous supply or accessory for use with any implanted total artificial heart for which payment was not made under Medicare part A

QXXX3 Filters for use with total artificial heart, replacement only

QXXX4 Power adaptor for use with total artificial heart, vehicle type

QXXX5 Backpack/bag for use with total artificial heart, replacement only

BACKGROUND

SynCardia Systems Inc., submitted a request to establish five new Level II HCPCS codes to identify supplies and accessories for the Freedom Portable Driver that powers the Syncardia total artificial heart (TAH-t) outside of the hospital. According to the applicant, the shoulder bag and backpack carry the portable driver. The car charger allows individuals to maintain Freedom Driver battery charge in a car. The Freedom filter pack replaces the foam filters used in the Driver system. The filters prevent dirt particles from entering into the Driver. The accessory bag and the tool kit allow individuals to store other components of the driver system.

All of the items are intended for repeated use. The Freedom filters are supplied in a pack of 5 and should be cleaned weekly. The filters should last for the entire time in which a patient has a TAH-t, unless there is a tear that requires replacement. The accessories and supplies are prescribed following the patient's discharge and used in the patient's homes.

The applicant comments that the five new codes are warranted because no current codes describe the accessories used only for the Freedom Portable Driver with TAH-t.

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PRELIMINARY HCPCS CODING RECOMMENDATION

Establish LXXXX "Miscellaneous component, supply or accessory for use with total artificial heart system". Effective 1/1/19.

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

If covered, payment will be based on the carrier's consideration of the item.

June 5, 2018

Application# 18.104

TOPIC

Request to establish a new Level II HCPCS code to identify the SynCardia Freedom portable driver used with the SynCardia temporary Total Artificial Heart (TAH-t), Trade Name: Freedom ® portable driver

Applicant's suggested language: QXXXX "Pneumatic biventricular driver, portable, total artificial heart"

BACKGROUND

SynCardia Systems Inc., submitted a request to establish a new Level II HCPCS code to identify a pneumatic, biventricular portable driver for use with the Syncardia Total Artificial Heart, (TAH-t). The Freedom portable driver is a piston-driven, pneumatic compressor that delivers regulated pressures and vacuum to the TAH-t drivelines. It is used to continuously operate the TAH-t.

According to the applicant, the Freedom driver is indicated for use as a bridge-to-transplant in cardiac transplant-eligible candidates at risk of death from biventricular failure. Use of the driver enables eligible patients to be discharged from the hospital and return home as they await a heart transplant. The applicant also adds that the FDA granted SynCardia's TAH-t an Investigational Device Exemption for "destination therapy" for persons who are ineligible for heart transplant. These patients would live the remainder of their lives using these devices. The device operates by sending pulses of air to the artificial heart to circulate blood throughout the body. A patient is provided 2 portable drivers, one of which serves as a backup, and is expected to return to the hospital every 120 days. In the hospital, the patient is connected to their second driver and receives a newly supplied back-up driver. The previously connected driver is returned for maintenance. Despite this, the SynCardia's portable driver is stated for use 100% of the time in the patient's home by the patient.

The applicant comments that a new code is warranted because no existing HCPCS codes describe the Freedom portable driver, which only operates with SynCardia's TAH-t.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish LXXXX "Miscellaneous component, supply or accessory for use with total artificial heart system". Effective 1/1/19.

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

If covered, payment will be based on the carrier's consideration of the item.

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HCPCS Public Meeting Agenda Item # 4

Application# 18.097

TOPIC

Request to establish a new Level II HCPCS "Addition" code to describe the function and benefit of the Silcare Breathe Prosthetic Liner, Trade Name: Endolite/Blatchford Silcare Breathe.

Applicant's suggested language: LXXXX-"Addition for moisture, temperature, air, and skin management interface liner with natural vacuum/suction suspension for volume control."

BACKGROUND

Endolite/Blatchford, Inc., submitted a request to establish a new Level II HCPCS code to identify Silcare Breathe Prosthetic Liners. According to the applicant, the first key element of the function of the Silcare Breathe family of liners is to provide dry skin interface management through moisture and temperature regulation. The second is volume control through natural vacuum produced on every step. The applicant comments that the product is solely used by patients' in their respective homes.

The applicant comments that Silcare Breathe liners are suitable for trans-tibial and trans-femoral amputees who participate in a variety of activities and whose prosthesis suspension is compromised due to perspiration or air entrapment, causing a loss of control, unwanted movement of the residual limb in the socket and associated risks of falls, shearing of skin and inner part of liner due to chafing and potential skin damage, causing tissue health issues. Silcare Breathe Liners are designed to be used with a pin-lock suspension system

The applicant comments that a new code is warranted because the unique product offers two key functions that are not adequately described by existing codes. The applicant also claims a significant therapeutic distinction between perforated and non-perforated liners, related to sweat reduction and ability to continue to use a perforated liner, "implying fewer restrictions on independence and thus improvements to quality of life."

PRELIMINARY HCPCS CODING RECOMMENDATION

A new "addition" code to identify perforated liners was not approved. Perforation of liners is not new technology. Applicant claims of significant therapeutic distinction for temperature regulation of suspension is not substantiated. Existing codes L5673, L5679, L5681 and L5683; and UE codes L6694, L6695, L6696 and L6697 describe existing insert. These are inclusive of perforation technology.

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PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

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

Pricing = 38

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HCPCS Public Meeting Agenda Item # 5

Application# 18.116

TOPIC

Request to revise the series of Level II HCPCS codes that describe CROS and BiCROS hearing aids and dispensing fee. The applicant suggested revising 8 existing Level II HCPCS codes and establishing 13 new Level II codes for contralateral routing hearing aid devices, commonly known as CROS/BiCROS hearing devices, Trade Name: Phonak

BACKGROUND

The American Academy of Audiology, American Speech-Language Hearing Association, and other audiology and speech organizations in partnership with their manufacturer, Phonak, submitted a request to revise 8 existing Level II HCPCS codes and to add 13 new Level II codes for contralateral routing hearing aid devices, commonly known as CROS/BiCROS hearing devices.

According to the applicant, the contralateral routing hearing devices are a specialized air conduction hearing aid. These hearing aids have the ability to wirelessly transfer the sound signal from an ear to an ear with an unaidable hearing loss on the other side. It is primarily used to treat patients with Single-Sided Deafness (SSD).

The applicant comments that a revision in existing codes and addition of new codes is warranted because the existing codes do not accurately describe the current devices being reported and to update this code series to reflect changes in technology. The use of old descriptors for newer technology is problematic.

The following codes that are currently being billed include:

V5170, V5180, V5190, V5200, V5210, V5220, V5230 and V5240.

The applicant suggests revising each of the existing codes to be unspecified contralateral routing codes; and adding a series of 13 new codes to specify monaural and binaural contralateral routing for ITE, ITC, and BTE combinations and for glasses mounting and dispensing fees.

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PRELIMINARY HCPCS CODING RECOMMENDATION

Establish/Discontinue the Cros/Bicros section of the Level II HCPCS code set. Effective 1/1/19, as follows:

Establish VXXX1 "Hearing aid, contralateral routing device, monaural, in the ear (ITE)"

Establish VXXX2 "Hearing aid, contralateral routing device, monaural, in the canal (ITC)"

Establish VXXX3 "Hearing aid, contralateral routing device, monaural, behind the ear (BTE)"

Establish VXXX4 "Hearing aid, contralateral routing system, binaural, ITE/ITE"

Establish VXXX5 "Hearing aid, contralateral routing system, binaural, ITE/ITC"

Establish VXXX6 "Hearing aid, contralateral routing system, binaural, ITE/BTE"

Establish VXXX7 "Hearing aid, contralateral routing system, binaural, ITC/ITC"

Establish VXXX8 "Hearing aid, contralateral routing system, binaural, ITC/BTE"

Establish VXXX9 "Hearing aid, contralateral routing system, binaural, BTE/BTE"

Discontinue V5170 "Hearing aid, cros, in the ear"

Discontinue V5180 "Hearing aid, cros, behind the ear"

Discontinue V5210 "Hearing aid, bicros, in the ear"

Discontinue V5220 "Hearing aid, bicros, behind the ear"

Revise V5190 "Hearing aid, cros contralateral routing, monaural, glasses", to instead read, "Hearing aid, contralateral routing, monaural, glasses ".

Revise V5200 "Dispensing fee, cros contralateral, monaural", to instead read, "Dispensing fee, contralateral, monaural".

Revise V5230 "Hearing aid, bicros,contralateral routing system, binaural, glasses ", to instead read, "Hearing aid, contralateral routing system, binaural, glasses ".

Revise V5240 "Dispensing fee, bicros contralateral routing system, binaural", to instead read, "Dispensing fee, contralateral routing system, binaural".

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PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

The payment rules associated with the existing codes apply to these products.

Pricing = 00

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HCPCS Public Meeting Agenda Item # 6

Application# 18.118

TOPIC

Request to establish two new Level II HCPCS codes to describe "microprocessor-controlled, custom fabricated upper extremity braces," Trade Name: MyoPro

Applicant's suggested language:

LXXX1: "elbow-wrist-hand orthosis"

LXXX2: "elbow-wrist-hand-finger orthosis"

BACKGROUND

Myomo, Inc. submitted a request to establish 2 new Level II HCPCS codes to describe microprocessor-controlled custom upper extremity braces. According to the applicant, the three models, Motions G, W, and E, support arms weakened by neuromuscular injury/illness. Motion G is an elbow-wrist-hand-finger orthosis that uses a microprocessor to control elbow and finger joints. This enables users to pronate/supinate, flex/extend, and deviate their weakened arms. Motion E and Motion W are both elbow-wrist-hand orthoses. Motion E uses a microprocessor-controlled wrist joint with a fixed wrist. Motion W is a microprocessor-controlled elbow and an articulating wrist joint. The items are powered by battery and myoelectricity, which uses electromyographic (EMG) signals to produce movement.

The product must be prescribed to patients with weak arms by a physician in an outpatient setting. A prescription is given only after occupational therapy has failed to restore optimal arm function.

The applicant comments that new codes are warranted because the E1399 code, of which it has been assigned, does not meet the payment method requirement established by the Social Security Act of 1834. E1399 also does not include DME manufacturers that produce custom products, such as the MyoPro. Additionally, no existing codes cover microprocessor-controlled devices.

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PRELIMINARY HCPCS CODING RECOMMENDATION

LXXXX1 "Powered upper extremity range of motion assist device, elbow, wrist, hand with single or double upright(s), includes microprocessor, sensors, all components and accessories, custom fabricated". Effective 1/1/19

LXXXX2 " Powered upper extremity range of motion assist device, elbow, wrist, hand, finger, single or double upright(s), includes microprocessor, sensors, all components and accessories, custom fabricated". Effective 1/1/19

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

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

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HCPCS Public Meeting Agenda Item # 7

Application# 18.099

TOPIC

18.099(a) Request to establish either a new Level II HCPCS base code or an add-on code to identify the James Ankle Foot Orthotic, Trade Name: JAFO.

18.099(b) Request to revise existing Level II HCPCS code L2820 to include the JAFO soft interface (padding) for use with rigid AFOs, Trade Name: JAFO.

BACKGROUND

18.099(a)

My JAFO, LLC submitted a request to establish either a new Level II HCPCS base code or an add-on code to identify the JAFO manufactured by New Option Sports.

According to the applicant, JAFO is made of 1/8" Cool-Flex neoprene with an anterior zipper for closure, a posterior inside chute and a hook and loop feature for the ankle. The applicant comments that the primary function of the JAFO is to secure any custom-fabricated AFO (and many other AFO's on the market today) to the user's limb. The JAFO performs many functions that the conventional strap does not.

The applicant comments that the JAFO is used by patients with Foot Drop, diabetics, and those with unhealthy blood flow and/or frail and atrophied legs. The JAFO promotes healthy blood flow to the patient's limbs, eliminates chaffing, reduces peroneal nerve entrapment, protects the patient's limb and AFO, prevents AFO fracture, reduces replacement, eliminates straps and pads, increases proprioception and balance.

The applicant comments that a new code is warranted because there are no L codes to identify this application and brand new concept.

18.099(b)

The sleeve is installed using a frontal zipper that begins at the ankle/foot, extends over the calf, and ends at the back of the knee. The JAFO sleeve is designed for patients with foot drop due to injury and neuromuscular illness. The item can be used by patients with or without an AFO. The sleeve may be measured and ordered by a clinician but does not require a prescription.

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The applicant comments that a code revision is warranted because the current JAFO code, L2820 includes JAFO that does not use padding or strapping. This differs from the 18.099 (a) code that uses padding but does not use strapping.

PRELIMINARY HCPCS CODING RECOMMENDATION

This request to establish a new Level II HCPCS code to identify the James' Ankle Foot Orthotic (JAFO) has not been approved. Existing code A4467 "Belt, strap, sleeve, garment, or covering, any type" adequately describes all items included in this application and is available for assignment by insurers if they deem appropriate.

Request to revise existing code L2820 to include the JAFO soft interface (padding) for use with rigid AFOs has not been approved. Code L2820 is an add-on to a custom-fabricated brace. The JAFO is not custom.

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

The payment rules associated with the existing codes apply to these products.

Pricing = 00

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HCPCS Public Meeting Agenda Item # 8

Application# 18.098

TOPIC

Request to establish two new Level II HCPCS codes; one code to identify the head mounted telemetry and video data collection system, and another to identify the Video Processing Unit (VPU), for use with an implanted Epiretinal Prosthesis System, Trade Name: Argus II Retinal System.

Applicant's suggested language: LXXXX-"Head mounted telemetry and video data collection system;"

LXXXX –"Video processing unit (VPU) for use with an implanted retinal prosthesis."

BACKGROUND

Second Sight Medical Products, Inc., submitted a request to establish 2 new Level II HCPCS codes to identify components of Argus II Retinal System: one to identify the Argus II head-mounted telemetry and video data collection system, and the other to identify the Video Processing Unit (VPU) used with the Argus II Retinal Prosthesis System. According to the applicant, "the Argus II enables blind individuals suffering from severe retinitis pigmentosa (RP) to regain some functional vision, greater independence, and an improved quality of life."

According to the applicant, the Argus II is the first and only approved treatment for people with severe to profound retinitis pigmentosa that provides electrical stimulation of the retina to induce visual perception. It consists of two major components: (1) surgically implanted retinal prosthesis and (2) external patient-worn system that collects and processes image data and integrates with the surgical implant.

The applicant comments that "providers need product-specific HCPCS codes to facilitate billing when patients need to replace the external, patient-worn Argus II prosthetic components," and "to ensure continued patient access to this technology, even if there is a relatively small patient population." According to the applicant, the existing code V2799 confuses the Argus II components with conventional eyeglasses and, because it is assigned this miscellaneous code, it adds to the administrative burden of providers/suppliers/payers;" and results in delays in processing payment. The applicant comments additionally that a new code is warranted because there is no existing code to describe the Telemetry System or the VPU.

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PRELIMINARY HCPCS CODING RECOMMENDATION

This request to establish 2 new Level II codes to separately identify the head-mounted telemetry and video data collection system, and the video processing unit (VPU) for use with an implanted retinal prosthesis has not been approved. Reported sales volume for each of these components is insufficient to support a request for a revision to the national codeset. In accordance with HCPCS criteria as published on CMS' HCPCS website, there must be sufficient claims activity or volume, as evidenced by 3 months of marketing activity, so that adding a new code enhances the efficacy of the system and justifies the administrative burden of adding a code. Existing code V2799, "Vision item or service, miscellaneous" is available for assignment by insurers to identify the replacement Head Mounted Telemetry System and the replacement VPU, if they deem appropriate. This code is not limited to reporting of conventional eyeglasses.

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

The payment rules associated with the existing code apply to these products if covered. Pricing = 46

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HCPCS Public Meeting Agenda Item # 9

Application# 18.095

TOPIC

Request to establish a new Level II HCPCS code to identify a vaginally-inserted rectal control system, Trade Name: Eclipse System.

Applicant's suggested language: Lxxxx-"Rectal control prosthetic, vaginally inserted by a licensed health care provider, any type."

BACKGROUND

Pevalon, Inc. submitted a request to establish a new Level II HCPCS code to identify the Eclipse System. According to the applicant, the Eclipse System is a prosthetic device intended to treat adult women with refractory fecal incontinence (FI). The Eclipse System is comprised of a vaginal prosthetic and a pressure-regulated pump. It restores normal bowel function by replacing the continence function normally provided by the rectum and the anal canal, which widen and narrow to control the passage of stool. The device expands and contracts against the recto-vaginal septum, which thereby causes the appropriate expansion and collapsing of the rectum.

While placed in the vagina, the Eclipse Insert dynamically controls the rectal space by deflecting the recto-vaginal septum, which separates the vagina and rectum. It consists primarily of a silicone and stainless-steel base with an inflatable Balloon. The pump is used by the patient for inflating and deflating the Eclipse Insert.

The applicant comments that a new code is warranted to address claims processing challenges because there are currently no HCPCS codes to identify the Eclipse System.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish LXXXX "Rectal control system for vaginal insertion, for long term use, includes pump and all supplies and accessories, any type each". Effective 1/1/19

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

We believe that the item would be paid in accordance with the payment rules that apply to Orthotics, Prosthetics, Prosthetic Devices, and Vision Services if covered.

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HCPCS Public Meeting Agenda Item # 10

Application# 18.096

TOPIC

Request to establish a new Level II HCPCS "L" code to identify an aquatic fin, Trade Name: AMP FIN; and to consider the fin to be a prosthetic.

BACKGROUND

AMP FINS, LLC submitted a request to establish a new Level II HCPCS code to identify the AMP FIN. According to the applicant, the AMP Fin is a custom-fit prosthetic fin designed to enable individuals who have lost all or part of a lower limb to amputation to participate in water activities. According to the applicant, the Fin should be considered a prosthesis because it is designed to replace any missing anatomy that would normally allow a person to propel themselves through the water. The fin is fabricated with a specially formulated PTE (thermos plastic elastomer). Using a Keasy cone or EverFlex liner/suspension sleeve provided by the patient's prosthetist, the AMP FIN is heated using a specialized heating process and then custom fit to the patient. The patient slides the AMP FIN over the liner/suspension enabling him/her to propel themselves through water.

The applicant comments that a new code is warranted and the Fin should be considered a base prosthesis because it replaces a body part and the fin fits onto the patient's residuum.

PRELIMINARY HCPCS CODING RECOMMENDATION

This request to establish a new Level II HCPCS code to separately identify Amp Fin, has not been approved. Existing code A9300, Exercise equipment, adequately describes this product and is available by insurers if they deem appropriate.

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

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

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HCPCS Public Meeting Agenda Item # 11

Application# 18.088

TOPIC

Request to revise existing Level II HCPCS codes, K0554 Receiver (Monitor), and K0553, Supply allowance for the Continuous Glucose Monitor (CGM), to revise the descriptor language, in order to specify "real time" monitoring.

Applicant's suggested language: K0554, Receiver (Monitor), dedicated, for use with real time therapeutic Continuous glucose monitor system and K0553, Supply allowance for real time therapeutic continuous glucose monitor (CGM), includes all supplies and accessories, 1 month supply= 1 unit of service.

BACKGROUND

Dexcom Inc., c/o Applied Policy., submitted a request to revise existing Level II HCPCS codes K0554 Receiver (Monitor) and K0553, Supply allowance for the Continuous Glucose Monitor (CGM), to revise the descriptor language to specify "real time" monitoring. For CGM products that are used in the home and approved by the FDA for use in place of a blood glucose monitor for making diabetes treatment decisions, these therapeutic CGMs are primarily and customarily used to serve a medical purpose because they are used by Medicare beneficiaries with diabetes who must measure their glucose level frequently and check trends in their glucose measurements for the purpose of adjusting their diet and insulin in the treatment of their diabetes. Because they are used directly in making diabetes treatment decisions, as opposed to alerting the patient to use a blood glucose monitor to make those decisions, they are not precautionary in nature. The transmitter is worn outside the body, generally under the patient's clothes, and is physically connected to the Sensor.

The CGM is indicated for the management of diabetes in persons age 2 years and older. The durable receiver for a therapeutic CGM is considered DME. For therapeutic CGMs, the glucose sensors and transmitters are considered essential accessories necessary for the effective use of the therapeutic CGM and replacement of the glucose sensors and transmitters are considered replacements of essential accessories necessary for the effective use of DME. Medicare also pays for replacement of essential accessories for necessary DME on the basis of fee schedule amounts. For 2017, the monthly fee schedule amount is $248.38 and is established in accordance with the fee schedule gap-filling instructions located at section 60.3 of chapter 23 of the Medicare Claims Processing Manual (Pub. 100-04). The CGM receivers can withstand at least 3 years of repeated use. The contents of the supply bundle (K0553) cannot stand repeated use, but are essential to the proper operation of the durable Receiver.

The applicant comments that revised codes are warranted to describe the functional distinctions and clinical utility for the realtime CGM.

June 5, 2018

PRELIMINARY HCPCS CODING RECOMMENDATION

This request to revise the descriptor of existing codes K0554 and K0553 has not been approved. The requested changes do not improve the codes. The existing descriptor of K0554, which reads, "Receiver (monitor), dedicated, for use with therapeutic glucose continuous monitor system", and K0553, "Supply allowance for therapeutic continuous glucose monitor (cgm), includes all supplies and accessories, 1 month supply = 1 unit of service", describe Therapeutic CGMs, supplies and are 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.

For K0554, Pricing = 32, K0553, Pricing = 34

June 5, 2018

Agenda # 12

Application# 18.089

TOPIC

Repeat request to revise the descriptor of existing Level II HCPCS code A9277, adding a unit of duration to the transmitter the following language 1 unit = 1 day, and to assign the revised code to identify a transmitter for use with the 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. According to the applicant, the existing HCPCS code lacks a duration for the transmitter. 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 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 as well as to describe duration of use.

The applicant comments that a revision to the existing code is warranted because the current code is insufficient to describe the multiplicity of Transmitters on the market.

June 5, 2018

PRELIMINARY HCPCS CODING RECOMMENDATION

This request to revise the descriptor of existing code A9277 has not been approved. The requested change does not improve the code. The existing descriptor of A9277, which reads, "Transmitter; external, for use with interstitial continuous glucose monitoring system", 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 applies to this product.

Pricing =00

June 5, 2018

HCPCS Public Meeting Agenda Item # 13

Application# 18.090

TOPIC

Request to revise Level II HCPCS code E0446, Topical oxygen delivery system, not otherwise specified, includes all supplies and accessories, and also establish 5 new Level II HCPCS codes to describe the device specific dressings with integrated oxygen cannula, used with the topical oxygen delivery system, which includes a portable continuous oxygen concentrator and charging system.

Request to revise an existing Level II HCPCS code E0446 for the TransCu Oxygen Generator and establish five new Level II HCPCS codes for the OxySpur Oxygen Diffusion Dressings for the treatment of chronic wounds.

Applicant's suggested language: Revise E0446 to read "Topical oxygen delivery system for continuous diffusion of oxygen rental, includes portable continuous oxygen concentrator, rechargeable batteries, charging system and charging case." Establish 5 new Level II HCPCS codes to describe the devise specific dressings with integrated oxygen cannula, used with the topical oxygen delivery system, which includes a portable continuous oxygen concentrator and charging system:

Xxxx2 composite dressing, sterile, 4 sq. in, sterile pad with integrated oxygen diffusion cannula with adhesive border, for use with topical oxygen delivery system for continuous diffusion of oxygen

Xxxx3 composite dressing, sterile, 20 sq. in, sterile pad with integrated oxygen diffusion cannula with adhesive border, for use with topical oxygen delivery system for continuous diffusion of oxygen

Xxxx4 composite dressing, sterile, 16 sq. in, sterile pad with integrated oxygen diffusion cannula with adhesive border, for use with topical oxygen delivery system for continuous diffusion of oxygen

Xxxx5 Specialty absorptive dressing, sterile, 4 sq. in, sterile pad with integrated oxygen diffusion cannula without adhesive border, for use with topical oxygen delivery system for continuous diffusion of oxygen

Xxxx6 Specialty absorptive dressing, sterile, 20 sq. in, sterile pad without integrated oxygen diffusion cannula without adhesive border, for use with topical delivery system for continuous diffusion of oxygen.

June 5, 2018

BACKGROUND

Request to revise an existing Level II HCPCS code E0446 for the TransCu Oxygen Generator and establish five new Level II HCPCS codes for the OxySpur Oxygen Diffusion Dressings for the treatment of chronic wounds.

Applicant's suggested language: Revise E0446 to read "Topical oxygen delivery system for continuous diffusion of oxygen rental, includes portable continuous oxygen concentrator, rechargeable batteries, charging system and charging case." Establish 5 new Level II HCPCS codes to describe the devise specific dressings with integrated oxygen cannula, used with the topical oxygen delivery system, which includes a portable continuous oxygen concentrator and charging system:

Xxxx2 composite dressing, sterile, 4 sq. in, sterile pad with integrated oxygen diffusion cannula with adhesive border, for use with topical oxygen delivery system for continuous diffusion of oxygen

Xxxx3 composite dressing, sterile, 20 sq. in, sterile pad with integrated oxygen diffusion cannula with adhesive border, for use with topical oxygen delivery system for continuous diffusion of oxygen

Xxxx4 composite dressing, sterile, 16 sq. in, sterile pad with integrated oxygen diffusion cannula with adhesive border, for use with topical oxygen delivery system for continuous diffusion of oxygen

Xxxx5 Specialty absorptive dressing, sterile, 4 sq. in, sterile pad with integrated oxygen diffusion cannula without adhesive border, for use with topical oxygen delivery system for continuous diffusion of oxygen

Xxxx6 Specialty absorptive dressing, sterile, 20 sq. in, sterile pad without integrated oxygen diffusion cannula without adhesive border, for use with topical delivery system for continuous diffusion of oxygen.

According to the applicant, existing HCPCS code E0446 Topical Oxygen System, not otherwise specified, includes all supplies and accessories describes a system. The TransCu 02 and OxySpur products are not sold as a comprehensive system. In addition, the HCPCS codes for Composite Dressing A6203-A6205 and Specialty Absorptive Dressing A6251-A6256 does not describe wound dressings with an integrated oxygen cannula and distribution channels.

June 5, 2018

PRELIMINARY HCPCS CODING RECOMMENDATION

Existing code E0446 is intended to be all inclusive. Depending upon insurer policy, separate reporting of dressing might be considered redundant. TransCu Oxygen Generator and Oxyspur Oxygen Diffusion dressings, if used, may be deemed by insurers to be included in the procedure or in the supply allowance for oxygen delivery system. Individual insurers have the necessary flexibility to assign individual products to existing codes as they deem appropriate. 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

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

Pricing=00

June 5, 2018

HCPCS Public Meeting Agenda Item # 14

Application# 18.107

TOPIC

Request to establish a new Level II HCPCS code to identify a high-voltage, rechargeable lithium-ion battery, Trade Name: "Hill-Rom Lithium-Ion Battery-24 Volt."

Applicant's suggested language: AXXXX- "Lithium Ion Battery, high voltage, rechargeable, for use with respiratory devices, each."

BACKGROUND

Hill-Rom Respiratory Care submitted a request to establish a new Level II HCPCS code to identify the Hill-Rom Lithium-Ion Battery, a high voltage (24 volt, 2700 mAh) battery, used to power Hill-Rom's respiratory devices, including the Monarch Airway Clearance System, a mobile High Frequency Chest Wall Oscillation (HFCWO) device.

The battery contains a Nickel Cobalt constitution of less than 5%. The battery pack consists of seven cells, a printed wiring board, electronic components, output connector and a complete plastic enclosure. The battery is rechargeable.

The applicant comments that a new code is warranted because existing codes do not describe the high-voltage battery required for the Monarch System.

PRELIMINARY HCPCS CODING RECOMMENDATION

This request to establish a new Level II HCPCS code to uniquely identify the Hill-Rom Lithium-Ion Battery-24 Volt, has not been approved. Existing code A4601, "Lithium ion battery, rechargeable, for non-prosthetic use, replacement", 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

June 5, 2018

HCPCS Public Meeting Agenda Item # 15

Application# 18.100

TOPIC

Request to establish three new Level II HCPCS codes to identify a trigeminal nerve electrical neurostimulator and the electrodes and types of gel used with the neurostimulator, Trade Name: CEFALY ACUTE

Applicant's suggested language:

EXXX1-"Trigeminal nerve electrode neurostimulator."

AXXX1-"Electrode for trigeminal nerve electric neurostimuator, with standard gel."

AXXX2-"Electrode for trigeminal nerve electrical neurostimulator, with hypoallergenic gel."

BACKGROUND

CEFALY Technologies, Inc., submitted a request to establish three new Level II HCPCS codes to identify the CEFALY ACUTE trigonomal nerve electrical neurostimulator device and electrodes used with it. According to the applicant, the CEFALY ACUTE is indicated for the acute treatment of migraine with or without aura in patients 18 years or older.

According to the applicant, CEFALY ACUTE is a constant current generator powered by a rechargeable 3.7V LiPO battery, which generates electrical energy in the form of rectangular biphasic pulses having specific electrical parameters for the stimulation of the upper branches of the trigeminal nerve. It uses a bipolar, self-adhesive electrode with magnets to attach the neurostimulator to the forehead. During a treatment session, CEFALY ACUTE generates specific electrical impulses that are transmitted via the supraorbital electrode to stimulate the supratrochlearis and supraorbitalis nerves, which are branches of the trigeminal nerve. This external trigeminal nerve stimulation induces a sedative effect and significant relief of pain caused by migraine attacks with or without aura. It is self-administered by the patient in the home upon the prescription of a physician.

CEFALY ACUTE is supplied in a set that contains the trigeminal nerve electrical neurostimulator device, one bipolar self-adhesive supraorbital electrode, a power adaptor and cable, a storage case and an instruction manual. Additional electrodes are supplied separately in a kit containing 3 electrodes, with standard conductive hydrogel or hypoallergenic gel (blue gel). Each electrode is reusable for up to 20 treatments.

The applicant comments that the requested new codes are warranted because there are no permanent HCPCS codes to adequately describe the CEPALY ACUTE device or its electrodes.

June 5, 2018

PRELIMINARY HCPCS CODING RECOMMENDATION

This request to establish a new Level II HCPCS code to separately identify Cepaly Acute, has not been approved. Existing code E0720, Transcutaneous electrical nerve stimulation (tens) device, two lead, localized stimulation 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

June 5, 2018

HCPCS Public Meeting Agenda Item # 16

Application# 18.094

TOPIC

Request to establish a new Level II HCPCS code to identify a Neuromodular Pain Therapy system for home use, Trade Name: Biowave HOME® Neuromodulation Pain Therapy System.

Applicant's suggested language: EXXXX-"High frequency electrical signal mixing pain relief therapy system, including pain blocking device, single lead wire and 30-day supply of noninvasive, reusable electrode pads, complete system."

BACKGROUND

Biowave Corporation submitted a request to establish a new Level II HCPCS code to identify the Biowave HOME Neuromodulation Pain Therapy System, (Biowave HOME).

According to the applicant, Biowave HOME® is a prescription therapy for treating chronic, acute or postoperative pain in the home setting. The Biowave HOME® neurostimulator utilizes a unique signal mixing technology to deliver electrical signals through the skin directly to nerves for inhibiting pain transmission and improving function. The device works by delivering high frequency signal deep into the tissue for penetrative pain relief. The applicant comments that the product can be used to treat pain in numerous locations including the lower and mid back, neck, hip, groin, knee, shoulder, ankle, foot, elbow, wrist and hand. In addition, it may provide profound pain relief from tendon issues like acute and chronic tendinopathies, and from ligamentous issues like joint pain.

According to the applicant, Biowave HOME® has a one year warranty for the main unit, electrodes are excluded from the warranty. The electrodes are disposable, but can be reused approximately 10 times. They are packed 10-pr per package for which is for 100 treatments or 3 months of treatment.

The applicant comments that a new code is warranted because existing codes describe DME items that deliver low frequency signals (such as TENS), whereas Biowave HOME® utilizes high frequency signals to deliver paired low-frequency signals directly to the nociceptive pain fibers.

June 5, 2018

PRELIMINARY HCPCS CODING RECOMMENDATION

This request to establish a new Level II HCPCS code to separately identify Biowave HOME, has not been approved. Existing E0720, "Transcutaneous electrical nerve stimulation (tens) device, two lead, localized stimulation"' is available for assignment by insurers if they deem appropriate to identify the Biowave Home Device. Existing code A4557, "Lead wires, (e.g., apnea monitor), per pair" and A4595, "Electrical stimulator supplies, 2 lead, per month, (e.g., tens, nmes)" are also available for assignment to identify associated supplies.

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

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

For E0720, Pricing = 32, For A4557 and A4595, Pricing= 34