
**Centers for Medicare & Medicaid Services' (CMS') First Biannual 2022 Healthcare
Common Procedure Coding System (HCPCS) Public Meeting Agenda**

**Zoom Meeting, for remote participation
Tuesday, June 7, 2022 9:00 am – 5:00 pm, eastern daylight time (e.d.t)**

8:45 am, e.d.t:

- Zoom meeting login:
<https://cms.zoomgov.com/meeting/register/vJIsd-mgpz4jEvObPtTKB0-BGiFBQ80CuHQ>
- Additional information regarding participation in the public meeting will be sent to participants after they register to attend the meeting.

9:00 am, e.d.t:

- Welcome
- Background and purpose of meeting
- Meeting format and ground rules

On December 21, 2021, the Centers for Medicare & Medicaid Services (CMS) issued a final rule that establishes procedures for making benefit category determinations and payment determinations for new DMEPOS items and services under Medicare Part B. The final rule is available on CMS.gov: <https://www.cms.gov/medicare/durable-medical-equipment-prostheticsorthotics-and-supplies-fee-schedule/dmepos-federal-regulations-and-notices>. This process is being used to address the benefit category and payment status of codes added to the HCPCS from 2020 through 2022 as well as new items in 2022 and future years.

The HCPCS day one and day two agenda provide preliminary benefit and payment decisions for items and services described by new codes created before the rule was effective from January 2020 through April 2022. In addition, the agenda for these two days includes continuous glucose monitor and related supplies and accessories coding and payment determinations and additional items added by CMS to address Medicare benefit category or payment determinations.

Each agenda item includes a written overview of the applicant's request, CMS' final coding determination, as well as CMS' preliminary Medicare benefit category and payment determination, if applicable. 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 any registered 5-minute speakers. Speaker presentations will be followed by an opportunity for questions regarding that particular agenda item. The public meeting provides an opportunity for stakeholders and interested parties to provide additional input related to the preliminary benefit category and payment determinations and requests to modify the HCPCS code set, where applicable. Final decisions are not made at the public meeting. CMS' final benefit category and payment decisions will be published on CMS' HCPCS website at:

<https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Prior-Years-CMS-HCPCS-LevelII-Coding-Decisions-Narrative-Summary> around September 2022 and will be effective October 1, 2022, unless otherwise specified.

This agenda includes a summary of each HCPCS code application being presented on Tuesday, June 7, 2022. 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.

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Agenda Item # 1

Lunoa System (NightBalance) – 19.118

Topic

Medicare Benefit Category and Payment Determination for sleep position therapy device, the Lunoa system.

Temporary HCPCS code: K1001 “Electronic positional obstructive sleep apnea treatment, with sensor, includes all components and accessories, any type.”

Applicant’s Summary

According to information submitted by Respironics, Inc., the Lunoa System is a device that provides treatment for positional obstructive sleep apnea (POSA) with a non-supine apnea-hypopnea index less than 20. The components and accessories include a sensor, chest strap, docking station, power adapter, travel case, and portal. The battery-operated, rechargeable sensor contains a digital accelerometer that continually monitors a patient's sleep position and is worn around the chest. By emitting the vibro-tactile feedback during sleep, the sensor helps keep patients with POSA from sleeping in the supine position by vibration until the patient moves to a non-supine position. When placed in the docking station to charge, the sensor encrypts and transmits the data to the cloud. The portal allows users, such as the patient and the physician to view the data.

Final CMS HCPCS Coding Action

Established new HCPCS Level II code K1001 effective January 1, 2020, “Electronic positional obstructive sleep apnea treatment, with sensor, includes all components and accessories, any type.”

Requested Benefit Category

Durable Medical Equipment – section 1861(s)(6) of the Social Security Act

Preliminary Benefit Category Determination

No benefit category

Durable medical equipment (DME) is defined in Medicare regulations at title 42 Code of Federal Regulations (CFR) 414.202, and means equipment, furnished by a supplier or a home health agency that meets the following conditions:

- (1) Can withstand repeated use.
- (2) Effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years.
- (3) Is primarily and customarily used to serve a medical purpose.

(4) Generally is not useful to an individual in the absence of an illness or injury.

(5) Is appropriate for use in the home.

All five of these conditions must be met in order for equipment to be classified as DME.

The Lunoa System and similar products are alert devices that are used to alert a sleeping person to move out of the supine position to prevent snoring and in some cases POSA. In the case of the Lunoa System, the device will continue to increase vibration intensity until the patient's body registers the subliminal irritant or alert and cues the body to move into a non-supine position. The vibration is the alert that provokes the patient to react. Without this alert, a patient using the Lunoa System might not know to move to a non-supine position while asleep. The Lunoa System works similar to other nonmedical, non-prescription devices such as SnoreLab to alert the patient to move out of the supine position. After review of the market, we believe this category of products as a whole are used for the nonmedical purpose of alerting the patient to move out of the supine position to prevent snoring. Since these devices are generally useful in preventing snoring, and the majority of people who snore do not have an illness like POSA, we do not believe these devices are DME. Comment is welcome on how the Lunoa System differs from devices used to prevent snoring. In addition, the Lunoa System does not directly treat positional obstructive sleep apnea, rather it acts to prevent supine sleep which may reduce pressure on the airway. An alert is not a medical treatment by itself. For example, supine sleep would not be prevented if acclimation to the alert occurs over time. We note the applicant may have similar or identical products under the brand name NightBalance.

Preliminary Medicare Payment Determination

No Medicare payment. Pricing = 00

Agenda Item # 2

Portable Hydrotherapy Units – 19.131

Topic

Medicare Benefit Category and Payment Determination for Portable Hydrotherapy tubs.

Temporary HCPCS code: K1003 “Whirlpool tub, walk-in, portable.”

Applicant’s Summary

According to information submitted by Portable Hydrotherapy Units LLC, portable hydrotherapy units are designed to be completely mobile. Hydrotherapy is a natural therapy of heat, water and air that invigorates and massages the body while easing aches, pains and relaxing sore muscles in an effort to stimulate the release of endorphins. These devices need to have access to a water line. Hydrotherapy may be used for pain management or to improve immunity, arthritis, fibromyalgia syndrome, cardiovascular, anorectal disorders, fatigue, respiratory, endocrine, gastrointestinal, musculoskeletal, urinary and heart diseases.

Final CMS HCPCS Coding Action

Established new HCPCS Level II code K1003 effective January 1, 2020, “Whirlpool tub, walk-in, portable.”

Requested Benefit Category

Durable Medical Equipment – section 1861(s)(6) of the Social Security Act

Preliminary Benefit Category Determination

No benefit category

Durable medical equipment (DME) is defined in Medicare regulations at title 42 Code of Federal Regulations (CFR) 414.202, and means equipment, furnished by a supplier or a home health agency that meets the following conditions:

- (1) Can withstand repeated use.
- (2) Effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years.
- (3) Is primarily and customarily used to serve a medical purpose.
- (4) Generally is not useful to an individual in the absence of an illness or injury.
- (5) Is appropriate for use in the home.

All five of these conditions must be met in order for equipment to be classified as DME.

A portable hydrotherapy unit or whirlpool is useful to individuals in the absence of an illness or injury for relaxation and soothing sore muscles. Per section 280.1 of chapter 1, part 4 of the Medicare National Coverage Determinations Manual (CMS Pub. 100-03), portable whirlpool pumps are not DME because they are not primarily medical in nature and are personal comfort items excluded from Medicare coverage in accordance with section 1862(a)(6) of the Social Security Act.

Preliminary Medicare Payment Determination

No Medicare payment. Pricing = 00

Agenda Item # 3

PainShield® – 19.125

Topic

Medicare Benefit Category and Payment Determination for PainShield®.

Temporary HCPCS code: K1004 “Low frequency ultrasonic diathermy treatment device for home use, includes all components and accessories.”

Applicant’s Summary

According to information submitted by Nanovibronix, the PainShield® is an ultrasonic device used to apply heat to the tissues in the body for the treatment of selected medical conditions such as pain relief, muscle spasm and joint contractures. The device includes a transducer/applicator, rechargeable battery-powered driver unit and a cable that connects the driver to the transducer. The PainShield® provides intermittent ultrasonic output at a preset, low intensity frequency of 90 kHz, which cannot be modified by the user. When the device is on, it alternates between two phases: an active phase and an idle phase, both lasting 30 minutes each. The device automatically turns off after 6.5 hours of treatment, in which time the battery needs to be recharged. The driver is intended to undergo up to or no more than 400 charging cycles. Treatment is delivered through an ultrasound actuator, which is applied and secured to the surface of the body using adhesive patches. According to the PainShield® user manual, the life expectancy of the driver is two years. The PainShield® is approved for single patient use only.

Final CMS HCPCS Coding Action

Established new HCPCS Level II code K1004 effective January 1, 2020, “Low frequency ultrasonic diathermy treatment device for home use, includes all components and accessories.”

Requested Benefit Category

Durable Medical Equipment – section 1861(s)(6) of the Social Security Act

Preliminary Benefit Category Determination

No benefit category

Durable medical equipment (DME) is defined in Medicare regulations at title 42 Code of Federal Regulations (CFR) 414.202, and means equipment, furnished by a supplier or a home health agency that meets the following conditions:

- (1) Can withstand repeated use.
- (2) Effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years.

- (3) Is primarily and customarily used to serve a medical purpose.
- (4) Generally is not useful to an individual in the absence of an illness or injury.
- (5) Is appropriate for use in the home.

All five of these conditions must be met in order for equipment to be classified as DME.

DME is a benefit for rental of equipment for use in the home and therefore DME items must be able to withstand repeated use by successive patients in accordance with Medicare regulations and as indicated in Medicare program instructions at chapter 15, section 110.1 of the Medicare Benefit Policy Manual (CMS Pub. 100-02) and chapter 1, part 4, section 280.1 of the Medicare National Coverage Determinations Manual (CMS Pub. 100-03). The PainShield device is approved for single patient use only; therefore, the device cannot withstand repeated use by successive patients. In addition, the life expectancy of the driver equipment is two years; therefore, the minimum lifetime requirement of three years is not met.

Preliminary Medicare Payment Determination

No Medicare payment. Pricing = 00

Agenda Item # 4

Willow™ Wearable Breast Pump Milk Bag – 19.136

Topic

Medicare Benefit Category and Payment Determination for Breast Pump Milk Bag.

Temporary HCPCS code: K1005 “Disposable collection and storage bag for breast milk, any size, any type, each.”

Applicant’s Summary

According to information submitted by Willow™, disposable milk collection bags are used as a supply to an electric or battery powered breast pump. Breast milk bags are intended for those lactating to store expressed breast milk. Milk collection bags are disposable, single use supplies. Collection and storage bags for breast milk would be used in conjunction with a breast pump.

Final CMS HCPCS Coding Action

Established new HCPCS Level II code K1005 effective January 1, 2020, “Disposable collection and storage bag for breast milk, any size, any type, each.”

Requested Benefit Category

Durable Medical Equipment – section 1861(s)(6) of the Social Security Act

Preliminary Benefit Category Determination

No benefit category when used with electric breast pumps; contractor discretion when used with manual breast pumps

Durable medical equipment (DME) is defined in Medicare regulations at title 42 Code of Federal Regulations (CFR) 414.202, and means equipment, furnished by a supplier or a home health agency that meets the following conditions:

- (1) Can withstand repeated use.
- (2) Effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years.
- (3) Is primarily and customarily used to serve a medical purpose.
- (4) Generally is not useful to an individual in the absence of an illness or injury.
- (5) Is appropriate for use in the home.

All five of these conditions must be met in order for equipment to be classified as DME.

Code K1005 was added for disposable storage bags for breast milk extracted using a breast pump. In order for disposable storage bags to fall under the DME benefit category they would need to be essential accessories for the DME item. There are currently two HCPCS codes for breast pumps with code E0602 for manual breast pumps with the Medicare coverage indicator of contractor discretion and code E0603 for electric breast pumps with the Medicare coverage indicator of not payable or noncovered by Medicare. Therefore, coverage of storage bags used with manual breast pumps would be based on contractor discretion while storage bags used with electric breast pumps would be not payable or noncovered by Medicare.

Preliminary Medicare Payment Determination

Pricing = 46

Agenda Item # 5

Dynamic Back – 19.120

Topic

Medicare Benefit Category and Payment Determination for wheelchair positioning hardware.

HCPCS code: E2398 “Wheelchair accessory, dynamic positioning hardware for back.”

Applicant’s Summary

According to information submitted by Sunrise Medical US LLC, the Dynamic Back 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. According to Sunrise Medical, 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. 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.

Final CMS HCPCS Coding Action

Established new HCPCS Level II code E2398 effective January 1, 2020, “Wheelchair accessory, dynamic positioning hardware for back.”

Requested Benefit Category

Durable Medical Equipment – section 1861(s)(6) of the Social Security Act

Preliminary Benefit Category Determination

Durable Medical Equipment

Durable medical equipment (DME) is defined in Medicare regulations at title 42 Code of Federal Regulations (CFR) 414.202, and means equipment, furnished by a supplier or a home health agency that meets the following conditions:

- (1) Can withstand repeated use.
- (2) Effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years.
- (3) Is primarily and customarily used to serve a medical purpose.
- (4) Generally is not useful to an individual in the absence of an illness or injury.
- (5) Is appropriate for use in the home.

All five of these conditions must be met in order for equipment to be classified as DME.

The information provided for the Dynamic Back supports the preliminary benefit category determination for durable medical equipment.

Preliminary Medicare Payment Determination

In accordance with regulations at 42 CFR § 414.238(b), fee schedule amounts for new HCPCS codes for items and services without a fee schedule pricing history are established using existing fee schedule amounts for comparable items when items with existing fee schedule amounts are determined to be comparable to the new items and services based on a comparison of: physical components; mechanical components; electrical components; function and intended use; and additional attributes and features. The preliminary payment determination for code E2398, for this particular wheelchair dynamic hardware, is to establish the fee schedule amounts using existing fee schedule amounts for comparable items described by HCPCS code E1015.

Dynamic positioning back hardware absorbs and diffuses the wheelchair user's uncontrolled movements and forces using elastomers, joints, linkages, and other components. Devices that fall under E1015 absorb the impact of a force at the point of vibration, energy, or where the force occurs and disperses the energy through the frame, with minimal displacement of the patient. Both the dynamic positioning back hardware and devices under E1015 reduce shear forces and allows movement with return to a neutral position. Also, both the dynamic positioning back hardware and devices under E1015 are mounted directly to the frame of a wheelchair. Common components include rubber, polymer, elastomer, hardware componentry (spring, screws, washers, etc.).

	E1015	Dynamic Back Hardware
Physical Components	Mounted directly to the frame of a wheelchair Rubber/polymer/elastomer Hardware componentry	Mounted directly to the frame of a wheelchair Rubber/polymer/elastomer Hardware componentry
Mechanical Components	Spring Gas filled cylinder	Spring
Electrical Components	N/a	N/a
Function and Intended Use	Shock absorber Reduces vibration Minimal displacement of the patient Allows movement with return to a neutral position	Shock absorber Reduces vibration Minimal displacement of the patient Allows movement with return to a neutral position
Additional Aspects and Features	Reduction of shear forces	Reduction of shear forces

The current 2022 fee schedule amounts for code E1015 when used with complex rehabilitative wheelchairs range from \$140.34 to \$168.37. The current 2022 fee schedule amounts for code E1015 when used with standard wheelchairs furnished in rural and noncontiguous areas range from \$137.55 to \$152.59. The current 2022 fee schedule amount for code E1015 when used with standard wheelchairs furnished in other areas ranges from

\$121.07 to \$133.07. The fee schedule amounts for this item are generally less than \$150 and therefore this item is inexpensive DME. Payment for the item would be made on a purchase or rental basis with total payments for any combination of claims for rental and/or purchase would be capped at the purchase fee schedule amount.

Pricing = 32

Agenda Item # 6

C-Brace® – 19.139

Topic

Medicare Benefit Category and Payment Determination for C-Brace®.

HCPCS code: L2006 “Knee ankle foot device, any material, single or double upright, swing and 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.”

Applicant’s Summary

According to information submitted by Ottobock, the C-Brace® is a microprocessor swing and stance phase control device controlled by a hydraulic knee joint unit. The C-Brace® is designed to help compensate for lower-limb mobility issues due to partial paralysis, incomplete spinal cord injury, post-polio syndrome, and quadriceps weakness due to a variety of conditions. The knee joint is a non-powered, passive hydraulic unit where all of the propulsive energy comes from the patient. The microprocessor-controlled knee joint is mounted on the lateral side of the device and the orientation of the joint unit in the frontal plane is fixed with the medial follower joint. The microprocessor is designed with a carbon fiber strut with integrated ankle-controlled moment sensor and a monocentric microprocessor-controlled knee joint. A knee angle sensor provides feedback on knee angle and knee angle velocity. Extension and flexion damping are adjusted at a frequency of 50 Hz by a microprocessor with the ankle moment, the knee angle, the knee angle velocity, and the temperature of the hydraulic as input signals. The C-Brace® controls flexion and extension resistance during the entire gait cycle and provides knee flexion during weight bearing for shock absorption and reciprocal (step-over-step) slope and stair descent. The C-Brace® stabilizes the knee in the sagittal plane mimicking the physiological eccentric function of the quadriceps muscle. The thigh shell, calf shell, and foot plate are custom-fabricated. The thigh and calf cuff are custom molded Prepreg carbon composite used to hold the inner and outer uprights (double upright) with knee joints in alignment. The C-Brace® can be configured for several different ankle joints. The C-Brace® can weigh from 4.5 to 7 pounds. The knee joint contains a knee angle sensor and a hydraulic pressure sensor to measure joint angle and hydraulic force, and inertial motion unit (IMU) with 3-axis accelerometer and 3-axis gyroscope, a real time chronometer, a dual mode Bluetooth module for data exchange and a rechargeable 3.3 Li-Ion battery. A fully charged battery can provide 18 hours of power. The C-Brace® then uses this information to control the flexion and extension values of the hydraulic unit that provides varying levels of resistance to the knee flexion (bending), mimicking eccentric contraction of the quadriceps, and to knee extension, mimicking eccentric contraction of the hamstrings.

Final CMS HCPCS Coding Action

Established new HCPCS Level II code L2006 effective January 1, 2020, “Knee ankle foot device, any material, single or double upright, swing and 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.”

Requested Benefit Category

Leg Brace – section 1861(s)(9) of the Social Security Act

Preliminary Benefit Category Determination

Leg brace (Orthotic)

Section 130 of Chapter 15 of the Medicare Benefit Policy Manual defines a brace as a rigid and semi-rigid device which are used for the purpose of supporting a weak or deformed body member or restricting or eliminating motion in a diseased or injured part of the body. The information submitted by the applicant was reviewed extensively and supports the preliminary benefit category determination of leg brace which requires the item to be used to support a weak or deformed lower extremity.

Preliminary Medicare Payment Determination

In accordance with regulations at 42 CFR § 414.238(b), fee schedule amounts for new HCPCS codes for items and services without a fee schedule pricing history are established using existing fee schedule amounts for comparable items when items with existing fee schedule amounts are determined to be comparable to the new items and services based on a comparison of: physical components; mechanical components; electrical components; function and intended use; and additional attributes and features. The preliminary payment determination for code L2006 for this particular leg brace is to establish the fee schedule amounts using existing fee schedule amounts for comparable items based on the sum of the following existing fee schedule amounts for comparable items consisting of a leg brace described by HCPCS code L2036, the additional feature described by HCPCS code L2755, and codes for various components of the C-Leg® prosthetic:

- L2036, knee ankle foot orthosis, full plastic, double upright, with or without free motion knee, with or without free motion ankle, custom fabricated;
- L5856, addition to lower extremity prosthesis, endoskeletal knee-shin system, microprocessor control feature, swing and stance phase, includes electronic sensor(s), any type;
- L5828, addition, endoskeletal knee-shin system, single axis, fluid swing and stance phase control;
- L5848, addition to endoskeletal knee-shin system, fluid stance extension, dampening feature, with or without adjustability;
- L5845, addition, endoskeletal, knee-shin system, stance flexion feature, adjustable;
- L2755, addition to lower extremity orthosis, high strength, lightweight material, all hybrid lamination/prepreg composite, per segment, for custom fabricated orthosis only.

Pricing for L2006 can be represented by the following formula: L2036 + L5856 + L5828 + L5848 + L5845 + L2755. This results in an average fee schedule amount for 2022 of approximately \$33,810.

C-Brace®	L2036	L5856	L5828	L5848	L5845	L2755
<u>Physical Components</u>						
Free motion knee	X					
Free motion ankle	X					
High strength material						X
Custom fabricated	X					X
Adjustable		X		X	X	
Double upright	X					
Lightweight						X
PrePreg/carbon composite						X
<u>Mechanical Components</u>						
Swing phase		X	X			
Stance phase		X	X	X	X	
Fluid control			X	X		
<u>Electrical Components</u>						
Microprocessor		X				
3-axis accelerometer		X				
3-axis gyroscope		X				
Battery		X				
<u>Function and Intended Use</u>						
Knee-Ankle-Foot Orthosis (KAFO)	X					
Lower extremity device/component	X	X	X	X	X	X
<u>Additional Aspects and Features</u>						

Payment for this leg brace would be made on a lump sum purchase basis.

Pricing = 38

Agenda Item # 7

PureWick™ Urine Collection System – 20.078

Topic

Medicare Benefit Category and Payment Determination for PureWick™ Urine Collection System.

Temporary HCPCS code: K1006 “Suction pump, home model, portable or stationary, electric, any type, for use with external urine management system.”

Applicant’s Summary

According to information submitted by Becton, Dickinson and Company (BD), the PureWick™ System is an alternative to an indwelling catheter for female adult patients suffering from permanent urinary incontinence. It is indicated for non-invasive urine output management in females and is contraindicated in patients with urinary retention. It funnels the urine and removes it to the collection canister once it passes through the patient tubing. Suction enables efficient removal of urine from the female external catheter with a minimum suction of 40 mmHg. The application stated, the PureWick™ Urine Collection System will be 100% used in a patient’s home; however, with components of the PureWick™ System can be used in the nursing facility, inpatient or outpatient hospital, or surgical center. Also, BD PureWick™ System’s website (<https://www.purewickathome.com/>) advertised the device is for home use. Review of the BD PureWick™ System’s website (<https://www.purewickathome.com/>) in March 2021 found information stating “...useful life of the PureWick™ Urine Collection System is one (1) year.” However, in April 2021, this statement was updated removing the quantitative number of years associated with the useful life of the PureWick™ System. In June 2021, BD submitted independent lab testing stating that the PureWick System has a useful life of a minimum of three years.

Final CMS HCPCS Coding Action

Established new HCPCS Level II code K1006 effective October 1, 2020, “Suction pump, home model, portable or stationary, electric, any type, for use with external urine management system.”

Requested Benefit Category

Durable Medical Equipment – section 1861(s)(6) of the Social Security Act

Preliminary Benefit Category Determination

No benefit category

Durable medical equipment (DME) is defined in Medicare regulations at title 42 Code of Federal Regulations (CFR) 414.202, and means equipment, furnished by a supplier or a home health agency that meets the following conditions:

- (1) Can withstand repeated use.

- (2) Effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years.
- (3) Is primarily and customarily used to serve a medical purpose.
- (4) Generally is not useful to an individual in the absence of an illness or injury.
- (5) Is appropriate for use in the home.

All five of these conditions must be met in order for equipment to be classified as DME.

We are aware that this equipment is commonly used in the hospital setting, but we have no evidence or information that would enable us to determine that it is appropriate for use in the home. Studies, data or other information demonstrating that the PureWick™ System is being used safely in the home setting by the patient are needed in order to determine if this equipment is appropriate for use in the home. We are only aware of one study¹ submitted that reviewed the effects of female external urinary catheters that was presented. This study used a different product than the PureWick™ System and was performed in an acute care or hospital setting.

Preliminary Medicare Payment Determination

No Medicare payment. Pricing = 00

¹ Zavodnick, Jillian et al. "Effect of a Female External Urinary Catheter on Incidence of Catheter-Associated Urinary Tract Infection." *Cureus* vol. 12,10 e11113. 23 Oct. 2020. doi:10.7759/cureus.11113

Agenda Item # 8

SpeechVive – 20.077

Topic

Medicare Benefit Category and Payment Determination for SpeechVive device.

Temporary HCPCS code: K1009 “Speech volume modulation system, any type, including all components and accessories.”

Applicant’s Summary

According to information submitted by SpeechVive, Inc., the SpeechVive device utilizes an ear device that plays background noise (multi-talker babble) in the patient’s ear only when the patient speaks. The noise elicits the Lombard Effect, automatically increasing the patient’s vocal intensity, slowing their speech rate, and/or increasing the clarity of their speech. The SpeechVive device is worn behind the ear. When the patient stops speaking, the device turns off. The lifespan of the SpeechVive is estimated to be 5 years. The SpeechVive is powered by an internal, rechargeable, lithium-ion battery. The applicant states the device is used to help Parkinson’s patients diagnosed with Dysarthria and Anarthria.

Final CMS HCPCS Coding Action

Established new HCPCS Level II code K1009 effective October 1, 2020, “Speech volume modulation system, any type, including all components and accessories.”

Requested Benefit Category

Durable Medical Equipment – section 1861(s)(6) of the Social Security Act

Preliminary Benefit Category Determination

Durable Medical Equipment

Durable medical equipment (DME) is defined in Medicare regulations at title 42 Code of Federal Regulations (CFR) 414.202, and means equipment, furnished by a supplier or a home health agency that meets the following conditions:

- (1) Can withstand repeated use.
- (2) Effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years.
- (3) Is primarily and customarily used to serve a medical purpose.
- (4) Generally is not useful to an individual in the absence of an illness or injury.
- (5) Is appropriate for use in the home.

All five of these conditions must be met in order for equipment to be classified as DME.

The information provided for the SpeechVive device supports the preliminary benefit category determination of durable medical equipment.

Preliminary Medicare Payment Determination

In accordance with regulations at 42 CFR § 414.238(c), fee schedule amounts for items and services without a fee schedule pricing history described by new HCPCS codes that are not comparable to items and services with existing fee schedule amounts may be established using supplier price lists, including catalogs and other retail price lists (such as internet retail prices) that provide information on commercial pricing for the item. If the only available price information is from a period other than the fee schedule base period, deflation factors are applied against current pricing in order to approximate the base period price. A 2016 article² lists the price of the SpeechVive at \$2,495. The annual deflation factors are specified in program instructions and the deflated amounts are then increased by the update factors specified in section 1834(a)(14) of the Act for DME.

Payment for the equipment would be made on a capped rental basis. The average 2022 capped rental fee schedule amount for K1009 would be \$184.34, which would pay \$1,935.57 over 13 months.

Pricing = 36

² <https://xconomy.com/indiana/2016/05/18/indianas-speechvive-nabs-2m-for-parkinsons-speech-devices/>

Agenda Item # 9

Acuvue® Oasys® – 20.074

Topic

Medicare Benefit Category and Payment Determination for ACUVUE® OASYS® Contact Lenses with Transitions

HCPCS code: V2524 “Contact lens, hydrophilic, spherical, photochromic additive, per lens.”

Applicant’s Summary

According to information submitted by Johnson and Johnson Vision Care, Inc., ACUVUE® OASYS® Contact Lenses with Transitions are soft (hydrophilic), spherical, contact lenses with light-adaptive technology. The lenses are made of silicone hydrogel material (senofilcon A) containing an internal wetting agent and UV absorbing monomers. A combination of the benzotriazole UV absorbing monomer and the naphthopyran monomer (photochromic additive) is used to block UV radiation. The contact lenses are for daily wear, optical correction of refractive ametropia (myopia and hyperopia), in phakic or aphakic persons with non-diseased eyes who may have 1.00D or less of astigmatism. It is also for attenuation of bright light to help protect against transmission of harmful UV radiation to the cornea and the eye. ACUVUE® OASYS® Contact Lenses with Transitions quickly adjusts from clear to dark and back in response to changing light conditions while reducing exposure to bright light indoors and out.

Final CMS HCPCS Coding Action

Established new HCPCS Level II code V2524 effective October 1, 2020, “Contact lens, hydrophilic, spherical, photochromic additive, per lens.”

Requested Benefit Category

Prosthetic Device – section 1861(s)(8) of the Social Security Act

Preliminary Benefit Category Determination

Prosthetic Device

Refractive lenses are covered when they are used to restore the vision normally provided by the natural lens of the eye of an individual lacking the organic lens because of surgical removal or congenital absence. Covered diagnoses are limited to pseudophakia (condition in which the natural lens has been replaced with an artificial intraocular lens [IOL]), aphakia (condition in which the natural lens has been removed but there is no IOL), and congenital aphakia. Lenses provided for other diagnoses will be denied as noncovered. Coverage may be limited to one pair of eyeglasses or contact lenses. Because coverage of refractive lenses is based upon the Prosthetic Device benefit category, there is no coverage for frames or lens add-on codes unless there is a covered lens(es). Tinted lenses, including photochromatic lenses, used as sunglasses, which are prescribed in addition to regular prosthetic lenses to a pseudophakic beneficiary, will be denied as noncovered.

Preliminary Medicare Payment Determination

In accordance with regulations at 42 CFR § 414.238(b), fee schedule amounts for new HCPCS codes for items and services without a fee schedule pricing history are established using existing fee schedule amounts for comparable items when items with existing fee schedule amounts are determined to be comparable to the new items and services based on a comparison of: physical components; mechanical components; electrical components; function and intended use; and additional attributes and features. The preliminary payment determination for code V2524 is to establish the fee schedule amounts using existing fee schedule amounts for comparable items described by HCPCS codes V2520 and V2744. The pricing comparative considers the base hydrophilic contact lens, spherical, code, V2520 and adds a photochromatic additive with code V2744. Pricing for V2744 can be represented by the following formula: $V2520 + V2744$.

The average 2022 fee schedule amount for V2524 would be approximately \$147. Payment would be on a lump sum purchase basis.

Pricing = 38

Agenda Item # 10

MiniACE® – 20.172

Topic

Medicare Benefit Category and Payment Determination for MiniACE®.

Temporary HCPCS code: K1013 “Enema tube, with or without adapter, any type, replacement only, each.”

Applicant’s Summary

According to information submitted by Applied Medical Technology, Inc., the AMT MiniACE® is a low profile, percutaneous antegrade continence enema (ACE) supply item. The MiniACE® is inserted into the cecum through either a cecostomy or a Malone/appendicostomy procedure. The MiniACE® is held in place by an internal silicone balloon and an external silicone bolster. The low-profile external bolster contains an irrigation port and a balloon inflation port; these features allow the user to administer an enema and inflate/deflate the balloon, respectively. Users are able to replace the MiniACE® at the hospital, in a clinic, or at home using the same replacement method as a low-profile gastrostomy tube. The MiniACE® is used to facilitate ante grade enemas (via cecostomy or Malone/appendicostomy) in patients who have non-functioning colons and have not responded to conservative treatments (i.e., high-fiber diets, laxatives, rectal enemas, etc.). The MiniACE® is not a bag or a pump; it is a conduit for administering an ante grade enema into a nonfunctioning colon.

Final CMS HCPCS Coding Action

Established new HCPCS Level II code K1013 effective April 1, 2021, “Enema tube, with or without adapter, any type, replacement only, each.”

Requested Benefit Category

Durable Medical Equipment – section 1861(s)(6) of the Social Security Act

Preliminary Benefit Category Determination

No benefit category

Durable medical equipment (DME) is defined in Medicare regulations at title 42 Code of Federal Regulations (CFR) 414.202, and means equipment, furnished by a supplier or a home health agency that meets the following conditions:

- (1) Can withstand repeated use.
- (2) Effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years.
- (3) Is primarily and customarily used to serve a medical purpose.

(4) Generally is not useful to an individual in the absence of an illness or injury.

(5) Is appropriate for use in the home.

All five of these conditions must be met in order for equipment to be classified as DME.

As indicated in Medicare program instructions at chapter 15, section 110.3 of the Medicare Benefit Policy Manual (CMS Pub. 100-02), payment may be made for supplies that are necessary for the effective use of covered DME. In accordance with Medicare program instructions at chapter 15, section 120 of the Medicare Benefit Policy Manual (CMS Pub. 100-02), prosthetic devices (other than dental) are devices which replace all or part of an internal body organ (including contiguous tissue), or replace all or part of the function of a permanently inoperative or malfunctioning internal body organ. The DME Medicare Administrative Contractors' policy article regarding bowel management devices (A54516), manual pump enema systems, gravity-administered enema systems, and rectal catheters or tubes specifies that these items are not DME because they do not meet the requirement of durability. Rectal catheters or tubes are not prosthetic devices because they do not replace all or part of an internal body organ or all or part of the function of a permanently inoperative or malfunctioning internal body organ. Supplies associated with a non-covered item are non-covered.

Preliminary Medicare Payment Determination

No Medicare payment. Pricing = 00

Agenda Item # 11

ALLUX™ – 20.156

Topic

Medicare Benefit Category and Payment Determination for ALLUX™.

Temporary HCPCS code: K1014 “Addition, endoskeletal knee-shin system, 4 bar linkage or multiaxial, fluid swing and stance phase control.”

Applicant’s Summary

According to information submitted by Proteor USA, the ALLUX™ microprocessor-controlled knee that utilizes a 4-bar geometry with hydraulic control of both stance and swing phases of gait. The ALLUX™ is intended for use by amputees that are missing their leg through knee joint or higher (KD through HD). An automatic stance-phase lock feature will lock knee flexion when the user maintains a load on a flexed, stationary knee. Upon knee extension, the lock is released, and the knee returns to normal function. The ALLUX™ has an internal lithium-ion battery that is regularly charged by the user. This internal battery will allow the user to walk approximately 30,000 steps on a single charge, or roughly four days of use before the ALLUX™ needs to be charged. The ALLUX™ is continually monitoring the battery level and will notify the user that the battery level is low (4-6 hours of remaining charge) through a series of vibrations. The user can also query the knee using the remote control for an immediate status of the battery. All accessories and software are included (remote, emergency back-up battery, charger, software download, and wireless USB dongle).

Final CMS HCPCS Coding Action

Established new HCPCS Level II code K1014 effective April 1, 2021, “Addition, endoskeletal knee-shin system, 4 bar linkage or multiaxial, fluid swing and stance phase control.”

Requested Benefit Category

Prosthetic (Artificial Leg) – section 1861(s)(9) of the Social Security Act

Preliminary Benefit Category Determination

Artificial Leg (prosthetic)

The application supports a preliminary benefit category determination that ALLUX™ replaces a missing leg through knee joint or higher (KD through HD) and would fall under the Medicare benefit for artificial legs (prosthetics).

Preliminary Medicare Payment Determination

In accordance with regulations at 42 CFR § 414.238(b), fee schedule amounts for new HCPCS codes for items and services without a fee schedule pricing history are established using existing fee schedule amounts for comparable items when items with existing fee

schedule amounts are determined to be comparable to the new items and services based on a comparison of: physical components; mechanical components; electrical components; function and intended use; and additional attributes and features. The preliminary payment determination for code K1014 for this particular endoskeletal knee-shin system is that this item should be priced using the existing fee schedule amounts for comparable items described by:

- L5613, addition to lower extremity, endoskeletal system, above knee-knee disarticulation, 4 bar linkage, with hydraulic swing phase control;
- L5828, addition, endoskeletal knee-shin system, single axis, fluid swing and stance phase control;
- L5826, addition, endoskeletal knee-shin system, single axis, hydraulic swing phase control, with miniature high activity frame;
- L5930, addition, endoskeletal system, high activity knee control frame.

Pricing for K1014 can be represented by the following formula: $L5613 + ((L5828 - L5826) + L5930)$. The average 2022 fee schedule amount for K1014 would be \$6,463.27.

K1014	L5613	L5828	L5826	L5930
<u>Physical Components</u>				
4-Bar linkage	X			
High activity frame			X	X
<u>Mechanical Components</u>				
Swing phase	X	X	X	
Stance phase		X		
Fluid control	X	X	X	
<u>Electrical Components</u>				
<u>Function and Intended Use</u>				
Endoskeletal knee shin system	X	X	X	X
Lower extremity device/component	X	X	X	X
<u>Additional Aspects and Features</u>				

The use of L5613 accounts for the 4-bar mechanical feature as the base knee code. The addition of L5828 adds the fluid swing and stance phase control features. This duplicates the hydraulic swing phase feature. This hydraulic swing phase duplication is then subtracted out by removing L5826. However, this removes the high activity frame feature, but is added back by the addition of L5930. The need to add back in the high activity frame is to equalize the deduction of L5826 knee unit since it contains a feature, miniature high active frame, that should not be removed.

Payment would be on a lump sum purchase basis.

Pricing = 38

Agenda Item # 12

UNFO – 20.159

Topic

Medicare Benefit Category and Payment Determination for UNFO.

Temporary HCPCS code: K1015 “Foot, adductus positioning device, adjustable.”

Applicant’s Summary

According to information submitted by Magic Orthopedics Ltd., UNFO-S is a thermoplastic elastomer foot positioning device. The UNFO-S functions by stabilizing the heel in the heel cage and the rest of the foot in the device while applying corrective pressures to the midfoot, thereby realigning the malformed pediatric foot. This is considered to be an alternative to serial casting. UNFO-S is not an arch support, nor is it molded to patient model or patient foot. UNFO-S treats newborns with semiflexible and rigid metatarsus adductus/varus, as well as flexible metatarsus adductus/varus that does not respond to stretching. The device is worn on the foot and does not involve the ankle. An adjustable Velcro strap immobilizes the foot in the device. This strap is fixed to the medial wall of the device and adjusts to the desired tension. UNFO-S cannot be used in a shoe attached to a brace. According to the manufacture, the longest period of time a patient should need to wear this is 16 weeks.

Final CMS HCPCS Coding Action

Established new HCPCS Level II code K1015 effective April 1, 2021, “Foot, adductus positioning device, adjustable.”

Requested Benefit Category

Leg Brace – section 1861(s)(9) of the Social Security Act

Preliminary Benefit Category Determination

Leg Brace

The information provided for the UNFO-S supports the preliminary benefit category determination of leg brace.

It is possible that this device could fall under the coverage exclusion by §1862(a)(8) for supportive devices for the feet. However, CMS feels that this would need to be addressed in rulemaking.

Preliminary Medicare Payment Determination

Due to expected low-volume Medicare use, the fee schedule amounts for this item will be developed by the contractors based on their individual consideration of each claim.

Pricing = 46

Agenda Item # 13

Ottobock Rotation Adapter 4R57 – 21.053

Topic

Medicare Benefit Category and Payment Determination for Ottobock Rotation Adapter.

Temporary HCPCS code: K1022 “Addition to lower extremity prosthesis, endoskeletal, knee disarticulation, above knee, hip disarticulation, positional rotation unit, any type.”

Applicant’s Summary

According to information submitted by Ottobock, Rotation Adapter 4R57 provides 360° rotation of the prosthetic limb to accommodate specific environmental situations such as (not all-inclusive): performing activities in confined spaces like small kitchens and walkways; entering and exiting a vehicle and while driving, enabling the user to swing the prosthesis out of the way; switching prosthetic feet, putting on shoes or changing socks because it brings the prosthetic foot within reach. This feature also allows the user to adjust their limb to the surroundings without putting additional torsional loads and strains on the socket and residual limb. The Rotation Adapter 4R57 is inserted between the socket and prosthetic knee joint. There is a release button on the adapter that will allow the unit to rotate when pressed. The adapter will lock automatically when in the neutral position.

Final CMS HCPCS Coding Action

Established new HCPCS Level II code K1022 effective October 1, 2021, “Addition to lower extremity prosthesis, endoskeletal, knee disarticulation, above knee, hip disarticulation, positional rotation unit, any type.”

Requested Benefit Category

Prosthetic (Artificial Leg) – section 1861(s)(9) of the Social Security Act

Preliminary Benefit Category Determination

Artificial Leg (Prosthetic)

The application supports a preliminary benefit category determination that the Rotation Adapter 4R57 is used in addition to a lower extremity prosthesis and would fall under the Medicare benefit for artificial legs (prosthetics).

Preliminary Medicare Payment Determination

In accordance with regulations at 42 CFR § 414.236, fee schedule amounts for new HCPCS codes for items and services that have a fee schedule pricing history, the previous fee schedule amounts for the old code(s) are mapped to the new code(s) to ensure continuity of pricing. Mapping fee schedule amounts can occur based on different kinds of coding changes. This includes when there is a single code that describes two or more distinct complete items (for example, two different but related or similar items), and separate codes are subsequently

established for each item, the fee schedule amounts that applied to the single code continue to apply to each of the items described by the new codes. In this case, the Ottobock Rotation Adapter 4R57 has a fee schedule pricing history of being previously classified and paid under HCPCS code L5984. Based on continuity of pricing, the preliminary payment determination for code K1022, for this particular positional rotation adapter, is that this item should be priced using the existing fee schedule amounts described by HCPCS code L5984.

Payment would be on a lump sum purchase basis. The average 2022 fee schedule amount for K1022 would be \$676.08.

Pricing = 38

Agenda Item # 14

Koya Dayspring® System – 21.032

Topic

Medicare Benefit Category and Payment Determination for Koya Dayspring® System.

Temporary HCPCS code: K1024 “Non-pneumatic compression controller with sequential calibrated gradient pressure.”

Applicant’s Summary

According to information submitted by Koya Medical, Inc., the Koya Dayspring® System is a device that employs sequential gradient non-pneumatic compression to treat and manage lymphedema. The Koya Dayspring® System moves excess fluid in a rhythmic, distal to proximal manner. The device contains biocompatible shape memory alloy actuators or flexframes to generate the compressive pressure instead of inflating and deflating air bladders. The controller is the power source and logical control for the segmental the Koya Dayspring® System. The controller allows programing of individualized pressure settings or pre-selected pressure settings for treatment. The controller can be used to start, pause or stop a treatment session at any time. The Koya Dayspring® System also provides a companion phone application as an alternative method to program the controller. The Koya Dayspring® System provides the ability to specify and generate desired compressive pressure and sequence to contract and relax each segment in the appliance independently.

Final CMS HCPCS Coding Action

Established new HCPCS Level II code K1024 effective October 1, 2021, “Non-pneumatic compression controller with sequential calibrated gradient pressure.”

Requested Benefit Category

Durable Medical Equipment – section 1861(s)(6) of the Social Security Act

Preliminary Benefit Category Determination

Durable Medical Equipment

Durable medical equipment (DME) is defined in Medicare regulations at title 42 Code of Federal Regulations (CFR) 414.202, and means equipment, furnished by a supplier or a home health agency that meets the following conditions:

- (1) Can withstand repeated use.
- (2) Effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years.
- (3) Is primarily and customarily used to serve a medical purpose.

(4) Generally is not useful to an individual in the absence of an illness or injury.

(5) Is appropriate for use in the home.

All five of these conditions must be met in order for equipment to be classified as DME.

The information for the Koya Dayspring® System was reviewed extensively and supports the preliminary durable medical equipment benefit category determination.

Preliminary Medicare Payment Determination

In accordance with regulations at 42 CFR § 414.238(b), fee schedule amounts for new HCPCS codes for items and services without a fee schedule pricing history are established using existing fee schedule amounts for comparable items when items with existing fee schedule amounts are determined to be comparable to the new items and services based on a comparison of: physical components; mechanical components; electrical components; function and intended use; and additional attributes and features. The preliminary payment determination for code K1024, for this particular lymphedema treatment equipment and accessories, is that this item should be priced using the existing fee schedule amounts for comparable items described by HCPCS code E0652.

The Koya Dayspring® System consists of a segmental calibrated gradient compression device that provides compression comparable to existing pneumatic pump (E0652) and garments (e.g., E0668) through segments that contract and relax flexible frames in a segmental appliance without the use of air. The clinical conditions and indications for use for the Koya Dayspring® System are the same to those under codes for the segmented gradient pneumatic pump E0652 and related garment accessory (e.g., E0668). We believe that a non-pneumatic system such as the Koya Dayspring® System as a whole (controller and garment accessory) is comparable to existing pneumatic systems as a whole (pump and garment accessory).

	Pneumatic Compression	Koya Dayspring® System
Physical Components	Air compressor Segmented appliance	Controller Segmented appliance
Mechanical Components	The segmental appliance contains air bladders in select number of chambers Pressure ranges from 0 – 100 mmHg Tubing to connect pump to appliance (used for air flow) Appliance can contain solenoid valves (usually the pump/compressor is connected to a manifold, which moves air to each cell by a dedicated solenoid valve) An air pump that compresses air that flows out the output port	The segmented appliance contains actuators (up to 14 segments) The actuators are the component that drives, or allows, movement – in this case compression and relaxation. This is done by converting energy and electrical signals into mechanical motion. Pressure ranges from 0 – 100 mmHg

<p>Electrical Components</p>	<p>Battery pack or electrically powered Variable pressure points can be set independently for each cell (or air bladder) Patient could program individualized pressure settings or can select pre-program pressure settings depending on device Could contain a microprocessor controller in the air compressor Various sensors can be used to detect changes in air pressure by converting the pressure into a voltage</p>	<p>Patient can program individualized pressure settings or can select pre-program pressure settings The controller is used to start, pause, or stop treatment Programming to avoid backflow Electrical wiring to connect the controller to the appliance Rechargeable battery The controller contains or houses all the electrical circuitry. A microcontroller/chip is located in the middle of the appliance, which controls the function of the appliance</p>
<p>Function and Intended Use</p>	<p>To move excess fluid in a rhythmic, distal to proximal manner Uses air to inflate and deflate a segmental appliance Generates pressure through compression of air Intended to treat many conditions such as: Lymphedema, Primary lymphedema, Post mastectomy edema, Edema following trauma and sports injury, Post immobilization edema, Venous insufficiency, and Reducing wound healing time</p>	<p>To move excess fluid in a rhythmic, distal to proximal manner Uses flexible frames or flexframe actuators in a segmental appliance Generates pressure through physical tension of the appliance frame Intended to treat many conditions such as: Lymphedema, Primary lymphedema, Post mastectomy edema, Edema following trauma and sports injury, Post immobilization edema, Venous insufficiency, and Reducing wound healing time</p>
<p>Additional Aspects and Features</p>	<p>Lightweight (~ 6 lbs or more) Could contain a separate controller</p>	<p>Allows mobility Lightweight (~3 lbs) Quiet Has a phone application that can monitor the device or control the controller pressure settings</p>

The average 2022 fee schedule amount for K1024 would be \$6,307.85. Payment for the equipment would be made on a capped rental basis in accordance with 42 CFR §414.229.

Pricing = 36

Agenda Item # 14

Koya Dayspring® System – 21.070

Topic

Medicare Benefit Category and Payment Determination for Koya Dayspring® garment.

Temporary HCPCS code: K1025 “Non-pneumatic sequential compression garment, full arm.”

Applicant’s Summary

According to information submitted by Koya Medical, Inc., the Koya Dayspring® System is a device that employs sequential gradient non-pneumatic compression to treat and manage lymphedema. The Koya Dayspring® System moves excess fluid in a rhythmic, distal to proximal manner. The device contains biocompatible shape memory alloy actuators or flexframes to generate the compressive pressure instead of inflating and deflating air bladders. The compression garment moves excess fluid in a rhythmic, distal to proximal manner for the full arm. The compression garment is used with the controller to provide sequential gradient compression. The garment is ambidextrous and sized to measure and is made of biocompatible soft-goods, shape-memory alloy actuators, and plastics. The garment can consist up to 14 segments depending on limb size.

Final CMS HCPCS Coding Action

Established new HCPCS Level II code K1025 effective October 1, 2021, “Non-pneumatic sequential compression garment, full arm.”

Requested Benefit Category

Durable Medical Equipment – section 1861(s)(6) of the Social Security Act

Preliminary Benefit Category Determination

Durable Medical Equipment

The preliminary determination is that the Koya Dayspring® System meets the definition of durable medical equipment (DME) found in 42 Code of Federal Regulations (CFR) 414.202. Section 110.3 of the Medical Benefit Policy Manual (CMS Pub. 100-03) indicates that payment may be made for replacement of essential accessories such as hoses, tubes, mouthpieces, etc., for necessary DME, only if the beneficiary owns or is purchasing the equipment.

Preliminary Medicare Payment Determination

In accordance with Medicare regulations at 42 CFR § 414.238 regarding establishing fee schedule amounts for new HCPCS codes for items and services without a fee schedule pricing history, the fee schedule amounts for HCPCS code K1025 for supplies non-pneumatic pumps described by HCPCS code K1024 would be established using the existing fee

schedule amounts for comparable items under code E0668. We believe that a non-pneumatic system such as the Koya Dayspring® System as a whole (controller and garment accessory) is comparable to existing pneumatic systems as a whole (pump and garment accessory).

The average 2022 fee schedule amount for K1025 would be \$512.49. Payment for the garment accessory would be made on a capped rental basis in accordance with 42 CFR §414.229.

Pricing = 36

Agenda Item # 14

Koya Dayspring® Lite - HCP210903LPG21

Topic

Medicare Benefit Category and Payment Determination for Koya Dayspring® Lite System.

Temporary HCPCS code: K1031 “Non-pneumatic compression controller without calibrated gradient pressure.”

Applicant’s Summary

According to information submitted by Koya Medical, Inc., the Koya Dayspring® Lite is a device that employs non-calibrated, non-pneumatic compression to treat and manage lymphedema. The Koya Dayspring® System moves excess fluid in a rhythmic, distal to proximal manner. The device contains biocompatible shape memory alloy actuators or flexframes to generate pressure instead of inflating and deflating air bladders. The controller is the power source and logical control for the segmental the Koya Dayspring® Lite. The controller can be used to start, pause or stop a treatment session at any time. The Koya Dayspring® System also provides a companion phone application as an alternative method to program the controller.

Final CMS HCPCS Coding Action

Established new HCPCS Level II code K1031 effective April 1, 2022, “Non-pneumatic compression controller without calibrated gradient pressure.”

Requested Benefit Category

Durable Medical Equipment – section 1861(s)(6) of the Social Security Act

Preliminary Benefit Category Determination

Durable Medical Equipment

Durable medical equipment (DME) is defined in Medicare regulations at title 42 Code of Federal Regulations (CFR) 414.202, and means equipment, furnished by a supplier or a home health agency that meets the following conditions:

- (1) Can withstand repeated use.
- (2) Effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years.
- (3) Is primarily and customarily used to serve a medical purpose.
- (4) Generally is not useful to an individual in the absence of an illness or injury.
- (5) Is appropriate for use in the home.

All five of these conditions must be met in order for equipment to be classified as DME.

The information for the Koya Dayspring® Lite reviewed extensively and supports the preliminary durable medical equipment benefit category determination.

Preliminary Medicare Payment Determination

In accordance with regulations at 42 CFR § 414.238(b), fee schedule amounts for new HCPCS codes for items and services without a fee schedule pricing history are established using existing fee schedule amounts for comparable items when items with existing fee schedule amounts are determined to be comparable to the new items and services based on a comparison of: physical components; mechanical components; electrical components; function and intended use; and additional attributes and features. The preliminary payment determination for code K1031, for this particular lymphedema treatment equipment and accessories, is that this item should be priced using the existing fee schedule amounts for comparable items described by HCPCS code E0651.

The Koya Dayspring® Lite consists of a segmental non-calibrated gradient compression device that provides compression comparable to existing pneumatic pump (E0651) and garments (e.g., E0668) through segments that contract and relax flexible frames in a appliance without the use of air. The clinical conditions and indications for use for the Koya Dayspring® Lite are the same to those under codes for the non-calibrated pneumatic pump E0651 and related garment accessory (e.g., E0668). We believe that a non-pneumatic system such as the Koya Dayspring® Lite as a whole (controller and garment accessory) is comparable to existing pneumatic systems as a whole (pump and garment accessory).

	Pneumatic Compression	Koya Dayspring® Lite
Physical Components	Air compressor Segmented appliance	Controller Segmented appliance
Mechanical Components	The segmental appliance contains air bladders in select number of chambers Pressure ranges from 0 – 100 mmHg Tubing to connect pump to appliance (used for air flow) Appliance can contain solenoid valves (usually the pump/compressor is connected to a manifold, which moves air to each cell by a dedicated solenoid valve) An air pump that compresses air that flows out the output port	The segmented appliance contains actuators (up to 14 segments) The actuators are the component that drives, or allows, movement – in this case compression and relaxation. This is done by converting energy and electrical signals into mechanical motion. Pressure ranges from 0 – 100 mmHg
Electrical Components	Battery pack or electrically powered	Patient can program individualized pressure settings or can select pre-program pressure settings

	<p>Variable pressure points can be set independently for each cell (or air bladder)</p> <p>Patient could program individualized pressure settings or can select pre-program pressure settings depending on device</p> <p>Could contain a microprocessor controller in the air compressor</p> <p>Various sensors can be used to detect changes in air pressure by converting the pressure into a voltage</p>	<p>The controller is used to start, pause, or stop treatment</p> <p>Programming to avoid backflow</p> <p>Electrical wiring to connect the controller to the appliance</p> <p>Rechargeable battery</p> <p>The controller contains or houses all the electrical circuitry.</p> <p>A microcontroller/chip is located in the middle of the appliance, which controls the function of the appliance</p>
Function and Intended Use	<p>To move excess fluid in a rhythmic, distal to proximal manner</p> <p>Uses air to inflate and deflate a segmental appliance</p> <p>Generates pressure through compression of air</p> <p>Intended to treat many conditions such as: Lymphedema, Primary lymphedema, Post mastectomy edema, Edema following trauma and sports injury, Post immobilization edema, Venous insufficiency, and Reducing wound healing time</p>	<p>To move excess fluid in a rhythmic, distal to proximal manner</p> <p>Uses flexible frames or flexframe actuators in a segmental appliance</p> <p>Generates pressure through physical tension of the appliance frame</p> <p>Intended to treat many conditions such as: Lymphedema, Primary lymphedema, Post mastectomy edema, Edema following trauma and sports injury, Post immobilization edema, Venous insufficiency, and Reducing wound healing time</p>
Additional Aspects and Features	<p>Lightweight (~ 6 lbs or more)</p> <p>Could contain a separate controller</p>	<p>Allows mobility</p> <p>Lightweight (~3 lbs)</p> <p>Quiet</p> <p>Has a phone application that can monitor the device or control the controller pressure settings</p>

The average 2022 fee schedule amount for K1031 would be \$1,063.24. Payment for the equipment would be made on a capped rental basis in accordance with 42 CFR §414.229.

Pricing = 36

Agenda Item # 14

Koya Dayspring® - HCP210903PMKF3

Topic

Medicare Benefit Category and Payment Determination for Koya Dayspring® garment.

Temporary HCPCS code: K1032 “Non-pneumatic sequential compression garment, full leg.”

Applicant’s Summary

According to information submitted by Koya Medical, Inc., the Koya Dayspring® System is a device that employs sequential gradient non-pneumatic compression to treat and manage lymphedema. The Koya Dayspring® System moves excess fluid in a rhythmic, distal to proximal manner. The device contains biocompatible shape memory alloy actuators or flexframes to generate the compressive pressure instead of inflating and deflating air bladders. The compression garment moves excess fluid in a rhythmic, distal to proximal manner for the full arm. The compression garment is used with the controller to provide sequential gradient compression. The garment is ambidextrous and sized to measure and is made of biocompatible soft-goods, shape-memory alloy actuators, and plastics. The garment can consist up to 14 segments depending on limb size.

Final CMS HCPCS Coding Action

Established new HCPCS Level II code K1032 effective April 1, 2022, “Non-pneumatic sequential compression garment, full leg.”

Requested Benefit Category

Durable Medical Equipment – section 1861(s)(6) of the Social Security Act

Preliminary Benefit Category Determination

Durable Medical Equipment

The preliminary determination is that the Koya Dayspring® System meets the definition of durable medical equipment (DME) found in 42 Code of Federal Regulations (CFR) 414.202. Section 110.3 of the Medical Benefit Policy Manual (CMS Pub. 100-03) indicates that payment may be made for replacement of essential accessories such as hoses, tubes, mouthpieces, etc., for necessary DME, only if the beneficiary owns or is purchasing the equipment.

Preliminary Medicare Payment Determination

In accordance with Medicare regulations at 42 CFR § 414.238 regarding establishing fee schedule amounts for new HCPCS codes for items and services without a fee schedule pricing history, the fee schedule amounts for HCPCS code K1032 for supplies non-pneumatic pumps described by HCPCS code K1031 or K1024 would be established using the existing fee schedule amounts for comparable items under code E0667. We believe that a non-

pneumatic system such as the Koya Dayspring® System as a whole (controller and garment accessory) is comparable to existing pneumatic systems as a whole (pump and garment accessory).

The average 2022 fee schedule amount for K1032 would be \$397.13. Payment for the garment accessory would be made on a capped rental basis in accordance with 42 CFR §414.229.

Pricing = 36

Agenda Item # 14

Koya Dayspring® - HCP210903WBEG8

Topic

Medicare Benefit Category and Payment Determination for Koya Dayspring® garment.

Temporary HCPCS code: K1033 “Non-pneumatic sequential compression garment, half leg.”

Applicant’s Summary

According to information submitted by Koya Medical, Inc., the Koya Dayspring® System is a device that employs sequential gradient non-pneumatic compression to treat and manage lymphedema. The Koya Dayspring® System moves excess fluid in a rhythmic, distal to proximal manner. The device contains biocompatible shape memory alloy actuators or flexframes to generate the compressive pressure instead of inflating and deflating air bladders. The compression garment moves excess fluid in a rhythmic, distal to proximal manner for the full arm. The compression garment is used with the controller to provide sequential gradient compression. The garment is ambidextrous and sized to measure and is made of biocompatible soft-goods, shape-memory alloy actuators, and plastics. The garment can consist up to 14 segments depending on limb size.

Final CMS HCPCS Coding Action

Established new HCPCS Level II code K1033 effective April 1, 2022, “Non-pneumatic sequential compression garment, half leg.”

Requested Benefit Category

Durable Medical Equipment – section 1861(s)(6) of the Social Security Act

Preliminary Benefit Category Determination

Durable Medical Equipment

The preliminary determination is that the Koya Dayspring® System meets the definition of durable medical equipment (DME) found in 42 Code of Federal Regulations (CFR) 414.202. Section 110.3 of the Medical Benefit Policy Manual (CMS Pub. 100-03) indicates that payment may be made for replacement of essential accessories such as hoses, tubes, mouthpieces, etc., for necessary DME, only if the beneficiary owns or is purchasing the equipment.

Preliminary Medicare Payment Determination

In accordance with Medicare regulations at 42 CFR § 414.238 regarding establishing fee schedule amounts for new HCPCS codes for items and services without a fee schedule pricing history, the fee schedule amounts for HCPCS code K1033 for supplies non-pneumatic pumps described by HCPCS code K1031 or K1024 would be established using the existing fee schedule amounts for comparable items under code E0669. We believe that a non-

pneumatic system such as the Koya Dayspring® System as a whole (controller and garment accessory) is comparable to existing pneumatic systems as a whole (pump and garment accessory).

The average 2022 fee schedule amount for K1033 would be \$221.93. Payment for the garment accessory would be made on a capped rental basis in accordance with 42 CFR §414.229.

Pricing = 36

Appendix: DMEPOS Payment Categories

The Social Security Act separates DMEPOS into different Medicare payment categories, each with its own unique payment rules. The pricing indicator codes in the HCPCS identify which major payment category a HCPCS code falls under. The pricing indicator codes applicable to DMEPOS.

Pricing = 00 Service Not Separately Priced

Items or services described by the HCPCS codes that are either not covered under Medicare Part B or for which payment is bundled into the payment some other Medicare service or procedure.

Pricing = 31 Frequently Serviced Items

Payment is generally made on a monthly rental fee schedule basis for items such as ventilators that require frequent and substantial servicing in order to avoid risk to the patient's health. Payment for E0935 is based on a daily rental fee schedule basis since coverage of this device is limited to 21 days.

Pricing = 32 Inexpensive and Other Routinely Purchased Items

Payment is made on a purchase or rental fee schedule basis. This category includes items that have a purchase price of \$150 or less, were purchased 75 percent of the time or more from July 1986 through June 1987, or which are accessories used in conjunction with a nebulizer, aspirator, continuous airway pressure device, or respiratory assist device. The beneficiary has the option to acquire the item on a purchase or monthly rental basis. Total payments for the item cannot exceed the purchase fee schedule amount for the item.

Pricing = 33 Oxygen and Oxygen Equipment

Monthly fee schedule payments are made for furnishing oxygen and oxygen equipment. This monthly payment includes payment for all stationary oxygen equipment, supplies, and accessories and delivery of oxygen contents (stationary and portable). A monthly add-on to this payment is made for portable oxygen equipment only for those beneficiaries who require portable oxygen. The monthly payments for oxygen equipment cap after the 36th monthly payment is made, after which payment for the ongoing delivery of contents continues for gaseous or liquid systems.

Pricing = 34 Supplies Necessary for the Effective Use of DME

Payment is made on a purchase fee schedule basis for supplies necessary for the effective use of DME (e.g., lancets that draw blood for use in blood glucose monitor).

Pricing = 35 Surgical Dressings

Payment is made on a purchase fee schedule basis for surgical dressings.

Pricing = 36 Capped Rental Items

Payment is made on a monthly rental fee schedule basis. The beneficiary takes over ownership of the item after the 13th rental payment is made. The rental fee for capped rental items, other than power wheelchairs, for each of the first 3 months of rental is equal to 10 percent of the purchase fee for the item. The rental fee for months 4 through 13 is equal to 7.5 percent of the purchase fee for the item. The rental fee for power wheelchairs for each of the first 3 months of rental is equal to 15 percent of the purchase fee for the item. The rental fee for power wheelchairs for months 4 through 13 is equal to 6 percent of the purchase fee for the item. Complex rehabilitative power wheelchairs can also be purchased in the first month.

Pricing = 37 Ostomy, Tracheostomy and Urological Supplies

Payment is made on a purchase fee schedule basis for ostomy, tracheostomy and urological supplies.

Pricing = 38 Orthotics, Prosthetics, Prosthetic Devices, and Vision Services (Prosthetic Lenses)

Payment is made on a purchase fee schedule basis for orthotics, prosthetics, and prosthetic devices & lenses.

Pricing = 39 Parenteral and Enteral Nutrition (PEN)

Payment is made on a purchase fee schedule basis for parenteral and enteral nutrients and supplies. Payment is made on a purchase or rental fee schedule basis for parenteral and enteral equipment. The beneficiary has the option to acquire the item on a purchase or monthly rental basis.

Pricing = 45 Customized DME

Payment is made for lump-sum purchase of DME that meets the Medicare regulatory definition of customized DME at 42 CFR 414.224. The payment amount is based on the carrier's individual consideration of the item and judgment of a reasonable payment amount, which, at a minimum, includes a review of the costs of labor and material used in constructing the equipment.

Pricing = 46 Carrier Priced Item

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