DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard,
Baltimore, Maryland 21244-1850

Centers for Medicare & Medicaid Services' (CMS') Healthcare Common Procedure Coding System (HCPCS) Level II Final Coding, Benefit Category and Payment Determinations

First Biannual (B1), 2022 HCPCS Coding Cycle

This document presents final Medicare benefit category and payment determinations for non-drug and non-biological items assigned a new HCPCS Level II code effective January 1, 2020 to April 1, 2022 and final coding, benefit category and payment determinations for HCPCS Level II applications processed in CMS' B1 2022 coding cycle for non-drug and non-biological items and services. Preliminary coding, benefit category and/or payment determinations for the items presented in the application summaries below were discussed at the HCPCS public meeting on June 7-10, 2022.

In accordance with the procedures at 42 CFR §414.240 and §414.114, final Medicare Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) benefit category and payment determinations are listed below, if applicable. These procedures follow HCPCS determinations and payment determinations for new DME under Medicare Part B following public consultation held through public meetings in accordance with section 531(b) of the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub L. 106-554). CMS started using these public meetings and procedures for HCPCS Level II code requests for items and services other than DME in 2005. The procedures for making Medicare benefit category and payment determinations for new DMEPOS items and services using the BIPA 531(b) public meeting process were promulgated through regulations. The final rule (86 FR 73902) is available at https://www.cms.gov/medicare/medicare-fee-for-service-payment/dmeposfeesched.

Whether or not an item or service falls under a Medicare benefit category, such as the Medicare Part B benefit category for DME, is a necessary step in determining whether an item may be covered under the Medicare program and, if applicable, what statutory and regulatory payment rules apply to the items and services. If the item is excluded from coverage by the Social Security Act or does not fall within the scope of a defined benefit category, the item cannot be covered under Medicare Part B. When the item is not excluded from coverage by statute and is found to fall within a benefit category, CMS needs to determine what payment rules apply to the item if other statutory criteria for coverage of the item are met. DMEPOS payment categories with corresponding HCPCS pricing indicator codes are included in the Appendix.

All new coding actions will be effective October 1, 2022, unless otherwise indicated.

The HCPCS coding decisions below will also be included in the October 2022 HCPCS Quarterly Update, pending publication by CMS in the coming weeks at: https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update

For inquiries regarding coverage, please contact the insurer(s) in whose jurisdiction(s) claim(s) would be filed. Specifically, contact the Medicaid agency in the state in which a Medicaid claim is filed, the individual private insurance entity, the Department of Veterans Affairs, or, for local Medicare coverage determinations, contact the Medicare contractor in the jurisdiction the claim would be filed. For detailed information describing CMS' national coverage determination process, refer to information published at https://www.cms.gov/Medicare/Coverage/DeterminationProcess and https://www.cms.gov/Center/Special-Topic/Medicare-Coverage-Center

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Final decisions for items discussed at the HCPCS Virtual Public Meeting on June 7-10, 2022.

June 7, 2022 Meeting Agenda Items

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(n) of the Social Security Act.

Preliminary Medicare Benefit Category Determination

No benefit category.

Durable medical equipment (DME) is defined in section 1861(n) of the Social Security Act and 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. 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

Summary of Public Feedback

Philips Respironics, Inc., the manufacturer of the NightBalance product disagreed with the preliminary benefit category determination, stating that the NightBalance is an FDA-cleared, clinically-validated, prescription-only treatment for POSA and is not indicated for snoring. The manufacturer said that the "Sleep Position Trainer versus Tennis Ball Technique in Positional Obstructive Sleep Apnea" study (2015) demonstrated that the NightBalance is more effective in the long term in treating POSA than the tennis ball technique (TBT) and has better compliance than auto-adjusting positive airway pressure (APAP) devices in treating POSA. The manufacturer added that the devices used to move and keep sleeping people out of the supine position to prevent snoring are over the counter (OTC) devices, whereas the NightBalance is a prescription-only device.

Final Medicare Benefit Category Determination

Durable Medical Equipment

We agree with the public comments and consider the NightBalance item to be distinct from other anti-snoring devices principally on the basis that the FDA clearance expressly states it is for the treatment of positional obstructive sleep apnea and is not clinically indicated or

marketed for anti-snoring. We believe this device is primarily and customarily used for the treatment of POSA and generally is not useful to an individual in the absence of an illness or injury.

Final Medicare Payment Determination

No determination. The payment determination for this item will be addressed at a subsequent HCPCS public meeting.

At this time, the DME fee schedule amounts for this item would be established by the DME MACs pending a payment determination established in accordance with the procedures at 42 CFR §414.240. If the purchase price used in calculating the fee schedule amounts is greater than $150, then payment would be made on a capped rental basis in accordance with our regulations at 42 CFR 414.229. If the purchase price used in calculating the fee schedule amounts is $150 or less, then payment would be made on a rental or purchase basis in accordance with our regulations at 42 CFR 414.220.

Pricing = 46

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(n) of the Social Security Act.

Preliminary Medicare Benefit Category Determination

No benefit category.

Durable medical equipment (DME) is defined in section 1861(n) of the Social Security Act and 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

Summary of Public Feedback

There were no public speakers or written comments on this item.

Final Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

Final Medicare Payment Determination

No Medicare DMEPOS 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(n) of the Social Security Act.

Preliminary Medicare Benefit Category Determination

No benefit category.

Durable medical equipment (DME) is defined in section 1861(n) of the Social Security Act and 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

Summary of Public Feedback

NanoVibronix, the manufacturer of the PainShield® device disagreed with the preliminary benefit category determination. The company indicated that the product, a "low frequency ultrasonic diathermy device for home use," was upgraded as of January 2021 with a new built-in rechargeable battery that can last for 500 cycles or 3 years. The company indicated that they have good manufacturing for the product process and a quality system that maintains these good processes, which leads them to believe the lifecycle of the device will be at least 3 years. The company indicated that "at the end of a patient's treatment regime, the PainShield® device could be returned to the patient's DME supplier. After cleaning and refurbishment (as needed), the DME supplier could furnish the same PainShield® device to another patient." The company indicated that the device was not cleared by the FDA as single patient use only (K081075) and that this was only guidance they provided on their website.

Final Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

Section 280.1 of chapter 1, part 4 of the Medicare National Coverage Determinations (NCD) Manual indicates that diathermy machines (standard pulses wave types) are not DME because they are inappropriate for home use. A consultant for NanoVibronix confirmed that the PainShield® device uses a continuous wave and not a pulsed wave during the active phase. Therefore, we do not believe the device falls under the existing NCD. However, the issue of whether the device has a lifetime of at least 3 years is still in question. The product manual for the device previously indicated that it had a lifetime of 2 years. Even if the battery used with the device was redesigned to have a longer lifetime, CMS has not yet been presented with evidence that the device itself would last for 3 years when used in conjunction with the new battery. Durability of an item should be tested over the entire system or device and not

just an individual component (e.g., battery). In general, the lifetime of the battery is dependent on the current being pulled from the whole device. This is why the lifetime of the battery itself cannot be used alone to justify the lifetime of a device. There are many ways to demonstrate lifetime durability to CMS. For example, the manufacturer can provide standardized test results from an independent testing laboratory demonstrating that the device itself can last for at least 3 years with the redesigned battery.

Final Medicare Payment Determination

No Medicare DMEPOS 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(n) of the Social Security Act.

Preliminary Medicare 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 section 1861(n) of the Social Security Act and 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

Summary of Public Feedback

There were no speakers at the public meeting for this item. Written comments were submitted indicating that the electric breast pumps (E0603) are DME items and so the bags should be covered as essential supplies for electric breast pumps classified as DME. However, electric breast pumps (E0603) are not classified as DME.

Final Medicare Benefit Category Determination

CMS is reaffirming its preliminary benefit category determination that there is no Medicare DMEPOS benefit category when used with electric breast pumps coverage of storage bags used with manual breast pumps would be based on contractor discretion.

Final 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(n) of the Social Security Act.

Preliminary Medicare Benefit Category Determination

Durable Medical Equipment.

Durable medical equipment (DME) is defined in section 1861(n) of the Social Security Act and 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

Summary of Public Feedback

Three manufacturers and the National Coalition for Assistive and Rehab Technology (NCART) provided comments that the dynamic back hardware is not comparable to the E1015 (shock absorber for manual wheelchair), indicating that the dynamic back hardware is not comparable in function, strength, or durability and handles a vastly different set of forces than shock absorbing devices described by HCPCS code E1015. Additional comments were provided by an occupational therapist familiar with the items who is also a consultant for several organizations and manufacturers, including Seating Dynamics, one of the three manufacturers of the item. The consultant provided written comments that items described by code E1015 are intended to provide suspension, which can reduce vibration and jarring from uneven terrain, but is different from dynamic seating, which is activated by client forces and then returns a client to a preferred starting position. All speakers asked us to delay a payment decision until they could provide a further analysis of the materials for CMS.

Final Medicare Benefit Category Determination

Durable Medical Equipment

Final Medicare Payment Determination

No determination with regard to the fee schedule calculations. We are delaying this item to allow consideration of additional material, if provided. In the meantime, payment for these items will be made at the discretion of the DME MACs. If the allowed amount determined by the DME MAC is more than $150, then payment for the item would need to be made on a capped rental basis.

Pricing = 46

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 Medicare 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
Physical Components						
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
Mechanical Components						
Swing phase		X	X			
Stance phase		X	X	X	X	
Fluid control			X	X		
Electrical Components						
Microprocessor		X				
3-axis accelerometer		X				
3-axis gyroscope		X				
Battery		X				
Function and Intended Use						
Knee-Ankle-Foot Orthosis (KAFO)	X					
Lower extremity device/component	X	X	X	X	X	X
Additional Aspects and Features						

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

Pricing = 38

Summary of Public Feedback

Comments were received from Ottobock, the manufacturer, and Hanger Inc., a supplier of braces, that the hours and work involved in fabricating the C-Brace®, including use of a test orthosis, is far more extensive than the work involved in fabricating items under the base brace code L2036. Ottobock suggested the addition of 128 units of the code L4205 (Repair of orthotic device, labor component, per 15 minutes) for labor/repair, codes L5620 and L5624 for prosthetic test sockets, and other codes (2 units each of L2220, L2390, and L2415) to the list of comparable items to account for the fabrication and use of a "test orthosis" to check alignment, volume, shapes, and lengths before fabrication of the final delivered C-Brace.

Ottobock also suggested removing codes L2036 and L2755 from the list of codes for comparable items and adding codes L2220, L2385, L5700, L5701, L5920, L5940, L5950, and L5976 to the list of comparable items to account for various features of the C-Brace®. Codes L5700, L5701, L5976, and L5920 would replace code L2036 and codes L5940 and L5950 would replace code L2755. Codes L2220 and L2385 would be added to describe additional features and components.

To reiterate, the preliminary payment determination for L2006 was to use fees for comparable items described by the following 6 codes:

L2036	L2755	L5828	L5845	L5848	L5856

Ottobock recommended using the fees for comparable items described by the following alternative list of 12 codes:

L2220	L2385	L5700	L5701	L5828*	L5845*
L5848*	L5856*	L5920	L5940	L5950	L5976

* in both lists

In addition, Ottobock recommended the addition of codes for labor (L4205 x 128) and the following 5 codes for a test orthosis to add payment for additional costs associated with fabricating and fitting the C-Brace® KAFO device:

L2220 x2	L2390 x2	L2415 x2	L5620	L5624

The following are the descriptors for the additional codes requested by Ottobock:

- L2220, addition to lower extremity, dorsiflexion and plantar flexion assist/resist, each joint
- L2385, addition to lower extremity, straight knee joint, heavy duty, each joint;
- L2390, addition to lower extremity, offset knee joint, each joint;
- L2415, addition to knee lock with integrated release mechanism (bail, cable, or equal), any material, each joint;
- L5620, addition to lower extremity, test socket, below knee;
- L5624, addition to lower extremity, test socket, above knee;
- L5700, replacement, socket, below knee, molded to patient model;
- L5701, replacement, socket, above knee/knee disarticulation, including attachment plate, molded to patient model;
- L5920, addition, endoskeletal system, above knee or hip disarticulation, alignable system;
- L5940, addition, endoskeletal system, below knee, ultra-light material (titanium, carbon fiber or equal);
- L5950, addition, endoskeletal system, above knee, ultra-light material (titanium, carbon fiber or equal);
- L5976, all lower extremity prostheses, energy storing foot (seattle carbon copy ii or equal).

Final Medicare Benefit Category Determination

Leg brace (Orthotic).

Final Medicare Payment Determination

The fee schedule amounts for HCPCS code L2006 will be established using the fee schedule amounts for comparable items made up by HCPCS codes L2036, L5828, L5856, L5848, L5845, and L2755 in accordance with the preliminary payment determination, with the addition of code L2385 and two units of L2220 as requested by the manufacturer in the public comments. Code L2385 for heavy duty knee joint is added as part of the final determination to recognize the need for the knee joint to accommodate the extra weight of the microprocessor and joint located on the opposite side of the brace. Although the additional ankle joint features described by L2220 do not come on all versions of the C-Brace®, they are present on a majority of the C-Brace® devices in use and are therefore added to the final determination. The revised list of codes for comparable items is as follows:

L2036	L2755	L5828	L5845	L5848	L5856

plus

L2220 x2	L2385

We do not agree that the alternative combination of codes recommended by Ottobock are accurate and are not adding codes L5700, L5701, L5920, L5940, L5950, and L5976 to the list of comparable items. HCPCS code L5700, AK replacement socket, and L5701, BK replacement socket, are intended to describe a replacement above and below knee portion of a prosthetic limb when the residual limb no longer fits into the prosthetic socket. They are not intended to describe features of a KAFO. HCPCS code L5920, alignable system, is included in the custom fabrication of the brace and would be duplicative. HCPCS code L5940, BK ultralight material, and L5950, AK ultralight material, are not applicable to the C-Brace® as the material used is best described by L2755, addition to lower extremity orthosis, high strength, lightweight material, all hybrid lamination/prepreg composite, per segment, for custom fabricated orthosis only. L5940 and L5950 do not describe features of a KAFO. HCPCS code L5976, energy storing foot, is not applicable to the C-Brace®. As indicated by the manufacturer, most C-Brace® devices have a foot plate and ankle joints. L5976 is a prosthetic foot and would be duplicative because code L5976 describes a whole prosthetic foot and the C-Brace® only has a brace foot plate that is accounted for in the base KAFO code L2036.

In addition, we are not adding additional codes for labor to represent additional costs associated with fabricating the C-Brace® KAFO versus KAFOs furnished today that are described by code L2036. We are also not adding additional codes for the components of a test orthosis. The statute mandates calculation of fee schedule amounts for all braces furnished to Medicare beneficiaries based on average reasonable charges for braces furnished from July 1986 through June 1987, increased by annual covered item update factors. The cost of fabricating KAFOs in 1986 and 1987 is built into the fee schedule amount and payment for KAFO code L2036, which is inclusive of payment for all costs, including all labor costs associated with fabrication involved in furnishing KAFO devices in 1986 and 1987. If the fee schedule amounts for braces become grossly excessive or grossly deficient over time (e.g., due to increases or decreases in the cost of evaluation, fitting, and fabrication), the statute at section 1842(b)(8) and (9) of the Social Security Act provides a specific process to adjust the fee schedule amounts to reflect the decrease or increase in the cost of furnishing braces today versus furnishing braces in 1986/87. It is possible that the time and costs associated with fabricating and fitting KAFOs described by code L2036 may have been significantly greater in 1986 than 2022 and could be an accurate reflection of the

time and costs associated with fabricating and fitting a C-Brace® KAFO and not an accurate reflection of the time and costs associated with fabricating and fitting KAFOs today that are described by code L2036. Adjusting the fee schedule amounts based on average reasonable charges from 1986 and 1987 to accurately reflect the costs of fabricating and furnishing KAFO products today would need to be performed using the authority and process under section 1842(b)(8) and (9) of the Social Security Act.

Payment will be made on a lump sum purchase basis for any covered claims.

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 Medicare Benefit Category

Durable Medical Equipment – section 1861(n) of the Social Security Act.

Preliminary Benefit Category Determination

No benefit category.

Durable medical equipment (DME) is defined in section 1861(n) of the Social Security Act and 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 study[1] 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

Summary of Public Feedback

Becton, Dickinson and Company (BD), the manufacturer of the PureWick™ System, indicated that the product has been used in both the home and clinical settings, has been marketed for use in the home, and data related to use in the home is forthcoming.

Final Medicare Benefit Category Determination

Durable Medical Equipment.

Third party user survey detailed in the public meeting presentation states that the average age of the study population is Medicare age. The study data is still pending publication, but in combination with sales information provided at the public meeting, this would suggest that the device is appropriate for use in the home.

Final Medicare Payment Determination

No determination. The payment determination for this item will be addressed at a subsequent HCPCS public meeting. In the meantime, the payment amounts for any covered claims for these items will be determined by the DME MACs.

[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

If the allowed amount determined by the DME MAC is more than $150, then payment for the item would need to be made on a capped rental basis.

Pricing = 46

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(n) of the Social Security Act.

Preliminary Medicare Benefit Category Determination

Durable Medical Equipment.

Durable medical equipment (DME) is defined in section 1861(n) of the Social Security Act and 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 article[2] 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 $1,935.52 over 13 months.

Pricing = 36

Summary of Public Feedback

SpeechVive, Inc., the manufacturer of the device, agreed with the benefit category determination of DME but indicated that the telehealth platform, software, and hardware updates increased costs and the price for the device changed to $3,495 in 2019, which is also the current list price. The telehealth platform allows the device to be shipped to the patient's home and the device programmed through a video conferencing telehealth platform reducing travel to a medical facility for in-person programming. As a result of this investment, including firmware updates and regular software updates, as well as changes to the battery life of the device, the manufacturer recommends that the current list price of $3,495 be used as the pricing source.

Final Medicare Benefit Category Determination

Durable Medical Equipment.

Final Medicare Payment Determination

We believe more time is needed to evaluate the pricing for this item. The regulations at 42 CFR 414.238(c) indicate that verifiable information from supplier invoices and non-Medicare payer data may be used to establish fee schedule amounts for new items. In the interim, the fee schedule amounts for this item will be developed by the contractors based on their individual consideration of each claim.

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 Medicare 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

Summary of Public Feedback

There were no speakers at the public meeting and no written consultation was received for this item.

Final Medicare Benefit Category Determination

Prosthetic Device.

Final Medicare Payment Determination

The fee schedule amounts for HCPCS code V2524 will be established using existing fee schedule amounts for comparable items described by HCPCS codes V2520 and V2744, resulting in an average 2022 fee schedule amount of approximately $147.

Payment will be made on a lump sum purchase basis for any covered claims.

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(n) of the Social Security Act.

Preliminary Medicare Benefit Category Determination

No benefit category.

Durable medical equipment (DME) is defined in section 1861(n) of the Social Security Act and 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

Summary of Public Feedback

There were no speakers at the public meeting and no written consultation was received for this item.

Final Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

Final Medicare Payment Determination

No Medicare DMEPOS 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 Medicare 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
Physical Components				
4-Bar linkage	X			
High activity frame			X	X
Mechanical Components				
Swing phase	X	X	X	
Stance phase		X		
Fluid control	X	X	X	
Electrical Components				
Function and Intended Use				
Endoskeletal knee shin system	X	X	X	X
Lower extremity device/component	X	X	X	X
Additional Aspects and Features				

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

Summary of Public Feedback

Proteor USA, the manufacturer of the ALLUX™, agreed with the preliminary benefit category and payment determinations.

Final Medicare Benefit Category Determination

Prosthetic (Artificial Leg).

Final Medicare Payment Determination

The fee schedule amounts for HCPCS code K1014 will be established using the fee schedule amounts for comparable items (HCPCS codes) represented by the following formula: L5613 + ((L5828 – L5826) + L5930), resulting in an average 2022 fee schedule amount of approximately $6,463.27.

Payment will be made on a lump sum purchase basis for any covered claims.

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 Medicare 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

Summary of Public Feedback

There were no speakers at the public meeting and no written consultation was received for this item.

Final Medicare Benefit Category Determination

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.

Final 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.

Payment will be made on a lump sum purchase basis for any covered claims.

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 Medicare 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

Summary of Public Feedback

Ottobock, the manufacturer of the Rotation Adapter 4R57, agreed with the preliminary benefit category and payment determinations. Proteor USA, a different manufacturer, felt the fee schedule amounts should be higher, indicating that the rotation adaptor described by code K1022 is more complicated to develop than other rotation adaptors under code L5984.

Final Medicare Benefit Category Determination

Prosthetic (Artificial Leg).

Final Medicare Payment Determination

The fee schedule amounts for HCPCS code L5984 will be crosswalked to HCPCS code K1022, resulting in an average 2022 fee schedule amount of $676.08. In response to the comments from Proteor USA, this item has a history of pricing under code L5984; and therefore, the fee schedule amounts used to pay for the item under code L5984 must be mapped to the new code K1022 in accordance with the continuity of pricing rules at 42 CFR 414.236.

Payment will be made on a lump sum purchase basis for any covered claims.

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(n) of the Social Security Act.

Preliminary Medicare Benefit Category Determination

Durable Medical Equipment.

Durable medical equipment (DME) is defined in section 1861(n) of the Social Security Act and 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

	Pneumatic Compression	Koya Dayspring® System
Electrical Components	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	Patient can program individualized pressure settings or can select pre-program pressure settings The controller is used to start, pause, or stop treatment Programing 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
Function and Intended Use	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	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
Additional Aspects and Features	Lightweight (~ 6 lbs or more) Could contain a separate controller	Allows mobility Lightweight (~3 lbs) Quiet Has a phone application that can monitor the device or control the controller pressure settings

The average 2022 purchase fee schedule amount for E0652 is approximately $6,307.85. Payment for the equipment described by code K1024 would be made on a capped rental basis in accordance with 42 CFR §414.229, with the rental fee schedule amount for months 1 through 3 equal to 10 percent of the purchase price, or approximately $630.78, and the rental fee schedule amount for months 4 through 13 equal to 7.5 percent of the purchase price, or approximately $473.09.

Pricing = 36

Summary of Public Feedback

Koya Medical, Inc., the manufacturer of the device, agreed with the benefit category determination of DME and payment determination.

Final Medicare Benefit Category Determination

Durable Medical Equipment.

Final Medicare Payment Determination

The fee schedule amounts for HCPCS code K1024 will be established using the fee schedule amounts for HCPCS code E0652, with the average rental fee schedule amount for months 1 through 3 being approximately $630.78, and the average rental fee schedule amount for months 4 through 13 being approximately $473.09.

Payment will be made on a capped rental basis for any covered claims.

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(n) of the Social Security Act.

Preliminary Medicare 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 purchase fee schedule amount for E0668 is approximately $512.49. Payment for the garment accessory described by code K1025 would be made on a capped rental basis in accordance with 42 CFR §414.229, with the rental fee schedule amount for months 1 through 3 equal to 10 percent of the purchase price, or approximately $51.25, and the rental fee schedule amount for months 4 through 13 equal to 7.5 percent of the purchase price, or approximately $38.44.

Pricing = 36

Summary of Public Feedback

Koya Medical, Inc., the manufacturer of the device, agreed with the benefit category determination of DME and payment determination.

Final Medicare Benefit Category Determination

Durable Medical Equipment.

Final Medicare Payment Determination

The fee schedule amounts for HCPCS code K1025 will be established using the fee schedule amounts for HCPCS code E0668, with the rental fee schedule amount for months 1 through 3 being approximately $51.25, and the rental fee schedule amount for months 4 through 13 being approximately $38.44.

Payment will be made on a capped rental basis for any covered claims.

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(n) of the Social Security Act.

Preliminary Medicare Benefit Category Determination

Durable Medical Equipment.

Durable medical equipment (DME) is defined in section 1861(n) of the Social Security Act and 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

	Pneumatic Compression	Koya Dayspring® Lite
Electrical Components	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	Patient can program individualized pressure settings or can select pre-program pressure settings The controller is used to start, pause, or stop treatment Programing 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
Function and Intended Use	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	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
Additional Aspects and Features	Lightweight (~ 6 lbs or more) Could contain a separate controller	Allows mobility Lightweight (~3 lbs) Quiet Has a phone application that can monitor the device or control the controller pressure settings

The average 2022 purchase fee schedule amount for E0651 is $1,063.24. Payment for the equipment described by code K1031 would be made on a capped rental basis in accordance with 42 CFR §414.229, with the rental fee schedule amount for months 1 through 3 equal to 10 percent of the purchase price, or approximately $106.32, and the rental fee schedule amount for months 4 through 13 equal to 7.5 percent of the purchase price, or approximately $79.74.

Pricing = 36

Summary of Public Feedback

Koya Medical, Inc., the manufacturer of the device, agreed with the benefit category determination of DME and payment determination.

Final Medicare Benefit Category Determination

Durable Medical Equipment.

Final Medicare Payment Determination

The fee schedule amounts for HCPCS code K1031 will be established using the fee schedule amounts for HCPCS code E0651, with the rental fee schedule amount for months 1 through 3 being approximately $106.32, and the rental fee schedule amount for months 4 through 13 being approximately $79.74.

Payment will be made on a capped rental basis for any covered claims.

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(n) of the Social Security Act

Preliminary Medicare 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 purchase fee schedule amount for E0667 is $397.13. Payment for the garment accessory described by code K1032 would be made on a capped rental basis in accordance with 42 CFR §414.229, with the rental fee schedule amount for months 1 through 3 equal to 10 percent of the purchase price, or approximately $39.71, and the rental fee schedule amount for months 4 through 13 equal to 7.5 percent of the purchase price, or approximately $29.78.

Pricing = 36

Summary of Public Feedback

Koya Medical, Inc., the manufacturer of the device, agreed with the benefit category determination of DME and payment determination.

Final Medicare Benefit Category Determination

Durable Medical Equipment.

Final Medicare Payment Determination

The fee schedule amounts for HCPCS code K1032 will be established using the fee schedule amounts for HCPCS code E0667, with the rental fee schedule amount for months 1 through 3 being approximately $39.71, and the rental fee schedule amount for months 4 through 13 being approximately $29.78.

Payment will be made on a capped rental basis for any covered claims.

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(n) of the Social Security Act.

Preliminary Medicare 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 purchase fee schedule amount for E0669 is $221.93. Payment for the garment accessory described by code K1033 would be made on a capped rental basis in accordance with 42 CFR §414.229, with the rental fee schedule amount for months 1 through 3 equal to 10 percent of the purchase price, or approximately $22.19, and the rental fee schedule amount for months 4 through 13 equal to 7.5 percent of the purchase price, or approximately $16.64.

Pricing = 36

Summary of Public Feedback

Koya Medical, Inc., the manufacturer of the device, agreed with the benefit category determination of DME and payment determination.

Final Medicare Benefit Category Determination

Durable Medical Equipment.

Final Medicare Payment Determination

The fee schedule amounts for HCPCS code K1033 will be established using the fee schedule amounts for HCPCS code E0669, with the rental fee schedule amount for months 1 through 3 being approximately $22.19, and the rental fee schedule amount for months 4 through 13 being approximately $16.64.

Payment will be made on a capped rental basis for any covered claims.

Pricing = 36

June 8, 2022 Meeting Agenda Items

Agenda Item # 1

Alpha-Stim® Cranial Electrotherapy Stimulation – 19.117

Topic

Medicare Benefit Category and Payment Determination for Alpha-Stim® Cranial Electrotherapy Stimulation.

Temporary HCPCS code: K1002 "Cranial electrotherapy stimulation (ces) system, includes all supplies and accessories, any type"

Applicant's Summary

According to information submitted by Electromedical Products International, Inc., the Alpha-Stim® Cranial Electrotherapy Stimulation (CES) device utilizes a microcurrent to deliver proprietary low-level electrical signals and applied trans cranially. The device is intended to treat insomnia, depression, anxiety, and pain. The device consists of an electric pulse generator operated with two AAA batteries, and patient connect hardware which consist of ear clip electrodes and an electro conductive solution for moistening the electrodes to assure good electrical contract through the skin. The device transmits the waveform through small clips attached to the ear lobes sending a microcurrent through the brain, modulating specific groups of nerve cells. The Alpha-Stim® CES has a pulsed, rectangular wave form and frequency range up to 100 Hz. The Alpha-Stim® CES device may be used as an adjunct or replacement to medication and/or physiotherapy. The stimulator lasts 5-years, ear clips 1-year, conducting solution 1 month, and the ear clip electrode pads are one-time use.

Final CMS HCPCS Coding Action

Established new HCPCS Level II code K1002 effective January 1, 2020, "Cranial electrotherapy stimulation (ces) system, includes all supplies and accessories, any type."

Requested Benefit Category

Durable Medical Equipment – section 1861(n) of the Social Security Act.

Preliminary Medicare Benefit Category Determination

Durable Medical Equipment.

Durable medical equipment (DME) is defined in section 1861(n) of the Social Security Act and 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 Alpha-Stim® Cranial Electrotherapy Stimulation (CES) was reviewed extensively and supports the preliminary durable medical equipment benefit category determination. As explained in more detail below, Medicare makes payment under the existing DME fee schedule for durable electrical stimulation devices used primarily and customarily for medical purposes and this device is comparable to these other electrical stimulation devices.

Preliminary Medicare Payment Determination

In accordance with Medicare regulations at 42 CFR § 414.238(b) regarding establishing fee schedule amounts for new HCPCS codes for items and services without a fee schedule pricing history, the fee schedule amounts for code K1002 for this particular electrical stimulation device would be established using the existing fee schedule amounts for comparable items (electrical stimulation devices) described by HCPCS code E0720.

Electrical nerve stimulation uses electrical current to activate or decrease activity of nerves to achieve a specific result to the body. The Alpha-Stim® Cranial Electrotherapy Stimulation and devices under E0720 are external, non-invasive electrical nerve stimulation devices that utilize electrodes placed on the skin for delivery of electrical stimulation. Devices under E0720 have a range of intensity, frequency, pulse width, adjustable or fixed, waveform, and treatment times to which the Alpha-Stim® Cranial Electrotherapy Stimulation device is comparable.

	E0720	**Alpha-Stim® CES**
Physical Components	-Electrodes (quantity can vary) -Stimulator	-Electrode -Stimulator
Mechanical Components	N/A	N/A
Electrical Components	-Variable frequency range, commonly less than 200 Hz -Could have adjustable frequency by the patient -Multiple wave patterns available (direct, alternating, or pulsed), (square, sine) -Pulsed, burst or continuous treatment -Has an anode and cathode electrode -Usually has a battery or could be rechargeable	-Frequency up to 100 Hz -Battery operated -Rectangular wave -Pulsed treatment

	E0720	Alpha-Stim® CES
Function and Intended Use	-Provides electrical stimulation using skin surface electrodes which has the intention of stimulating nerves -Can be placed almost any location on the body -Typical indication is to treat pain -Commonly stimulates peripheral nerves	-Provides electrical stimulation using skin surface electrodes which has the intention of stimulating nerves -Worn on behind the ear -Indication to treat insomnia, depression, anxiety, and pain -Stimulates various nerves
Additional Aspects and Features	-Non-invasive -Self-administered -Time worn can vary	-Non-invasive -Self-administered -20 to 60-minute session

CMS recognizes the new indications through our preliminary valuation to compare the technology to E0720 devices prior to competitive bidding, when devices to treat a range of conditions like insomnia, depression, anxiety, and pain were not available to suppliers engaging in the competitive bidding program. As such, CMS would establish the fees for K1002 using fees for E0720 that were not adjusted using information from the DMEPOS Competitive Bidding Program. Based on this preliminary determination, the average 2022 fee schedule amount for K1002 would be based on the unadjusted purchase fee schedule amounts for E0720 of approximately $429 on average. Since the purchase price for this item are more than $150, payment for this device would be made on a capped rental basis in accordance with 42 CFR §414.229, with the capped rental fee schedule amounts for months 1 thru 3 based on 10 percent of the purchase price or approximately $42.90 on average. The capped rental fee schedule amounts for months 4 thru 13 based on 7.5 percent of the purchase price or approximately $32.17 on average. Total payments after 13 months would be approximately $450.40 on average.

Pricing = 36

Summary of Public Feedback

Electromedical Products International, Inc., the manufacturer of the Alpha-Stim® Cranial Electrotherapy Stimulation (CES) device, believes the device is not comparable to devices described by HCPCS code E0720 and that a more comparable item would be the pelvic floor stimulator (HCPCS code E0740), which is an electrical muscle stimulator. Electromedical Products International, Inc. stated that both codes E0740 and K1002 include the supplies and accessories for the device and code E0720 does not as the supplies are billed separately using code A4595.

Final Medicare Benefit Category Determination

Durable Medical Equipment.

Final Medicare Payment Determination

We do not agree that the Alpha-Stim® Cranial Electrotherapy Stimulation (CES) device, which is an electrical nerve stimulator, is comparable to electrical muscle stimulators described by HCPCS code E0740. The Alpha-Stim® Cranial Electrotherapy Stimulation (CES) device is an electrical nerve stimulator and is not an electrical muscle stimulator.

Electrical muscle stimulators are designed to make the muscles significantly contract. The Alpha-Stim® CES is an electrical nerve stimulator that stimulates a group of nerves at the base of the brainstem. The Alpha-Stim® CES stimulates nerves rather than muscles. We believe payment for any covered claims for supplies and accessories used with the device should be made separate from the payment for any covered claims for the device. Therefore, the descriptor for HCPCS code K1002 will be revised to remove the words "includes all supplies and accessories." The fee schedule amounts for revised HCPCS code K1002 will be established using the unadjusted fee schedule amounts for HCPCS code E0720, with the rental fee schedule amounts for months 1 thru 3 being approximately $42.90 on average, and the rental fee schedule amounts for months 4 thru 13 being approximately $32.17 on average. New code (A4596) will be added to the HCPCS for the monthly supplies (ear clips, ear clip electrode pads, conductive solution, and batteries) for the device and the fee schedule amounts for this code will be established using the unadjusted fee schedule amounts for HCPCS code A4595, or approximately $35.24 on average.

Payment for code K1002 will be made on a capped rental basis for any covered claims. A monthly payment using the new, separate code will be made for all covered claims for supplies or accessories necessary for the effective use of the device described by code K1002.

K1002 - Pricing = 36; A4596 – Pricing = 34

Agenda Item # 2

Monarch external Trigeminal Nerve Stimulation (eTNS) System® – 20.070

Topic

Medicare Benefit Category and Payment Determination for Monarch external Trigeminal Nerve Stimulation (eTNS) System®.

Temporary HCPCS code: K1016 "Transcutaneous electrical nerve stimulator for electrical stimulation of the trigeminal nerve"

Applicant's Summary

According to information submitted by NeuroSigma Inc., the Monarch external Trigeminal Nerve Stimulation (eTNS) System® is a non-implantable trigeminal nerve stimulation device for the treatment for pediatric attention deficit hyperactivity disorder (ADHD). This device is used during periods of sleep. This system acts by providing therapeutic electrical stimulation of the V1 branch of the trigeminal nerve in the forehead. To administer therapy with the Monarch eTNS System®, a patient places a disposable electric patch in the center of their forehead just above the eyebrows. When applied in this manner, the electrodes within the patch will be oriented on top of the Supraorbital and Supratrochlear nerves located above the eyes. The patch is secured to the skin of the forehead by hypoallergenic hydrogel and medical grade foam and adhesive. The patch is connected to a hand-held pulse generator that creates and transmits an electrical signal to the patch with two lead wires. The Monarch eTNS System® has been tested to withstand 5 years of nightly use.

Final CMS HCPCS Coding Action

Established new HCPCS Level II code K1016 effective April 1, 2021, "Transcutaneous electrical nerve stimulator for electrical stimulation of the trigeminal nerve."

Requested Benefit Category

Durable Medical Equipment – section 1861(n) of the Social Security Act.

Preliminary Medicare Benefit Category Determination

Durable Medical Equipment.

Durable medical equipment (DME) is defined in section 1861(n) of the Social Security Act and 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.

Monarch external Trigeminal Nerve Stimulation System® meets the definition of durable medical equipment. As explained in more detail below, Medicare makes payment under the existing DME fee schedule for durable electrical stimulation devices used primarily and customarily for medical purposes and this device is comparable to these other electrical stimulation devices.

Preliminary Medicare Payment Determination

In accordance with Medicare regulations at 42 CFR § 414.238(b) regarding establishing fee schedule amounts for new HCPCS codes for items and services without a fee schedule pricing history, the fee schedule amounts for code K1016 for this particular electrical stimulation device would be established using the existing fee schedule amounts for comparable items (electrical stimulation devices) described by HCPCS code E0720.

Electrical nerve stimulation uses electrical current to activate or decrease activity of nerves to achieve a specific result to the body. The Monarch eTNS System® and devices under E0720 are external, non-invasive electrical nerve stimulation devices that utilize electrodes placed on the skin for delivery of electrical stimulation. Devices under E0720 have a range of intensity, frequency, pulse width, adjustable or fixed, waveform, and treatment times which the Monarch eTNS System® can be compared to.

	E0720	**Monarch eTNS®**
Physical Components	-Electrodes (quantity can vary) -Charger, if needed -Stimulator	-Electrode -Charging station -Stimulator
Mechanical Components	N/A	N/A
Electrical Components	-Variable frequency range, commonly less than 200 Hz -Could have adjustable frequency by the patient -Multiple wave patterns available (direct, alternating, or pulsed), (square, sine) -Pulsed, burst or continuous treatment -Has an anode and cathode electrode -Usually has a battery or could be rechargeable	-Frequency of 120 Hz -Fixed frequency -Rechargeable battery -Square wave -Pulsed stimulation

	E0720	Monarch eTNS®
Function and Intended Use	-Provides electrical stimulation using skin surface electrodes which has the intention of stimulating nerves -Can be placed almost any location on the body -Typical indication is to treat pain -Commonly stimulates peripheral nerves	-Provides electrical stimulation using skin surface electrodes which has the intention of stimulating nerves -Worn on the forehead -Indication to treat ADHD -Stimulates trigeminal nerve
Additional Aspects and Features	-Non-invasive -Self-administered -Time worn can vary	-Non-invasive -Self-administered -7 to 8-hour session

CMS recognizes the new indications through our preliminary valuation to compare the technology to E0720 devices prior to competitive bidding, when devices to treat conditions like ADHD were not available to suppliers engaging in the competitive bidding program. As such, CMS would establish the fees for K1016 using fees for E0720 that were not adjusted using information from the DMEPOS Competitive Bidding Program. Based on this preliminary determination, the average 2022 fee schedule amount for K1016 would be based on the unadjusted purchase fee schedule amounts for E0720 of approximately $429 on average. Since the purchase price for this item are more than $150, payment for this device would be made on a capped rental basis in accordance with 42 CFR §414.229, with the capped rental fee schedule amounts for months 1 thru 3 based on 10 percent of the purchase price or approximately $42.90 on average. The capped rental fee schedule amounts for months 4 thru 13 based on 7.5 percent of the purchase price or approximately $32.17 on average. Total payments after 13 months would be approximately $450.40 on average.

Pricing = 36

Summary of Public Feedback

NeuroSigma Inc., the manufacturer of the Monarch eTNS System®, believes the device is not comparable to devices described by HCPCS code E0720, and that, due to the average treatment length time, a more comparable item would be one of three osteogenesis stimulators: electromagnetic field generators falling under HCPCS codes E0747 or E0748 or the ultrasonic version described by HCPCS code E0760.

Final Medicare Benefit Category Determination

Durable Medical Equipment.

Final Medicare Payment Determination

We do not agree that the Monarch device, which is an electrical nerve stimulator, is comparable to the devices described by HCPCS codes E0747 or E0748, which are electromagnetic field generators, or HCPCS code E0760, a code for ultrasonic generators. The Monarch eTNS System® is an electrical nerve stimulator and is not an electromagnetic field generator or ultrasonic generator. The electromagnetic field generators described by HCPCS codes E0747 and E0748 are electrical osteogenesis stimulators which provide electrical stimulation to augment bone repair either invasively or non-invasively. A non-

invasive electrical stimulator is characterized by an external power source attached to a coil or electrodes placed on the skin or on a cast or brace over a fracture or fusion site. An electromagnetic field is created between the pads at the fracture site. Invasive devices provide electrical stimulation directly at the fracture site either through percutaneously placed cathodes or by implantation of a coiled cathode wire into the fracture site. An ultrasonic osteogenesis stimulator (HCPCS code E0760) is a noninvasive device that emits low intensity, pulsed ultrasound. The ultrasound signal is applied to the skin surface at the fracture location with ultrasound conductive gel in order to stimulate fracture healing. The Monarch is a non-invasive trigeminal nerve stimulation device that provides a fixed, non-pulsed, frequency of 120 Hz. As such, we believe the electrical nerve stimulation devices described by HCPCS code E0720 are more comparable to the Monarch device than the devices described by HCPCS codes E0747, E0748, or E0760. The fee schedule amounts for HCPCS code K1016 will be established using the unadjusted fee schedule amounts for HCPCS code E0720, with the rental fee schedule amounts for months 1 thru 3 being approximately $42.90 on average, and the rental fee schedule amounts for months 4 thru 13 being approximately $32.17 on average.

Payment will be made on a capped rental basis for any covered claims.

Pricing = 36

Agenda Item # 2

Monarch external Trigeminal Nerve Stimulation (eTNS)® Supplies – 20.070

Topic

Medicare Benefit Category and Payment Determination for Monarch external Trigeminal Nerve Stimulation (eTNS) System® supplies.

Temporary HCPCS code: K1017 "Monthly supplies for use of device coded at K1016"

Applicant's Summary

According to information submitted by NeuroSigma Inc., the Monarch external Trigeminal Nerve Stimulation (eTNS) System® is a non-implantable trigeminal nerve stimulation device for the treatment for pediatric attention deficit hyperactivity disorder (ADHD). This device is to be used during periods of sleep. This system acts by providing therapeutic electrical stimulation of the V1 branch of the trigeminal nerve in the forehead. To administer therapy with the Monarch eTNS System®, a patient places a disposable electric patch (called NS-2 electric patches) in the center of their forehead just above the eyebrows. When applied in this manner, the electrodes within the patch will be oriented on top of the Supraorbital and Supratrochlear nerves located above the eyes. The patch is secured to the skin of the forehead by hypoallergenic hydrogel and medical grade foam and adhesive. The patch is connected to a hand-held pulse generator that creates and transmits an electrical signal to the patch with two lead wires. The patches are single use disposable.

Final CMS HCPCS Coding Action

Established new HCPCS Level II code K1017 effective April 1, 2021, "Monthly supplies for use of device coded at K1016."

Requested Benefit Category

Durable Medical Equipment – section 1861(n) of the Social Security Act.

Preliminary Medicare Benefit Category Determination

Durable Medical Equipment.

The preliminary benefit category determination for the Monarch eTNS® equipment (code K1016) is that it meets the definition of durable medical equipment (DME) found in 42 Code of Federal Regulations (CFR) 414.202. Chapter 15, section 110.3 of the Medical Benefit Policy Manual (CMS Pub. 100-02) states payment may be made for supplies that are necessary for the effective use of durable medical equipment.

Preliminary Medicare Payment Determination

In accordance with Medicare regulations at 42 CFR § 414.238(b) 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 K1017 for supplies for electrical

stimulation devices described by HCPCS code K1016 would be established using the existing fee schedule amounts for comparable items (supplies for electrical stimulation devices) under code A4595. Electrical stimulation supplies coded under A4595 covers a wide range of sizes (e.g., 4cm and 4" x 7"), shapes (e.g., round, oval, and butterfly), and materials which Monarch eTNS is comparable to.

A monthly payment would be made for all supplies necessary for one month.

Pricing = 34

Summary of Public Feedback

NeuroSigma Inc., the manufacturer of the Monarch external Trigeminal Nerve Stimulation (eTNS) System®, disagrees with the payment determination for the supplies and believes the payment amounts should be higher.

Final Medicare Benefit Category Determination

Durable Medical Equipment.

Final Medicare Payment Determination

The fee schedule amounts for HCPCS code K1017 will be established using the unadjusted fee schedule amounts for HCPCS code A4595, or approximately $35.24 on average.

A monthly payment would be made for for any covered claims for all supplies necessary for one month.

Pricing = 34

Agenda Item # 3

Cala Trio™ – 20.086

Topic

Medicare Benefit Category and Payment Determination for Cala Trio™.

Temporary HCPCS code: K1018 "External upper limb tremor stimulator of the peripheral nerves of the wrist"

Applicant's Summary

According to information submitted by Cala Health Inc., the Cala Trio™ is a non-invasive, wrist-worn stimulator that delivers electrical stimulation to the nerves in the wrist to stimulate the peripheral nervous system for the treatment of essential tremors. The Cala Trio™ device is provided with two components: rechargeable stimulator that generates electrical impulses during times of active therapy together with a base station to recharge the stimulator; and wrist-worn connector that securely attaches the stimulator to the patient's wrist and assures that electrical impulses are properly targeted to each individual patient's nerves. The Cala Trio™ uses circumferential stimulation with three access points to target the median and radial nerves at the wrist. The Cala Trio™ stimulator can last up to 3 years. The wrist worn connector and electrodes has a useful life of 90 days. The stimulator is powered with a lithium-ion rechargeable battery, which can be recharged with the base station. The current is delivered to alternating electrode pairs in the band that target the peripheral nerves on the wrist. The tremor frequency is measured by motion sensors (accelerometer and gyroscope) contained within the stimulator which gathers kinematic data. An on-board microcontroller alternates the current between the electrode pairs.

Final CMS HCPCS Coding Action

Established new HCPCS Level II code K1018 effective April 1, 2021, "External upper limb tremor stimulator of the peripheral nerves of the wrist."

Requested Benefit Category

Durable Medical Equipment – section 1861(n) of the Social Security Act.

Preliminary Medicare Benefit Category Determination

Durable Medical Equipment.

Durable medical equipment (DME) is defined in section 1861(n) of the Social Security Act and 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.

Cala Trio™ device meets the definition of durable medical equipment. As explained in more detail below, Medicare makes payment under the existing DME fee schedule for durable electrical stimulation devices used primarily and customarily for medical purposes and this device is comparable to these other electrical stimulation devices.

Preliminary Medicare Payment Determination

In accordance with Medicare regulations at 42 CFR § 414.238(b) regarding establishing fee schedule amounts for new HCPCS codes for items and services without a fee schedule pricing history, the fee schedule amounts for code K1018 for this particular electrical stimulation device would be established using the existing fee schedule amounts for comparable items (electrical stimulation devices) described by HCPCS code E0720.

Electrical nerve stimulation uses electrical current to activate or decrease activity of nerves to achieve a specific result to the body. The Cala Trio™ and devices under E0720 are external, non-invasive electrical nerve stimulation devices that utilize electrodes placed on the skin for delivery of electrical stimulation. Devices under E0720 have a range of intensity, frequency, pulse width, adjustable or fixed, waveform, and treatment times which the Cala Trio™ can be compared to.

	E0720	**Cala Trio™**
Physical Components	-Electrodes (quantity can vary) -Charger, if needed -Stimulator	-Electrodes (three) -Charging station -Stimulator
Mechanical Components	-Could contain an accelerometer. One such device provides a measurement of shock impact that indicates when the electrode simpedance has changed and adjusts the level of therapy accordingly.	-Gyroscope -Accelerometer

	E0720	Cala Trio™
Electrical Components	-Variable frequency range, commonly less than 200 Hz -Could have adjustable stimulation by the patient -Multiple wave patterns available (direct, alternating, or pulsed), (square, sine) -Pulsed, burst or continuous treatment -Has an anode and cathode electrode -Could contain a microprocessor. We are aware of other devices that incorporate microprocessors with real-time biofeedback functions built-in that read a patient's electrical parameters and make constant adjustments to match the patient's immediate nerve function. -Usually has a battery or could be rechargeable	-Frequency of 150 Hz -Adjustable stimulation by the patient -Square wave -Burst frequency -Lithium rechargeable battery -Alternating electrode pairs stimulated at any moment; always an anode and cathode at any moment. -Microcontroller
Function and Intended Use	-Provides electrical stimulation using skin surface electrodes which has the intention of stimulating nerves -Can be placed almost any location on the body -Typical indication is to treat pain -Commonly stimulates peripheral nerves	-Provides electrical stimulation using skin surface electrodes which has the intention of stimulating nerves -Worn on the wrist -Indication to reduce tremors -Stimulates peripheral nerves
Additional Aspects and Features	-Non-invasive -Self-administered -Time worn can vary	-Non-invasive -Self-administered -40-minute session

In our preliminary view, Cala Trio™ has utilized and applied comparable technologies to now generate a specific clinical outcome to effect treatment of essential tremors.

CMS recognizes the new indications through our preliminary valuation to compare the technology to E0720 devices prior to competitive bidding, when devices to treat conditions like essential tremors were not available to suppliers engaging in the competitive bidding program. As such, CMS would establish the fees for K1018 using fees for E0720 that were not adjusted using information from the DMEPOS Competitive Bidding Program. Based on this preliminary determination, the average 2022 fee schedule amount for K1018 would be based on the unadjusted purchase fee schedule amounts for E0720 of approximately $429 on average. Since the purchase price for this item are more than $150, payment for this device would be made on a capped rental basis in accordance with 42 CFR §414.229, with the capped rental fee schedule amounts for months 1 thru 3 based on 10 percent of the purchase price or approximately $42.90 on average. The capped rental fee schedule amounts for months 4 thru 13 based on 7.5 percent of the purchase price or approximately $32.17 on average. Total payments after 13 months would be approximately $450.40 on average.

Pricing = 36

Summary of Public Feedback

Cala Health Inc., the manufacturer of the Cala Trio™, did not agree with the determination that the device is comparable to a TENS device. They indicated that Cala Trio™ has special controls and advanced components including accelerometer, microprocessor, and software algorithms. Cala Trio™ applies Trancutaneous Afferent Patterned Stimulation (TAPS) therapy and patient-specific alternating and oscillating timed stimulation of medial and radial nerves. A consultant for the company said that TENS devices are simple and not precise. It was pointed out at the public meeting that patents for the Cala Trio™ state that the device is most comparable to a TENS device. A consultant for Cala Health Inc. indicated in written comments that this reference appeared in only one patent filing and that the filing went on to characterize the similarities between the two technologies as being limited to the fact that both deliver electrical stimulation to peripheral nerves. We note that the exact statement in the patent filings is "perhaps the technology most closely related to our approach is transcutaneous electrical nerve stimulation (TENS)," and that this statement appeared in three of the patent filings by the company for the technology.

Final Medicare Benefit Category Determination

Durable Medical Equipment.

Final Medicare Payment Determination

We agree that the special componentry and patterned stimulation produced by the device described by code K1018 (e.g., Cala Trio™) warrants a determination that the device is not comparable to other electrical nerve stimulation devices classified under HCPCS code E0720. The fee schedule amounts for HCPCS code K1018 will be established using the current price of $6,400. In accordance with regulations at 42 CFR 414.238(c), the current pricing of $6,400 is deflated to the 1986 fee schedule base period using the percentage change in the consumer price index for all urban consumers (CPI-U) from the mid-point of the year the prices are in effect to the mid-point of the fee schedule base period. The price is then updated to 2022 using the covered item update factors at section 1834(a)(14) of the Social Security Act, resulting in a 2022 purchase price of approximately $3,849.11. Payment for the device described by code K1018 would be made on a capped rental basis for any covered claims. In accordance with 42 CFR §414.229, the capped rental fee schedule amount for months 1 through 3 is equal to 10 percent of the purchase price, or approximately $384.91, and the capped rental fee schedule amount for months 4 through 13 is equal to 7.5 percent of the purchase price, or approximately $288.68.

Pricing = 36

Agenda Item # 3

Cala Trio™ Supplies – 20.086

Topic

Medicare Benefit Category and Payment Determination for Cala Trio™ supplies.

Temporary HCPCS code: K1019 "Monthly supplies for use of device coded at K1018"

Applicant's Summary

According to information submitted by Cala Health Inc., the Cala Trio™ is a non-invasive, wrist-worn stimulator that delivers electrical stimulation to the nerves in the wrist to stimulate the peripheral nervous system for the treatment of essential tremors. The Cala Trio™ device is provided with two components: rechargeable stimulator that generates electrical impulses during times of active therapy together with a base station to recharge the stimulator; and wrist-worn connector that securely attaches the stimulator to the patient's wrist and assures that electrical impulses are properly targeted to each individual patient's nerves. The Cala Trio™ uses circumferential stimulation with three access points to target the median and radial nerves at the wrist embedded in the band. The band is available in left or right handed to target the appropriate nerve locations. The wrist worn connector electrodes has a useful life of 90 days. The current is delivered to alternating electrode pairs in the band that target the nerves. The tremor frequency is measured by motion sensors (accelerometer and gyroscope) contained within the stimulator which gathers kinematic data. An on-board microcontroller alternates the current between the electrode pairs.

Final CMS HCPCS Coding Action

Established new HCPCS Level II code K1019 effective April 1, 2021, "Monthly supplies for use of device coded at K1018."

Requested Benefit Category

Durable Medical Equipment – section 1861(n) of the Social Security Act.

Preliminary Medicare Benefit Category Determination

Durable Medical Equipment.

The preliminary benefit category determination for the Cala Trio™ (code K1018) is that this equipment meets the definition of durable medical equipment (DME) found in 42 Code of Federal Regulations (CFR) 414.202. Chapter 15, section 110.3 of the Medical Benefit Policy Manual (CMS Pub. 100-02) states payment may be made for supplies, that are necessary for the effective use of durable medical 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 K1019 for supplies for electrical stimulation devices described by HCPCS code K1018 would be established using the existing fee schedule amounts for comparable items (supplies for electrical stimulation devices) under code A4595.

The Cala Trio™ connector has alternating electrode pair, only two of the three electrodes are used at a given moment. Electrical stimulation supplies coded under A4595 covers a wide range of sizes (e.g., 4cm and 4" x 7"), shapes (e.g., round, oval, and butterfly), and materials.

A monthly payment would be made for all supplies necessary for one month.

Pricing = 34

Summary of Public Feedback

No comments were provided specifically on the pricing for the supplies and accessories.

Final Medicare Benefit Category Determination

Durable Medical Equipment.

Final Medicare Payment Determination

No determination. More time is needed to evaluate pricing information for these items. In the meantime, payment for these items will be made at the discretion of the MACs.

The Cala Trio stimulator is powered with a lithium-ion rechargeable battery, which can be recharged with the base station. The recharging base station would also fall under HCPCS code A4595. The electrical stimulator supplies described by HCPCS code A4595 include electrodes (any type), conductive paste or gel (if needed, depending on the type of electrode), tape or other adhesive (if needed, depending on the type of electrode), adhesive remover, skin preparation materials, batteries (9 volt or AA, single use or rechargeable), and a battery charger (if rechargeable batteries are used).

The special componentry and patterned stimulation is produced by the Cala Trio™ stimulation device and not by the wristband/electrode accessory, which are reusable electrodes and which may be comparable to electrodes coded and paid for using existing code A4595. HCPCS code A4595, electrical stimulator supplies, 2 lead, per month, (e.g., tens, nmes), covers a wide range of electrodes and supplies. When it comes to electrodes, there are many options based on shape, size, and configuration to fit the need of the patient and therapeutic goal for electrical stimulation. The electrodes can vary from the size (e.g., 4 cm and 4" x 7"), the shape (e.g., round, oval, and butterfly), and the materials. The materials and properties of the electrodes that fall within A4595 can include metal plates, rubber, self-adhering, single use, multiple use, etc. When it comes to the Cala Trio's electrodes, there are three electrodes embedded in the band of the device that function as two pairs (positive and negative) that target the median and radial nerves. Current is delivered to alternating electrode pairs in the band. Since the stimulation alters between the electrode pair, only two electrodes of the three electrodes are active at a time. The Cala Trio uses dry, metal electrodes that last up to three months. The fixed, metal electrodes used in the Cala Trio wrist band seem to be comparable to other reusable or fixed electrodes coded using A4595. As a

result, CMS is considering adopting a pricing methodology similar to that of 20.070, which would be approximately $106 for a 3 month supply. We are open to receiving feedback on this approach.

The descriptor for HCPCS code K1019, which reads “Monthly supplies for use of device coded at K1018” will be revised to read “Replacement supplies and accessories for external upper limb tremor stimulator of the peripheral nerves of the wrist.”

Pricing = 34

Agenda Item # 4

gammaCore Sapphire™ – 20.173

Topic

Medicare Benefit Category and Payment Determination for gammaCore Sapphire™.

Temporary HCPCS code: K1020 "Non-invasive vagus nerve stimulator"

Applicant's Summary

According to information submitted by Electrocore, Inc., the gammaCore Sapphire D™ device is a non-invasive vagus nerve stimulator that externally stimulates the cervical branch of the vagus nerve. This stimulation is conducted on the side of the neck. The gammaCore™ device is a multiuse, handheld, rechargeable, portable device consisting of a rechargeable battery, signal-generating and -amplifying electronics, with a control switch for user/operator control of the signal amplitude (stimulation level). The device provides non-invasive vagus nerve stimulation when applied to the side of the neck through two stainless steel stimulation surfaces. The vagus nerve runs through the neck and carries information to the central nervous system. Each stimulation with gammaCore™ lasts 2 minutes. It delivers up to 30 stimulations in a 24-hour period. Once the maximum daily number of treatments has been reached, the device will not deliver any more treatments until the following 24-hour period. The device comes loaded with approximately 36 months (1,116 days) of therapy. It provides visible (light and display) and audible (beep) feedback regarding the device and stimulation status. The number of remaining stimulations available in a 24-hour period is indicated on the display screen as well as the remaining number of months or days available. Each gammaCore comes with 6 tubes of conductive electrode gel.

Final CMS HCPCS Coding Action

Established new HCPCS Level II code K1020 effective April 1, 2021, "Non-invasive vagus nerve stimulator."

Requested Benefit Category

Durable Medical Equipment – section 1861(n) of the Social Security Act.

Preliminary Medicare Benefit Category Determination

Durable Medical Equipment.

Durable medical equipment (DME) is defined in section 1861(n) of the Social Security Act and 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 gammaCore Sapphire D™ device meets the definition of durable medical equipment.

Preliminary Medicare Payment Determination

In accordance with Medicare regulations at 42 CFR § 414.238(b) regarding establishing fee schedule amounts for new HCPCS codes for items and services without a fee schedule pricing history, the fee schedule amounts for code K1020 for this particular electrical stimulation device would be established using the existing fee schedule amounts for comparable items (electrical stimulation devices) described by HCPCS code E0720.

Electrical nerve stimulation uses electrical current to activate or decrease activity of nerves to achieve a specific result to the body. The gammaCore Sapphire D™ and devices under E0720 are external, non-invasive electrical nerve stimulation devices that utilize electrodes placed on the skin for delivery of electrical stimulation. Types of electrodes can vary from metal plates, rubber, self-adhering, and single-use. Devices under E0720 have a range of intensity, frequency, pulse width, adjustable or fixed, waveform, and treatment times which the gammaCore Sapphire D™ can be compared to.

	E0720	**gammaCore Sapphire D™**
Physical Components	-Electrodes (quantity can vary) -Charger, if needed -Stimulator	-Electrode (metal) -Charging adapter -Stimulator
Mechanical Components	N/A	N/A
Electrical Components	-Variable frequency range, commonly less than 200 Hz -Could have adjustable stimulation by the patient -Multiple wave patterns available (direct, alternating, or pulsed), (square, sine) -Pulsed, burst or continuous treatment -Has an anode and cathode electrode -Usually has a battery or could be rechargeable	-Frequency of 25 Hz -Pulsed sine waveform -Burst frequency -Rechargeable battery

	E0720	gammaCore Sapphire D™
Function and Intended Use	-Provides electrical stimulation using skin surface electrodes which has the intention of stimulating nerves -Can be placed almost any location on the body -Typical indication is to treat pain -Commonly stimulates peripheral nerves	-Provides electrical stimulation using skin surface electrodes which has the intention of stimulating nerves -Placed on the neck -Indication to treat cluster headaches -Stimulates vagus nerves
Additional Aspects and Features	-Non-invasive -Self-administered -Time worn can vary	-Non-invasive -Self-administered -2-minute sessions

CMS recognizes the new indications through our preliminary valuation to compare the technology to E0720 devices prior to competitive bidding, when devices to treat conditions like cluster headaches were not available to suppliers engaging in the competitive bidding program. As such, CMS would establish the fees for K1020 using fees for E0720 that were not adjusted using information from the DMEPOS Competitive Bidding Program. Based on this preliminary determination, the average 2022 fee schedule amount for K1020 would be based on the unadjusted purchase fee schedule amounts for E0720 of approximately $429 on average. Since the purchase price for this item are more than $150, payment for this device would be made on a capped rental basis in accordance with 42 CFR §414.229, with the capped rental fee schedule amounts for months 1 thru 3 based on 10 percent of the purchase price or approximately $42.90 on average. The capped rental fee schedule amounts for months 4 thru 13 based on 7.5 percent of the purchase price or approximately $32.17 on average. Total payments after 13 months would be approximately $450.40 on average.

Pricing = 36

Summary of Public Feedback

Electrocore, Inc., the manufacturer of the gammaCore Sapphire D™ device, believes the device is not comparable to devices described by HCPCS code E0720 and that a more comparable item would be an implanted vagus nerve stimulator described by HCPCS code L8679 since the devices described by codes K1020 and L8679 both stimulate the vagus nerve.

Final Medicare Benefit Category Determination

Durable Medical Equipment.

Final Medicare Payment Determination

We do not agree that the gammaCore Sapphire D™ device, which is an external electrical nerve stimulator, is comparable to devices described by HCPCS code L8679, which is an implanted electrtical nerve stimulator. The fee schedule amounts for HCPCS code K1020 will be established using the unadjusted fee schedule amounts for HCPCS code E0720, with the rental fee schedule amounts for months 1 thru 3 being approximately $42.90 on average, and the rental fee schedule amounts for months 4 thru 13 being approximately $32.17 on average.

Payment will be made on a capped rental basis for any covered claims.

Pricing = 36

Agenda Item # 5

Nerivio™ – 21.033

Topic

Medicare Benefit Category and Payment Determination for Nerivio™.

Temporary HCPCS code: K1023 "Distal transcutaneous electrical nerve stimulator, stimulates peripheral nerves of the upper arm"

Applicant's Summary

According to information submitted by Theranica Bio-Electronics Ltd, Israel, the Nerivio™ device is a neuromodulation device for the acute treatment of episodic and chronic migraine. The device stimulates the peripheral nerves in the upper arm to induce conditioned pain modulation. The Nerivio™ device is a wireless wearable battery-operated stimulation unit controlled by a smartphone software application. Treatments with Nerivio™ are self-administered by the user at the onset of a migraine attack. The system delivers low energy electrical pulses to the upper arm for 45 minutes per treatment, after which the device turns off automatically. The device hardware consists of an armband intended to be worn on a user's upper arm. The armband contains the electronic circuitry and the battery in a plastic storage case as well as two electrodes that are attached to the interior of the armband and placed against the user's skin. The device is operated and controlled via software that is installed and run on a user's personal mobile device such as a mobile phone or tablet. The plastic electronics case contains an on/off switch and an LED indicator. The Nerivio™ device can be used for 12 treatments of 45 minutes each. These treatments can be exercised over an 18-month period.

Final CMS HCPCS Coding Action

Established new HCPCS Level II code K1023 effective October 1, 2021, "Distal transcutaneous electrical nerve stimulator, stimulates peripheral nerves of the upper arm."

Requested Benefit Category

Durable Medical Equipment – section 1861(n) of the Social Security Act.

Preliminary Medicare Benefit Category Determination

No benefit category.

Durable medical equipment (DME) is defined in section 1861(n) of the Social Security Act and 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.

Once used, the Nerivio™ can support 540 minutes of treatments, or 12 treatments of 45 minutes, but only up to an 18-month period. The Nerivio™ device can be used up to an 18-month period; therefore, the minimum lifetime requirement of three years is not met. According to the Nerivio™ user manual, when there are no more treatments left, the device should be disposed. 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).

Preliminary Medicare Payment Determination

No Medicare payment. Pricing = 00

Summary of Public Feedback

There were no speakers at the public meeting and no written consultation was received for this item.

Final Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

Final Medicare Payment Determination

No Medicare DMEPOS payment. Pricing = 00

Agenda Item # 6

Alzair™ Allergy Blocker – 21.048

Topic

Medicare Benefit Category and Payment Determination for Alzair™ Allergy Blocker.

Temporary HCPCS code: K1026 "Mechanical allergen particle barrier/inhalation filter, cream, nasal, topical"

Applicant's Summary

According to information submitted by HS Pharma, Alzair™ Allergy Blocker is a gel barrier that blocks inhaled allergens within the nasal cavity. It is administered by insufflation into the nose using a spray bottle, so a fine mist covers the nasal cavity. Alzair™ is composed of pharmaceutical grade Hydroxypropyl Methylcellulose (HPMC; 98.5%) and high-quality peppermint (1.5%) formulated into a micronized powder of fine particles of inert cellulose. Alzair™ is indicated to treat hay fever and allergy sufferers by promoting alleviation of mild allergic symptoms (i.e., mild nasal irritation including itchy, runny, or congested nasal passages) triggered by the inhalation of various airborne allergens including indoor and outdoor environmental pollens, house dust, animal hairs, and dust mites. It is a drug free product that has zero contraindications. It is supplied in a patented bottle that produces a specific particle size that allows for the proper efficacy and dose of the Methylcellulose. The spray bottle enables the powder to be applied evenly as a fine mist. The current bottle size contains 800 mg of powder that equates to approximately 200 inhalations. HS Pharma recommends for Alzair™ to be taken three times a day in both nostrils per day, this equates to 28-33 days of treatment.

Final CMS HCPCS Coding Action

Established new HCPCS Level II code K1026 effective October 1, 2021, "Mechanical allergen particle barrier/inhalation filter, cream, nasal, topical."

Requested Benefit Category

Durable Medical Equipment – section 1861(n) of the Social Security Act.

Preliminary Medicare Benefit Category Determination

No benefit category.

Durable medical equipment (DME) is defined in section 1861(n) of the Social Security Act and 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 Alzair™ Allergy Blocker is disposed of after 200 inhalations when used as suggested three times per day per nostril, which equates to 28 to 33 days of use; therefore, the minimum lifetime requirement of three years is not met. 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 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 Alzair™ Allergy Blocker device cannot be rented and used by successive patients.

Preliminary Medicare Payment Determination

No Medicare payment. Pricing = 00

Summary of Public Feedback

There were no speakers at the public meeting and no written consultation was received for this item.

Final Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

Final Medicare Payment Determination

No Medicare DMEPOS payment. Pricing = 00

Agenda Item # 7

Slow Wave – 21.034

Topic

Medicare Benefit Category and Payment Determination for Slow Wave.

Temporary HCPCS code: K1027 “Oral device/appliance used to reduce upper airway collapsibility, without fixed mechanical hinge, custom fabricated, includes fitting and adjustment”

Applicant’s Summary

According to information submitted by Slow Wave Inc., the Slow Wave DS8 is an intra-oral device intended to reduce or alleviate snoring and mild to moderate Obstructive Sleep Apnea (OSA) while sleeping in adults. The Slow Wave DS8 consists of two custom fitted trays used to reposition the mandible. The trays are designed to be worn on the upper and lower teeth where they act to increase the patient's pharyngeal space by reducing obstructions of the airway during sleep. The device is designed to be retained on the teeth with saliva and surface tension and functions without any screws or fastening mechanism. The patient-custom devices are 3D print manufactured and made from biocompatible material. The Slow Wave DS8, is a mandibular repositioning device that acts to increase the users' pharyngeal space and improves their ability to exchange air during sleep. The device consists of two separate trays worn on the maxilla and mandible, which allow the user to open and close their jaw when asleep, provide full lateral movement of the mandible, move the tongue naturally forward to enhance air exchange during sleep. The DS8 trays worn on the maxilla and mandible with integrally formed molar extensions forming forward-leaning left and right ramps configured so that when the apparatus is in a users' mouth, the ramps create a tendency for the lower tray, lower dentition and mandible to move in a normal downward position keeping users' airway open by maintaining an anterior gap making more space for the tongue. The Slow Wave DS8 does not utilize fixed mechanical hinges at the sides, front or palate. Nor does it incorporate a mechanism to allow the mandible to be advanced in increments of 1 mm.

Final CMS HCPCS Coding Action

Established new HCPCS Level II code K1027 effective October 1, 2021, “Oral device/appliance used to reduce upper airway collapsibility, without fixed mechanical hinge, custom fabricated, includes fitting and adjustment.”

Requested Benefit Category

Durable Medical Equipment – section 1861(n) of the Social Security Act.

Preliminary Medicare Benefit Category Determination

No determination.

More time is needed to evaluate this complex issue to determine how these items and services can be classified under Medicare Part B. In the meantime, classification, coverage, and payment for these items will be made on an individual claim-by-claim basis by the MACs.

Preliminary Medicare Payment Determination

No determination.

Summary of Public Feedback

Slow Wave Inc., the manufacturer of the Slow Wave DS8 product, believes the item is DME. The manufacturer stated that their product is more effective in treating obstructive sleep apnea (OSA) than the devices currently covered as DME under HCPCS code E0486 and that more treatment options for OSA are needed.

Final Medicare Benefit Category Determination

No determination.

More time is needed to evaluate this complex issue to determine how these items and services can be classified under Medicare Part B. In the meantime, classification, coverage, and payment for these items will be made on an individual claim-by-claim basis by the MACs.

Final Medicare Payment Determination

No determination.

Agenda Item # 8

eXciteOSA® Control Unit - HCP210826HY98M

Topic

Medicare Benefit Category and Payment Determination for eXciteOSA® Control Unit.

Temporary HCPCS code: K1028 "Power source and control electronics unit for oral device/appliance for neuromuscular electrical stimulation of the tongue muscle for the reduction of snoring and obstructive sleep apnea, controlled by phone application"

Applicant's Summary

According to information submitted by Signifier Medical Technologies, LLC (SMT), the eXciteOSA® control unit is a tongue neuromuscular stimulation device. The eXciteOSA® starter kit consists of a control unit, disposable one-size fits all flexible silicone mouthpiece, and USB-C charger. A smartphone application is used to control all functions of the device, such as turning the device on and off. The eXciteOSA® functions by delivering neuromuscular electrical stimulation therapy to the tongue during the wakeful state. A patient operates the device by inserting the mouthpiece into the control unit, connecting the device to a patient-controlled phone application, and placing the mouthpiece on the tongue. The neuromuscular electrical stimulation effect is achieved with a low-pulsed frequency whose intensity can be modified by the user. The electrical stimulation is a series of pulsed bursts with a sequence of alternating pulse and rests periods. The control unit can be repurposed for multiple, successive patients.

Final CMS HCPCS Coding Action

Established new HCPCS Level II code K1028 effective April 1, 2022, "Power source and control electronics unit for oral device/appliance for neuromuscular electrical stimulation of the tongue muscle for the reduction of snoring and obstructive sleep apnea, controlled by phone application."

Requested Benefit Category

Durable Medical Equipment – section 1861(n) of the Social Security Act.

Preliminary Medicare Benefit Category Determination

No benefit category.

Durable medical equipment (DME) is defined in section 1861(n) of the Social Security Act and 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 stated in the 2011 final rule, CMS-1577-F (76 FR 70291), a multi-component device consisting of durable and non-durable components is considered non-durable if the component that performs the medically necessary function of the device is non-durable, even if other components that are part of the device are durable. The eXciteOSA® software application and smartphone performs the medically necessary function of driving the neuromuscular electrical stimulation therapy and intensity, which includes starting and stopping the therapy by activating the electrodes. We note that without the software application and phone, the device does not function. Since the component that performs the medically necessary function of the device is a smartphone which is useful to an individual in the absence of an illness or injury and software application which is nondurable, the eXciteOSA® device does not meet the definition of durable medical equipment.

Preliminary Medicare Payment Determination

No Medicare payment. Pricing = 00

Summary of Public Feedback

Signifier Medical Technologies, LLC (SMT), the manufacturer of the eXciteOSA® product indicated that they neither opposed nor supported the preliminary benefit category determination. They questioned the CMS statement that the “medically necessary function of the device is a smartphone,” and indicated that the FDA has authorized SMT to market eXciteOSA® with a remote control to address the smartphone concern. Due to this complexity, they requested CMS to finalize a “no determination” BCD to allow more time to evaluate this complex issue and for the MACs to make decisions on a claim-by-claim basis.

Final Medicare Benefit Category Determination

No Medicare DMEPOS benefit category. We are finalizing the determination based on the device characteristics presented for review that rely on a smartphone. We understand that the manufacturer may be developing equipment that performs the functions now performed by the non-DME smartphone and would consider classification of the modified product if and when it is brought to market.

Final Medicare Payment Determination

No Medicare DMEPOS payment. Pricing = 00

Agenda Item # 8

eXciteOSA® Mouthpiece - HCP210826HY98M

Topic

Medicare Benefit Category and Payment Determination for eXciteOSA® Mouthpiece.

Temporary HCPCS code: K1029 "Oral device/appliance for neuromuscular electrical stimulation of the tongue muscle, used in conjunction with the power source and control electronics unit, controlled by phone application, 90-day supply"

Applicant's Summary

According to information submitted by Signifier Medical Technologies, LLC (SMT), the eXciteOSA® is a tongue neuromuscular stimulation device with a disposable silicone mouthpiece that contains four electrodes. The mouthpiece is disposable, or considered the non-durable component, and is one-size fits all. The eXciteOSA® functions by delivering neuromuscular electrical stimulation therapy to the tongue during the wakeful state. A patient operates the device by inserting the mouthpiece into the control unit, connecting the device to a patient-controlled phone application, and placing the mouthpiece on the tongue. The electrical stimulation is a series of pulsed bursts with a sequence of alternating pulse and rests periods. The mouthpiece contains four electrodes, two located above (superior and posterior) and two to each side of the tongue. The mouthpiece can be washed after each use and lasts up to 90 days.

Final CMS HCPCS Coding Action

Established new HCPCS Level II code K1028 effective April 1, 2022, "Oral device/appliance for neuromuscular electrical stimulation of the tongue muscle, used in conjunction with the power source and control electronics unit, controlled by phone application, 90-day supply."

Requested Benefit Category

Durable Medical Equipment – section 1861(n) of the Social Security Act.

Preliminary Medicare Benefit Category Determination

No benefit category.

Durable medical equipment (DME) is defined in section 1861(n) of the Social Security Act and 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. The preliminary benefit category determination for the eXciteOSA® control unit is no benefit category; therefore, supplies used with this item would also have no benefit category.

Preliminary Medicare Payment Determination

No Medicare payment. Pricing = 00

Summary of Public Feedback

Signifier Medical Technologies, LLC (SMT), the manufacturer of the eXciteOSA® product indicated that they neither opposed nor supported the preliminary benefit category determination. They questioned the CMS statement that the "medically necessary function of the device is a smartphone," and indicated that the FDA has authorized SMT to market eXciteOSA® with a remote to address the smartphone concern. Due to this complexity, they requested CMS to finalize a "no determination" BCD to allow more time to evaluate this complex issue and for the MACs to make decisions on a claim-by-claim basis.

Final Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

Final Medicare Payment Determination

No Medicare DMEPOS payment. Pricing = 00

Agenda Item # 9

Optimizer® Patient Charger - HCP21090362W2D

Topic

Medicare Benefit Category and Payment Determination for Optimizer® Patient Charger.

Temporary HCPCS code: K1030 "External recharging system for battery (internal) for use with implanted cardiac contractility modulation generator, replacement only"

Applicant's Summary

According to information submitted by Impulse Dynamics, Inc., the Optimizer® Patient Charger is used for the Optimizer® Smart System that delivers cardiac contractility modulation therapy. The Optimizer® Smart System is a hermetically-sealed implantable pulse generator and external battery charger that provides electrical stimulation of the cardiac muscle with the intent to increase exercise tolerance, functional capacity, and quality of life for a subset of heart failure patients with very limited therapeutic options. The energy required to deliver cardiac contractility modulation therapy exceeds the capacity of any available non-rechargeable battery, necessitating use of a rechargeable battery and external charging unit. Patients receive periodic cardiac contractility modulation therapy daily, as programmed by their prescribing physicians, and recharge their device approximately weekly. A typical charging session lasts approximately 45 minutes, during which the device conducts a series of self-checks to confirm appropriate function. Without an external recharging device, a patient's battery will drain and render a cardiac contractility modulation device inoperable after approximately 3 weeks.

Final CMS HCPCS Coding Action

Established new HCPCS Level II code K1030 effective April 1, 2022, "External recharging system for battery (internal) for use with implanted cardiac contractility modulation generator, replacement only."

Requested Benefit Category

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

Preliminary Medicare Benefit Category Determination

No determination.

More time is needed to evaluate this complex issue to determine how these items and services can be classified under Medicare Part B. In the meantime, classification, coverage, and payment for these items will be made on an individual claim-by-claim basis by the MACs.

Preliminary Medicare Payment Determination

No determination.

Summary of Public Feedback

Impulse Dynamics, Inc., the manufacturer of the Optimizer® Patient Charger, believes the implanted Optimizer® device is similar to an implantable neurostimulator and meets the Medicare definition of prosthetic device because it increases or improves the functions of the heart.

Final Medicare Benefit Category Determination

No determination. More time is needed to evaluate this complex issue to determine how these items and services can be classified under Medicare Part B. In the meantime, classification, coverage, and payment for these items will be made on an individual claim-by-claim basis by the MACs.

Final Medicare Payment Determination

No determination.

Agenda Item # 10

Pear Therapeutics - HCP21090135K6E, HCP210902RNB7C, HCP2109034KYG9

Topic

Medicare Benefit Category and Payment Determination for reSET, reSET-O, and Somryst.

HCPCS code: A9291 "Prescription digital behavioral therapy, fda cleared, per course of treatment"

Applicant's Summary

According to information submitted by Pear Therapeutics, reSET®, reSET-O®, and Somryst® are intended to provide cognitive behavioral therapy or neurobehavior intervention, as an adjunct to a contingency management system, for patients who are currently enrolled in outpatient treatment under the supervision of a clinician. The manufacturer states that prescription digital therapeutics (PDTs) is a therapeutic class that is regulated and clinically validated prescription software. PDTs delivers therapy based on the community reinforcement approach, an intensive form of validated neurobehavioral therapy, along with contingency management and fluency training to enhance learning. PDTs are prescribed in conjunction with outpatient treatment. According to the applicant, the provider does not a) pay for, b) take ownership/title over, or c) dispense Pear's prescription digital therapeutics. The provider writes a prescription which is sent to a specialty pharmacy. The specialty pharmacy is the sole entity who verifies the prescription, submits a claim to an insurer, and dispenses the product to the patient. For the reset-O®, therapy lesson content is delivered primarily via text or audio, and may include videos, animations and graphics.

Final CMS HCPCS Coding Action

Established new HCPCS Level II code A9291 effective April 1, 2022, "Prescription digital behavioral therapy, fda cleared, per course of treatment."

Requested Benefit Category

Durable Medical Equipment – section 1861(n) of the Social Security Act.

Preliminary Medicare Benefit Category Determination

No benefit category.

Durable medical equipment (DME) is defined in section 1861(n) of the Social Security Act and 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.

Digital therapies or computer software are not devices, equipment, or supplies and therefore would not fall under a DMEPOS benefit category. Whether or not the item could fall under some other Medicare benefit category can be considered, but would not be addressed under the DMEPOS BCD process.

Preliminary Medicare Payment Determination

No Medicare payment. Pricing = 00

Summary of Public Feedback

Pear Therapeutics, the manufacturer of the product, disagreed with the preliminary benefit category determination that Pear's digital behavioral therapy (DBT) devices do not meet the definition of DME. The primary speaker stated that as a threshold matter, CMS is incorrect that Pear's DBT devices are not "devices": Pear's DBTs are legally classified and authorized/cleared as medical devices under the Food, Drug, and Cosmetic Act by the FDA. Both Congress and CMS have historically deferred to the FDA on fundamental questions regarding the classification of medical technology for marketing in the U.S. Further, as medical devices, the speaker felt Pear's DBT devices met all five prongs of the regulatory definition for DME. In particular, by virtue of their digital nature, Pear's DBTs are durable because they can withstand repeated use and have a minimum lifetime of at least 3 years. Pear's DBTs also serve a medical purpose because they are cleared by the FDA with special controls to support clinically validated health claims. The software applications are not generally useful to a patient in the absence of an injury/illness because they are specifically authorized/cleared by the FDA to treat psychiatric disorders and cannot be accessed without a prescription. A commenter noted that even though a patient's smartphone used to run the DBT device may be generally useful for non-medical purposes, the smartphone's general usefulness is irrelevant in evaluating a DBT devices' general usefulness. Finally, Pear's DBTs are intended for self-administration in the home without the assistance of a healthcare professional, and thus they are appropriate for use in the home.

Final Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

We continue to believe these products falloutside the definition of DME. The durable medical equipment benefit is for equipment such as a wheelchair, hospital bed, ventilator, or oxygen concentrator rented to a patient for use in their home. Software that is run on computers would not work unless the patient also has a smartphone, computer or another type of durable device that would enable use of the software. Smartphones and computers are generally useful to individuals in the absence of illness or injury and are therefore not DME. Without the computer, the software would not work. Digital therapies or computer software are

housed on non-medical devices like smartphones or computers and the equipment and software as a whole are not DME.Whether or not the item could fall under some other Medicare benefit category can be considered, but would not be addressed under the DMEPOS BCD process.

Final Medicare Payment Determination

No Medicare DMEPOS payment. Pricing = 00

Agenda Item # 11

MiSight® 1 day - HCP210904KY8NE

Topic

Medicare Benefit Category and Payment Determination for MiSight® 1 day contact lens.

HCPCS code: V2525 “Contact lens, hydrophilic, dual focus, per lens”

Applicant’s Summary

According to information submitted CooperVision, Inc., the MiSight® 1-day (omafilcon A) soft contact lens is indicated for the correction of myopic ametropia and for slowing the progression of myopia in children, who at the initiation of treatment, are 8-12 years of age and have a refraction of -0.75 D to -4.00 D (spherical equivalent) with less than or equal to 0.75 diopters of astigmatism. The MiSight® 1-day lens employs a dual-focus design which has a central zone containing distance vision and concentric peripheral zones to provide peripheral myopic defocus. Dual focus design has multiple rings of correction zone and treatment zone. The correction zone is where the light refraction is like a traditional contact lens. It corrects the myopia so one can enjoy clear vision, just like they would in an ordinary single vision contact lens. The treatment zone provides an appropriate signal to slow down the pathologic eye growth.

Final CMS HCPCS Coding Action

Established new HCPCS Level II code V2525 effective April 1, 2022, “Contact lens, hydrophilic, dual focus, per lens.”

Requested Benefit Category

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

Preliminary Medicare Benefit Category Determination

No benefit category.

These lenses do not qualify as prosthetic devices under any of the categories for prosthetic lenses under section 120.B of chapter 15 of the Medicare Benefit Policy Manual.

Preliminary Medicare Payment Determination

No Medicare payment. Pricing = 00

Summary of Public Feedback

There were no speakers at the public meeting and no written consultation was received for this item.

Final Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

Final Medicare Payment Determination

No Medicare DMEPOS payment. Pricing = 00

Agenda Item # 12

ReWalk Personal Prosthetic Exoskeleton System – 20.085

Topic

Medicare Benefit Category and Payment Determination for ReWalk Exoskeleton System.

Temporary HCPCS code: K1007 "Bilateral hip, knee, ankle, foot device, powered, includes pelvic component, single or double upright(s), knee joints any type, with or without ankle joints any type, includes all components and accessories, motors, microprocessors, sensors"

Applicant's Summary

According to information submitted by ReWalk Robotics, the ReWalk Personal Prosthetic Exoskeleton System (ReWalk) is a wearable, motorized, computerized, personal lower body exoskeleton system with adjustable ankle joints. The ReWalk is used by individuals with lower body paralysis due to spinal cord injury (SCI) at levels T7 to L5 to restore the function of motor movement controlled by the spinal cord. The device enables individuals with SCI to stand upright and walk again. The ReWalk is placed over a patient's paralyzed or weakened limbs for the purpose of providing ambulation. Patients can control walking initiation, speed, and direction through a combination of controller commands and shifts in their body weight. The ReWalk is configured and custom fit for each patient. A personal computer is provided with the device and used for installation/configuration, upgrading and servicing of the ReWalk device. The ReWalk allows for multiple patient uses through adjustments in length and or weight to align with the patients joints. The ReWalk is programed to the patient by a trained healthcare professional. It consists of three main parts: remote control communicator, exoskeleton and control unit. The remote control communicator is a small wireless device that provides two-way communication between the user and the ReWalk unit. The remote control allows the user to select different modes and presents a visual indication of the status of the system, which includes the mode in which the device is operating (walking, standing, sitting, etc.). The exoskeleton consists of four components: the articulating legs, the pelvic band, the straps, padding, and knee bracket and the ankle-foot plate. The control unit is attached the pelvic band of the exoskeleton. The control unit consists of an outer shell and an inner compartmentalized shell with power management and computer control system components. The main battery is a lithium-ion battery that is capable of allowing the patient to walk continuously for more than three hours on a charge. The ReWalk must be used with supervision of a specially trained companion.

Final CMS HCPCS Coding Action

Established new HCPCS Level II code K1007 effective October 1, 2020, "Bilateral hip, knee, ankle, foot device, powered, includes pelvic component, single or double upright(s), knee joints any type, with or without ankle joints any type, includes all components and accessories, motors, microprocessors, sensors."

Requested Benefit Category

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

Preliminary Medicare Benefit Category Determination

No determination.

More time is needed to evaluate this complex issue related to the scope of the benefit for artificial legs and arms. We will be providing more information on this topic in the near future. In the meantime, coverage and payment for these items will be made at the discretion of the MACs.

Preliminary Medicare Payment Determination

No determination.

Summary of Public Feedback

ReWalk Robotics, the manufacturer of the ReWalk product, believes the device acts as artificial legs and meets the Medicare definition of prosthetic device. The manufacturer believes that the device replaces the function of the spinal cord and also restores all or part of the function of otherwise inoperative legs. The company indicated that the device is not a brace.

Final Medicare Benefit Category Determination

No determination. More time is needed to evaluate this complex issue related to the scope of the benefit for artificial legs and arms. We will be providing more information on this topic in the near future. In the meantime, coverage and payment for these items will be made at the discretion of the MACs.

Final Medicare Payment Determination

No determination.

Agenda Item # 13

MyoPro® – 18.118

Topic

Medicare Benefit Category and Payment Determination for MyoPro® devices.

HCPCS code: L8701 "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"

Applicant's Summary

According to information submitted by Myomo, Inc., the MyoPro® is a wearable, motorized, microprocessor controlled, elbow-wrist-hand device used for patients suffering from complications of stroke or other neurological/neuromuscular injury and illness. The MyoPro® Motion E is an elbow-wrist-hand device that has one degree of freedom and a fixed wrist joint. The MyoPro® Motion W is an elbow-wrist-hand device that has one degree of freedom and a multi-articulating wrist joint. Motion E and Motion W cover the upper end of the humerus to the palm of the hand. Common components are upper-arm shell, harness attachment, upper-arm sensor cuff, upper arm closure, battery compartment, forearm closure, forearm bar, forearm shell, control panel, elbow motor, wrist joint (fixed or flexion), and hand support shell. The wrist and hand shells are attached by a rigid wrist extension and is at a fixed angle. The entire device for Motion E and Motion W utilizes a single rigid metal upright linking all components to the joints into a single device. Straps and padding are used to anchor the device to the patient's upper extremity. Both models have two replaceable batteries with charging stand, circuit board, and a motor mounted at the elbow joint, permitting microprocessor mediated, volitionally controlled, elbow flexion and extension. Patients can also use a laptop with software-based, settings-control interface accessed through wireless connectivity to adjust the input settings/sensitivity in real-time when needed. Patients use their muscle signals to control movements of a paretic or weakened limb. When the patient tries to bend the arm, precision sensors in the brace detect the weak muscle signals which activate motors to move the arm in the desired directions. The surface EMG sensors continuously monitors and senses, but does not stimulate, the patient's muscles. The MyoPro® filters and processes the EMG signal, and translates this information into motor movement. The power assist moves the motor with speed proportional to patient's exertion. The direction of motion is determined by which set of sensors are triggered. A microprocessor amplifies the acquired signal to power electric motors to initiate and complete desired movement in the elbow. The primary purpose of the MyoPro® is to assist upper extremity joint motion in a weakened body member to improve the beneficiary's functional activities of daily living.

Final CMS HCPCS Coding Action

Established new HCPCS Level II code L8701 effective January 1, 2019, "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."

Requested Benefit Category

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

Preliminary Medicare Benefit Category Determination

No determination.

More time is needed to evaluate this complex issue related to the scope of the benefit for leg and arm braces. We will be providing more information on this topic in the near future. In the meantime, coverage and payment for these items will be made at the discretion of the MACs.

Preliminary Medicare Payment Determination

No determination.

Summary of Public Feedback

Certified orthotists/prosthetists who disclosed that they are paid consultants for Myomo, Inc, the manufacturer of the device, as well as the ITEM Coalition indicated that the device is rigid and supports a weak arm and prevents catastrophic buckling and therefore meets the Medicare definition of brace.

Final Medicare Benefit Category Determination

No determination. More time is needed to evaluate this complex issue related to the scope of the benefit for artificial legs and arms. We will be providing more information on this topic in the near future. In the meantime, coverage and payment for these items will be made at the discretion of the MACs.

Final Medicare Payment Determination

No determination.

Agenda Item # 13

MyoPro® – 18.118

Topic

Medicare Benefit Category and Payment Determination for MyoPro® devices.

HCPCS code: L8702 "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"

Applicant's Summary

According to information submitted by Myomo, Inc., the MyoPro® is a wearable, motorized, microprocessor controlled, elbow-wrist-hand-finger device used for patients suffering from complications of stroke or other neurological/neuromuscular injury and illness. The MyoPro® Motion G is an elbow-wrist-hand-finger device that has two degrees of freedom and a multi-articulating wrist joint. Common components are upper-arm shell, harness attachment, upper-arm sensor cuff, upper arm closure, battery compartment, forearm closure, forearm bar, forearm shell, control panel, elbow motor, wrist joint, hand motor and hand support shell. The wrist and hand shells are attached by a rigid wrist extension and is at a fixed angle. The entire device for utilizes a single rigid metal upright linking all components to the joints into a single device. Straps and padding are used to anchor the device to the patient's upper extremity. This device has two replaceable batteries with charging stand, circuit board, and a motor mounted at the elbow joint, permitting microprocessor mediated, volitionally controlled, elbow flexion and extension. Patients can also use a laptop with software-based, settings-control interface accessed through wireless connectivity to adjust the input settings/sensitivity in real-time when needed. Patients use their muscle signals to control movements of a paretic or weakened limb. When the patient tries to bend their arm, or open and close their hand, precision sensors in the brace detect the weak muscle signals which activate motors to move the hand and arm in the desired directions. The surface EMG sensors continuously monitors and senses, but does not stimulate, the patient's muscles. The MyoPro® filters and processes the EMG signal, and translates this information into motor movement. The power assist moves the motor with speed proportional to patient's exertion. The direction of motion is determined by which set of sensors are triggered. A microprocessor amplifies the acquired signal to power electric motors to initiate and complete desired movement in the elbow and fingers. The primary purpose of the MyoPro® is to assist upper extremity joint motion in a weakened body member to improve the beneficiary's functional activities of daily living.

Final CMS HCPCS Coding Action

Established new HCPCS Level II code L8701 effective January 1, 2019, "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."

Requested Benefit Category

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

Preliminary Medicare Benefit Category Determination

No determination.

More time is needed to evaluate this complex issue related to the scope of the benefit for leg and arm braces. We will be providing more information on this topic in the near future. In the meantime, coverage and payment for these items will be made at the discretion of the MACs.

Preliminary Medicare Payment Determination

No determination.

Summary of Public Feedback

Certified orthotists/prosthetists who disclosed that they are paid consultants for Myomo, Inc, the manufacturer of the device, as well as the ITEM Coalition indicated that the device is rigid and supports a weak arm and prevents catastrophic buckling and therefore meets the Medicare definition of brace.

Final Medicare Benefit Category Determination

No determination. More time is needed to evaluate this complex issue related to the scope of the benefit for artificial legs and arms. We will be providing more information on this topic in the near future. In the meantime, coverage and payment for these items will be made at the discretion of the MACs.

Final Medicare Payment Determination

No determination.

Agenda Item # 14

Continuous Glucose Monitor (CGM) – HCP220201FMV4A

Topic

Request to revise existing Continuous Glucose Monitor (CGM) and related supply and accessory HCPCS Level II codes K0553, K0554, A4238 and E2102 and a discussion of adjunctive CGM pricing.

Applicant's suggested language:

1. K0553, which currently reads "Supply allowance for therapeutic continuous glucose monitor (cgm), includes all supplies and accessories, 1 month supply = 1 unit of service" to A423X, to instead read "Supply allowance for non-adjunctive, non-implanted continuous glucose monitor (cgm), includes all supplies and accessories, 1 month supply = 1 unit of service"

2. K0554, which currently reads "Receiver (monitor), dedicated, for use with therapeutic glucose continuous monitor system" to E210X, to instead read "Non-adjunctive, non-implanted continuous glucose monitor or receiver"

3. A4238, which currently reads "Supply allowance for adjunctive continuous glucose monitor (cgm), includes all supplies and accessories, 1 month supply = 1 unit of service" to instead read "Supply allowance for adjunctive, non-implanted continuous glucose monitor (cgm), includes all supplies and accessories, 1 month supply = 1 unit of service"

4. E2102, which currently reads "Adjunctive continuous glucose monitor or receiver" to instead read "Adjunctive, non-implanted continuous glucose monitor or receiver"

Applicant's Summary

On December 28, 2021, the Centers for Medicare & Medicaid Services (CMS) published a final rule in the Federal Register entitled "Medicare Program; Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Policy Issues, and Level II of the Healthcare Common Procedure Coding System (HCPCS); DME Interim Pricing in the CARES Act; Durable Medical Equipment Fee Schedule Adjustments to Resume the Transitional 50/50 Blended Rates to Provide Relief in Rural Areas and Non-Contiguous Areas" (86 FR 73860) that addressed the classification and payment of continuous glucose monitors (CGMs) under the Medicare Part B benefit for durable medical equipment (DME). The final rule can be downloaded at: https://www.federalregister.gov/documents/2021/12/28/2021-27763/medicare-program-durable-medical-equipment-prosthetics-orthotics-and-supplies-dmepos-policy-issues.

This rule expanded the classification of DME to a larger group of CGMs regardless of whether the CGMs are non-adjunctive (can alert patients when glucose levels are approaching dangerous levels, including while they sleep and also replace blood glucose monitors) or adjunctive (can alert patients when glucose levels are approaching dangerous levels, including while they sleep but do not replace blood glucose monitors), as long as the CGMs satisfy the regulatory definition of DME. As such, adjunctive CGMs and related

supplies and accessories with dates of service on or after the effective date of the final rule, February 28, 2022, can now be covered under the Part B DME benefit category when the system meets the DME definition.

Preliminary CMS HCPCS Coding Recommendations

1. Revise existing HCPCS Level II code K0553, which currently reads "Supply allowance for therapeutic continuous glucose monitor (cgm), includes all supplies and accessories, 1 month supply = 1 unit of service" to A423X, to instead read "Supply allowance for non-adjunctive, non-implanted continuous glucose monitor (cgm), includes all supplies and accessories, 1 month supply = 1 unit of service"

2. Revise existing HCPCS Level II code K0554, which currently reads "Receiver (monitor), dedicated, for use with therapeutic glucose continuous monitor system" to E210X, to instead read "Non-adjunctive, non-implanted continuous glucose monitor or receiver"

3. Revise existing HCPCS Level II code A4238, which currently reads "Supply allowance for adjunctive continuous glucose monitor (cgm), includes all supplies and accessories, 1 month supply = 1 unit of service" to instead read "Supply allowance for adjunctive, non-implanted continuous glucose monitor (cgm), includes all supplies and accessories, 1 month supply = 1 unit of service"

4. Revise existing HCPCS Level II code E2102, which currently reads "Adjunctive continuous glucose monitor or receiver" to instead read "Adjunctive, non-implanted continuous glucose monitor or receiver"

Effective: 10/1/2022

Code A4238 "Supply allowance for adjunctive continuous glucose monitor (cgm), includes all supplies and accessories, 1 month supply = 1 unit of service" was added to the HCPCS file effective 4/1/22 to identify one month of adjunctive CGM supplies and accessories. Code E2102 "Adjunctive continuous glucose monitor or receiver" was added to the HCPCS file effective 4/1/22 to identify adjunctive CGM receivers. This request revises the descriptor of A4238 and E2102 to add "non-implanted" to clarify intended use. Implantable CGMs have no durable component, cannot withstand repeated use because they are totally implanted, single patient use devices, and are paid for incident to the implantation procedure. Implantable CGMs therefore do not fall under the Medicare benefit for durable medical equipment and cannot be billed as such; implantable CGMs are typically covered by Medicare under an outpatient benefit, such as Hospital Outpatient. We have heard from providers and suppliers that there is confusion among some payers with regard to whether these codes applied to implantable CGMs, and thus, these coding changes are intended to resolve that confusion.

We are also making conforming changes to the existing K0553 and K0554 codes to revise the code descriptors and to convert them to "A" and "E" codes. These changes include adding "non-implanted" to the code descriptor.

Lastly, we seek feedback on the 4/1/2022 coverage indicator change for the following codes that made them invalid for Medicare use: A9276 "Sensor; invasive (e.g., subcutaneous),

disposable, for use with interstitial continuous glucose monitoring system, one unit = 1 day supply; A9277 Transmitter; external, for use with interstitial continuous glucose monitoring system; and A9278 Receiver (monitor); external, for use with interstitial continuous glucose monitoring system.

Medicare Benefit Category Determination

Durable Medical Equipment

Preliminary Medicare Payment Determination

There is a substantial difference in the utility and capabilities of adjunctive CGMs versus non-adjunctive CGMs. Non-adjunctive CGMs are able to: A) alert the patient about dangerous glucose levels while they sleep; and B) replace the use of a blood glucose monitor (BGM) for accurate glucose measuring/testing purposes. Adjunctive CGMs are able to alert the patient about potentially dangerous glucose levels while they sleep, but the CGM results must be verified by a BGM and all other glucose measuring and testing must be performed by a separate BGM. Because the combination of using an adjunctive CGM (A) and a separate BGM (B) are comparable to the services provided by a non-adjunctive CGM (A + B), the fee schedule amounts for the adjunctive CGM and related supplies can be established using the existing fee schedule amounts for non-adjunctive CGMs and related supplies reduced by the amounts paid separately for the BGM and related supplies. The combination of payments made for the adjunctive CGM and related supplies and BGM and related supplies is then equal to the payments made for the non-adjunctive CGM and related supplies, which performs the functions of both of these separate items.

At this time, we are only aware of class III adjunctive CGMs. Claims for class III DME items are identified using the HCPCS modifier KF. Payment for the monthly CGM supplies used with an FDA Class III adjunctive CGM, described by the HCPCS code and modifier combination of A4238KF, would be established using the fee schedule amounts for the monthly CGM supplies used with an FDA Class III non-adjunctive CGM, described by the HCPCS code and modifier combination of K0553KF minus the average monthly payment for BGM supplies for insulin-treated beneficiaries with diabetes, which according to our November 4, 2020 proposed rule (85 FR 70403) was $34.35 in 2020. Updated to 2022 using the former Competitive Bidding Area update factors of 0.6% (2021) and 5.0% (2022), the average 2022 monthly payment for BGM supplies for insulin-treated beneficiaries with diabetes is $36.29. This calculation is represented below and results in a 2022 monthly fee schedule amount for A4238KF of $236.68:

K0553KF ($272.97) – $36.29 (average monthly payment for BGM supplies for insulin-treated beneficiary with diabetes) = A4238KF ($236.68)

As discussed in the final rule, the fee schedule amounts for the non-adjunctive CGM receiver (K0554KF) were established using the average reasonable charge data for blood glucose monitors from 1986 and 1987, updated to the current year using the Class III update factors. We are establishing lower receiver fees for adjunctive CGMs in accordance with our gap-filling regulations since the adjunctive monitor does not replace the functions of a blood glucose monitor. Payment for the Class III adjunctive CGM receiver, described by the HCPCS code and modifier combination of E2102KF, would be established using the 2022 Class III fee schedule amounts for the non-adjunctive receiver, code K0554KF, minus the

2022 fee schedule amounts for the home blood glucose monitor (E0607). This calculation is represented below and results in an average 2022 purchase fee schedule amount for E2102KF of $195.66:

K0554KF (average of $278.06) – E0607 (average of $82.39) = E2102KF (average of $195.66)

The 2022 monthly fee schedule amount for A4238KF would be $236.68.

The average 2022 purchase fee schedule amount for E2102KF would be approximately $195.66.

Effective 10/1/2022

Summary of Public Feedback

Medtronic, Inc., a manufacturer of adjunctive CGM sensors and transmitters that work in conjunction with Medtronic brand insulin infusion pumps that also function as an adjunctive CGM receiver believes HCPCS codes A9276, A9277, and A9278 should be made valid for Medicare so that payers secondary to Medicare that use these codes can receive Medicare denied claims for these codes for secondary payer purposes. Other commenters also recommended that the conversion of existing K codes K0553 and K0554 to permanent A and E codes, respectively, should be delayed until January 1, 2023, to allow time for the updating of billing software and instructions. Finally, the manufacturer pointed out that payment for the blood glucose monitor (BGM) function of accurate glucose monitoring has been backed out of both the preliminary fee schedule amounts for the adjunctive CGM receiver (HCPCS code E2102) and the preliminary fee schedule amounts for the monthly supplies for the adjunctive CGM receiver (HCPCS code A4238). Medtronic, Inc., recommended that the error be addressed by not backing out the payment for the BGM function from the payment for the adjunctive CGM receiver code E2102.

Final Medicare Benefit Category Determination

Durable Medical Equipment.

CMS Final HCPCS Coding Decision[3]

1. Revise existing K0553, “Supply allowance for therapeutic continuous glucose monitor (cgm), includes all supplies and accessories, 1 month supply = 1 unit of service” to read: A4239, “Supply allowance for non-adjunctive, non-implanted continuous glucose monitor (cgm), includes all supplies and accessories, 1 month supply = 1 unit of service”

2. Revise existing K0554, “Receiver (monitor), dedicated, for use with therapeutic glucose continuous monitor system” to read: E2103, “Non-adjunctive, non-implanted continuous glucose monitor or receiver”

3. Revise A4238, “Supply allowance for adjunctive continuous glucose monitor (cgm), includes all supplies and accessories, 1 month supply = 1 unit of service” to read: A4238,

[3] Revised November 2, 2022 to add the HCPCS Level II coding changes that are to become effective January 1, 2023.

"Supply allowance for adjunctive, non-implanted continuous glucose monitor (cgm), includes all supplies and accessories, 1 month supply = 1 unit of service"

4. Revise E2102, "Adjunctive continuous glucose monitor or receiver" to read: E2102, "Adjunctive, non-implanted continuous glucose monitor or receiver"

5. Change the administrative fields for A9276, A9277 and A9278 from coverage = "I" to "S" with a citation to 1861(n) and revise the descriptors to read:

   A9276, "Sensor; invasive (e.g., subcutaneous), disposable, for use with non-durable medical equipment interstitial continuous glucose monitoring system, one unit = 1 day supply"

   A9277, "Transmitter; external, for use with non-durable medical equipment interstitial continuous glucose monitoring system"

   A9278, "Receiver (monitor); external, for use with non-durable medical equipment interstitial continuous glucose monitoring system"

Effective January 1, 2023

Final Medicare Payment Determination

In response to the public comment regarding codes A9276, A9277, and A9278, these codes were used previously for claims for adjunctive CGMs and related supplies that were not classified as DME. Now that both non-adjunctive and adjunctive CGMs are classified as DME, the only items that might be billed under these codes for the purpose of receiving Medicare denial notices would be sensors (A9276) and transmitters (A9277) used with items that are not classified as DME such as a smartphone used as a CGM receiver (A9278). We therefore agree with the public comment to make codes A9276, A9277, and A9278 valid for Medicare for billing non-DME CGM items for the purpose of receiving Medicare denials. Effective January 1, 2023, the descriptors for codes A9276, A9277, and A9278 will be revised to read as follows:

> A9276 Sensor; invasive (e.g., subcutaneous), disposable, for use with non-durable medical equipment interstitial continuous glucose monitoring system, one unit = 1 day supply
> A9277 Transmitter; external, for use with non-durable medical equipment interstitial continuous glucose monitoring system
> A9278 (Receiver (monitor); external, for use with non-durable medical equipment interstitial continuous glucose monitoring system)

The proposed code descriptor changes for codes K0553, K0554, A4238, and E2102 as well as the conversion of codes K0553 and K0554 to A and E codes, respectively, will be finalized and the effective date delayed until January 2023, as commenters suggested, to allow time for billing software and procedures to be updated to reflect the changes to the HCPCS.

The monthly fee schedule amounts for code A4238 will be adjusted (increased) so that payment for the BGM function is not backed out of the payment for the adjunctive CGM system twice, as the public comment noted. Since the BGM function is performed by the

non-adjunctive CGM receiver and is absent from the adjunctive CGM receiver, the payment for the adjunctive CGM receiver should not include payment for the BGM function it does not perform. This will result in an increase in the monthly fee schedule amounts for code A4238KF of approximately $4 from approximately $236.68 to $240.98.

June 9, 2022 Meeting Agenda Items

Agenda Item # 1

Automated Lateral Turning System - HCP211220VECUE

Topic/Issue

Request to establish a new HCPCS Level II code to identify Automated Lateral Turning System.

Applicant's suggested language: XXXXX, "Automated lateral turning system: positioned beneath patient's mattress"

Applicant's Summary

Frontier Therapeutics submitted a request to establish a new HCPCS Level II code to identify Toto automated lateral turning system. Toto is an automated lateral turning system consisting of a digital control unit and platform which is fitted beneath the patient's mattress. Toto effectively is designed to reposition the patient to an angle of approximately 30 degrees at regular intervals and thus reduce the risk of pressure damage to at risk patients. It works by tilting the patient from side to side using discreet inflatable air cells; evenly, smoothly, and consistently even while they are sleeping. Toto is suitable for the following patient types: Weighing up to 250kg (551 lbs.), who are unable to change their position without assistance, identified as requiring regular repositioning and are non-compliant with manual turning. Toto supports the National Pressure Ulcer Advisory Panel guideline recommendations and is also designed to help reduce the risk of personal injury to patient and caregiver. The platform is controlled by a touch-control unit, which allows the platform to work automatically, turning the patient at regular intervals that can be set for the individual patient. Toto platform is positioned beneath the patient's mattress.

Preliminary CMS HCPCS Coding Recommendation

Establish new HCPCS Level II code EXXXX, "Powered pressure reducing underlay/pad, alternating, with pump, includes heavy duty"

Preliminary Medicare 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 Toto System 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 EXXXX, for this particular device, is to establish the fee schedule amounts using existing fee schedule amounts for comparable items described by HCPCS code E0181.

The Toto device can provide pressure relief to patients similar to devices under E0181. Toto uses inflatable air cells that inflate and deflate at set alternating intervals that are controlled by a control unit and pump similar to devices under E0181.

	E0181	Toto
Physical Components	Goes on top of a mattress Air cells or chambers	Goes underneath a mattress Air cells or chambers
Mechanical and Electrical Components	Air pump or blower	Air pump or blower
Function and Intended Use	Provide pressure relief to patients by sequential alternating inflation and deflation of air cells on top of a mattress Air pressure can produce patient lift	Provide pressure relief to patients by sequential alternating inflation and deflation of air cells underneath a mattress Air pressure can produce patient lift
Additional Aspects and Features	Could assist with adjustments of positioning a patient	Assists with adjustments of positioning a patient

The average 2022 fee schedule amount for EXXXX would be $22.78. Payment for the equipment would be made on a capped rental basis, if covered.

Pricing = 36

Summary of Public Feedback

CMS received written comment from the applicant in support of the published preliminary HCPCS coding recommendation to establish a new HCPCS Level II code to identify the Automated Lateral Turning System.

CMS Final HCPCS Coding Decision

We appreciate the written comment provided in response to CMS' published preliminary recommendation. Based on the information provided in the application to establish a new HCPCS Level II code, and after consideration of the applicant's written comment, CMS is finalizing its preliminary recommendation to:

Establish new HCPCS Level II code E0183, "Powered pressure reducing underlay/pad, alternating, with pump, includes heavy duty"

Final Medicare Benefit Category Determination

Durable Medical Equipment

Final 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 payment determination for code E0183 is to establish the fee schedule amounts using existing fee schedule amounts for comparable items described by HCPCS code E0181.

The average 2022 fee schedule amount for E0183 would be $22.78. Payment for the equipment would be made on a capped rental basis, if covered.

Pricing = 36

Agenda Item # 2

Doula Birth Worker - HCP211001WRVXM

Topic/Issue

Request to establish a new HCPCS Level II code to identify Doula birth worker.

Applicant's suggested language: XXXXX, "Doula birth worker attendance at labor and delivery"

Applicant's Summary

Maryland Department of Health submitted a request to establish a new HCPCS Level II code to identify doula birth worker attendance at labor and delivery. This code would cover birth worker attendance and services during birth, whether vaginal or caesarian, live or stillbirth. Services provided during labor and delivery may include emotional support as well as physical comfort measures to the individual and their partner while giving birth that are not clinical interventions. This service can only be conducted while a qualifying attending provider (e.g., Obstetrician-Gynecologist, Family Medicine Practitioner, or Certified Nurse Midwife) is also in attendance during the birthing process. Many states are now reimbursing doula birth workers through Medicaid for physical, emotional and psychosocial support throughout the perinatal period. However, codes used in other states for attendance at labor and delivery, such as CPT® codes 59400 and 59409 are obstetric codes meant to be used by clinical provider types while CPT® codes 99199 and 99499 are unlisted codes meant to capture other medical services or evaluation by physicians. Upon further analysis of HCPCS codes, Maryland was unable to find a suitable code that adequately captures the function of this service without making substantial coding edits to accommodate this new provider type and will be using a home-grown HCPCS code in the interim while requesting a new code be created as more states seek to reimburse this service.

Preliminary CMS HCPCS Coding Recommendation

Establish the following two new HCPCS Level II codes:

1. TXXXX, "Services performed by a doula birth worker, per 15 minutes"
2. TXXXX, "Services performed by a doula birth worker, per diem"

From prior experience, Medicaid agencies have indicated interest in options to make payment using per diem and time-based codes. Individual state Medicaid agencies have the flexibility to further define doula birth worker services by assigning one or more state defined HCPCS modifiers in the U1 through U9 series.

Summary of Public Feedback

Maryland Department of Health respectfully declined the opportunity to present at the public meeting, as they commented that they were in agreement with CMS' HCPCS preliminary recommendation to establish two new HCPCS Level II codes.

CMS Final HCPCS Coding Decision

We appreciate the comment provided in response to CMS' published preliminary recommendation. Based on the information provided in the application to establish a new HCPCS Level II code, and after consideration of the applicant's comment, CMS is finalizing its preliminary recommendation to:

Establish the following two new HCPCS Level II codes:

1. T1032, "Services performed by a doula birth worker, per 15 minutes"

2. T1033, "Services performed by a doula birth worker, per diem"

Agenda Item # 3

PermeaDerm B - HCP210922AG6K1

Topic/Issue

Request to establish a new HCPCS Level II code to identify PermeaDerm B.

Applicant's suggested language: QXXXX, "PermeaDerm B, per sq cm"

Applicant's Summary

Stedical Scientific submitted a request to establish a new HCPCS Level II code to identify PermeaDerm B, as there is currently no HCPCS code that describes this product. PermeaDerm B is an FDA 510(k) cleared biosynthetic wound covering. PermeaDerm B is intended for use as a wound covering and to provide a moist wound healing environment on cleanly prepared wounds after hemostasis has been established. PermeaDerm B is indicated for partial thickness burn wounds, donor sites and coverage of meshed autograft. PermeaDerm B is comprised of an adherent and transparent monofilament nylon knitted fabric that is bonded to a thin, slitted, silicone membrane. PermeaDerm B contains physical slits that are configured to create pores (similar to human skin) when the product is stretched. The nylon side is coated with a mixture of USP Pharmaceutical Grade hypoallergenic porcine gelatin and a pure fraction of Aloe Vera. PermeaDerm B contains 2,280 parallel slits per square foot. PermeaDerm B is supplied in 5 x 10, 10 x 15 or 15 x 30-inch sheets. Key characteristics of PermeaDerm B include transparency, porosity, strength, stretchability and stability, all qualities which are essential for healing. PermeaDerm B is applied to a prepared wound and covered with any clinician chosen secondary absorbent outer dressing.

Preliminary CMS HCPCS Coding Recommendation

Establish new HCPCS Level II code AXXXX, "Permeaderm b, per square centimeter"

In accordance with HCPCS Level II codes CMS effectuated for similarly situated products in 2022 and the Calendar Year 2022 Physician Fee Schedule Final Rule (86 FR 64996), Medicare payment for this product will be determined by the Medicare Administrative Contractors.

Summary of Public Feedback

CMS received written comment on behalf of the manufacturer in support of the published preliminary HCPCS coding recommendation to establish a new HCPCS Level II code to identify PermeaDerm B.

CMS Final HCPCS Coding Decision

We appreciate the written comment provided in response to CMS' published preliminary recommendation. Based on the information provided in the application to establish a new HCPCS Level II code, and after consideration of the applicant's written comment, CMS is finalizing its preliminary recommendation to:

Establish new HCPCS Level II code A2016, “Permeaderm b, per square centimeter” to describe PermeaDerm B.

In accordance with HCPCS Level II codes CMS effectuated for similarly situated products in 2022 and the Calendar Year 2022 Physician Fee Schedule Final Rule (86 FR 64996), Medicare payment for this product will be determined by the Medicare Administrative Contractors.

Agenda Item # 3

PermeaDerm Glove - HCP210922ABGQC

Topic/Issue

Request to establish a new HCPCS Level II code to identify the PermeaDerm Glove.

Applicant's suggested language: QXXXX, "PermeaDerm Glove, each"

Applicant's Summary

Stedical Scientific submitted a request to establish a new HCPCS Level II code to identify the PermeaDerm Glove, as there is currently no HCPCS code that describes this product. The PermeaDerm Glove is intended for use as a wound covering and to provide a moist wound healing environment on cleanly prepared wounds after hemostasis has been established. The PermeaDerm Glove is indicated for debrided partial thickness hand burns. The PermeaDerm Glove is an FDA 510(k) cleared biosynthetic wound covering that is comprised of an adherent and transparent monofilament nylon knitted fabric that is bonded to a thin, slitted, silicone membrane. The PermeaDerm Glove has physical slits that are configured to create pores (similar to human skin) when the product is stretched. The nylon side of this wound covering is coated with a mixture of USP Pharmaceutical Grade hypoallergenic porcine gelatin and a pure fraction of aloe vera. The PermeaDerm Glove is available in sizes extra small to extra-large. Key characteristics of the PermeaDerm Glove include transparency, porosity, strength, stretchability and stability, all qualities which are essential for healing. The PermeaDerm Glove is applied to a prepared wound and covered with any clinician chosen secondary absorbent outer dressing.

Preliminary CMS HCPCS Coding Recommendation

Establish new HCPCS Level II code AXXXX, "Permeaderm glove, each"

In accordance with HCPCS Level II codes CMS effectuated for similarly situated products in 2022 and the Calendar Year 2022 Physician Fee Schedule Final Rule (86 FR 64996), Medicare payment for this product will be determined by the Medicare Administrative Contractors.

Summary of Public Feedback

CMS received written comment on behalf of the manufacturer in support of the published preliminary HCPCS coding recommendation to establish a new HCPCS Level II code to identify PermeaDerm Glove.

CMS Final HCPCS Coding Decision

We appreciate the written comment provided in response to CMS' published preliminary recommendation. Based on the information provided in the application to establish a new HCPCS Level II code, and after consideration of the applicant's written comment, CMS is finalizing its preliminary recommendation to:

Establish new HCPCS Level II code A2017, “Permeaderm glove, each” to describe the PermeaDerm Glove.

In accordance with HCPCS Level II codes CMS effectuated for similarly situated products in 2022 and the Calendar Year 2022 Physician Fee Schedule Final Rule (86 FR 64996), Medicare payment for this product will be determined by the Medicare Administrative Contractors.

Agenda Item # 3

PermeaDerm C - HCP210922MBCG1

Topic/Issue

Request to establish a new HCPCS Level II code to identify PermeaDerm C.

Applicant's suggested language: QXXXX, "PermeaDerm C, per sq cm"

Applicant's Summary

Stedical Scientific submitted a request to establish a new HCPCS Level II code to identify PermeaDerm C, as there is currently no HCPCS code that describes this product. PermeaDerm C is intended for use as a wound covering and to provide a moist wound healing environment on cleanly prepared wounds after hemostasis has been established. PermeaDerm C is indicated for partial thickness wounds, pressure sores, venous ulcers, diabetic ulcers, chronic vascular ulcers, surgical wounds (donor sites/grafts, post-Mohs, post-laser surgery, podiatric, wound dehiscence, trauma wounds (abrasions, lacerations, second-degree burns, and skin tears) and draining wounds. PermeaDerm C is an FDA 510(k) cleared biosynthetic wound covering that is comprised of an adherent and transparent monofilament nylon knitted fabric that is bonded to a thin, slitted, silicone membrane. PermeaDerm C contains physical slits that are configured to create pores (similar to human skin) when the product is stretched. The nylon side is coated with a mixture of USP Pharmaceutical Grade hypoallergenic porcine gelatin and a pure fraction of Aloe Vera. PermeaDerm C has 4,464 slits per square foot, which are parallel and perpendicular in orientation. PermeaDerm C is supplied in 5 x 5-inch sheets. Key characteristics of PermeaDerm C include transparency, porosity, strength, stretchability and stability, all qualities which are essential for healing. PermeaDerm C is applied to a prepared wound and covered with any clinician chosen secondary absorbent outer dressing.

Preliminary HCPCS Coding Recommendation

Upon review of the information submitted with this application, the applicant submitted a 510(k) clearance from the FDA without PermeaDerm C listed. CMS has determined that all device listings should include all of the current proprietary names that are used to market the devices in the United States. As a result, CMS is denying the request to establish a new HCPCS Level II code to identify PermeaDerm C. The applicant is encouraged to review the FDA's requirements for device distributions in the United States. The applicant is welcome to submit a new HCPCS Level II coding application in a subsequent coding cycle.

Summary of Public Feedback

CMS received written comment on behalf of the manufacturer in support of the published preliminary HCPCS coding recommendation and appreciated CMS' review of their request to establish a new HCPCS Level II code for PermeaDerm C. Stedical Scientific stated the company has added the trade name "PermeaDerm C" to the FDA device listing registration.

CMS Final HCPCS Coding Decision

We appreciate the written comment provided in response to CMS' published preliminary recommendation. CMS has verified that PermeaDerm C has been added to the FDA device listing registration for the 510(k) clearance. As a result, CMS is revising its preliminary recommendation and finalizing the decision to:

Establish new HCPCS Level II code A2018, "Permeaderm c, per square centimeter" to describe PermeaDerm C.

In accordance with HCPCS Level II codes CMS effectuated for similarly situated products in 2022 and the Calendar Year 2022 Physician Fee Schedule Final Rule (86 FR 64996), Medicare payment for this product will be determined by the Medicare Administrative Contractors.

Agenda Item # 4

PHOENIX Wound Matrix - HCP211231RA6TG

Topic/Issue

Request to establish a new HCPCS Level II code to identify PHOENIX Wound Matrix.

Applicant's suggested language: XXXXX, "Resorbable synthetic graft per square cm"

Applicant's Summary

Nanofiber Solutions, LLC submitted a request to establish a new HCPCS Level II code to identify PHOENIX Wound Matrix, which is a sterile, 3D electrospun synthetic polymer matrix. Comprised of two non-woven bioresorbable synthetic polymers, polyglycolic acid (PGA) and polylactide-co-caprolactone (PLCL), PHOENIX Wound Matrix is designed to provide scaffold support for cellular migration, adherence, and proliferation for tissue regeneration and repair of acute and chronic wounds and burns. PHOENIX Wound Matrix is indicated for the management of partial to full thickness acute and chronic wounds, and burns including; pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds (donor sites/grafts, post-Mohs surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, second-degree burns, skin tears) and draining wounds. PHOENIX Wound Matrix ranges in size from a 16mm disc to a 20 x 10cm sheet, providing flexibility in product selection to minimize the risk of product waste. After thorough debridement, PHOENIX Wound Matrix is used as a synthetic graft/skin substitute, placed within the confines of the wound environment to support wound healing. PHOENIX Wound Matrix acts as a protective barrier and persists within the wound environment until it completely degrades via hydrolysis, within 7-14 days. It is not meant to be removed. PHOENIX Wound Matrix should be reapplied every 7-14 days, or as clinically necessary, following the appropriate preparation and application steps along with best-practice standard of care for wound management. PHOENIX Wound Matrix is intended to be used as clinically necessary for wound healing and can be used from the wound onset through to wound closure. PHOENIX Wound Matrix is packaged as a sterile, single-use product, within an inner protective pouch, packaged in a shelf box. 1 matrix per pouch/box.

Preliminary CMS HCPCS Coding Recommendation

Establish new HCPCS Level II code AXXXX, "Phoenix wound matrix, per square centimeter"

In accordance with HCPCS Level II codes CMS effectuated for similarly situated products in 2022 and the Calendar Year 2022 Physician Fee Schedule Final Rule (86 FR 64996), Medicare payment for this product will be determined by the Medicare Administrative Contractors.

Summary of Public Feedback

The primary speaker agreed with CMS' published preliminary HCPCS coding recommendation to establish a new HCPCS Level II code to identify the PHOENIX Wound Matrix.

CMS Final HCPCS Coding Decision

We appreciate the comments provided in response to CMS' published preliminary recommendation. Based on the information provided in the application to establish a new HCPCS Level II code, and after consideration of the comments we received, CMS is finalizing its preliminary recommendation to:

Establish new HCPCS Level II code A2015, "Phoenix wound matrix, per square centimeter" to describe the PHOENIX Wound Matrix.

In accordance with HCPCS Level II codes CMS effectuated for similarly situated products in 2022 and the Calendar Year 2022 Physician Fee Schedule Final Rule (86 FR 64996), Medicare payment for this product will be determined by the Medicare Administrative Contractors.

Agenda Item # 5

Omeza® Collagen Matrix - HCP210930GLM48

Topic/Issue

Request to establish a new HCPCS Level II code to identify Omeza® Collagen Matrix.

Applicant's suggested language: QXXXX, "Omeza® Collagen Matrix per 1.6g"

Applicant's Summary

Omeza LLC submitted a request to establish a new HCPCS Level II code to identify Omeza® Collagen Matrix. Name/Description: Omeza® Collagen Matrix is an anhydrous acellular matrix comprised of hydrolyzed fish collagen infused with cod liver oil and other plant-derived oils and waxes. Function: Omeza® Collagen Matrix's primary intended clinical purpose is to support the critical phases of wound healing by delivering diverse collagen types in an anhydrous carrier that creates a conforming physical collagen microstructure at the wound site for cellular migration and wound revascularization. It softens and spreads at body temperature, creating a three-dimensional microstructural framework that conforms with surface tissues within the wound bed. Over time, the patient's cells replace the acellular matrix with a native extracellular matrix, and the hydrolyzed fish collagen microstructure biodegrades. The cod liver oil and other oils and waxes within the Omeza® Collagen Matrix enhance the final product's conformability to the irregularities of the wound site. Why Existing HCPCS Codes do not adequately describe it: Currently the HCPCS coding system for cellular and/or tissue-based products for skin wounds (skin substitutes) is product and brand specific. For dates of service on or after January 1, 2009, product specific Q codes replaced non- product specific J codes. Therefore, no existing HCPCS Level II codes currently describe Omeza® Collagen Matrix. Indications for Use: Omeza® Collagen Matrix is used to treat chronic non-healing wounds such as venous, diabetic and pressure injury/ulcers, as well as surgical sites and trauma wounds to help in the healing process. It is intended for homologous use only. Action: Omeza® Collagen Matrix's primary intended clinical purpose is to support the critical phases of wound healing by delivering diverse collagen types in an anhydrous carrier that creates a conforming physical collagen microstructure at the wound site for cellular migration and wound revascularization. It softens and spreads at body temperature, creating a three-dimensional microstructural framework that conforms with surface tissues within the wound bed. Over time, the patient's cells replace the acellular matrix with a native extracellular matrix, and the hydrolyzed fish collagen microstructure biodegrades. The cod liver oil and other oils and waxes within the Omeza® Collagen Matrix enhance the final product's conformability to the irregularities of the wound site. Dosage/Route of Administration: Omeza® Collagen Matrix is supplied in a sterile, single use 1.6g vial. It is dispensed from the vial and applied directly or via suitable applicator to the wound bed by a physician, podiatrist, nurse practitioner, surgeon. Packaging: Omeza® Collagen Matrix is supplied in a sterile, single use 1.6g vial. It should be stored at room temperature (77°F/ 25°C) and should kept away from sunlight.

Preliminary CMS HCPCS Coding Recommendation

Establish new HCPCS Level II code AXXXX, "Omeza collagen matrix, per 100 mg"

In accordance with HCPCS Level II codes CMS effectuated for similarly situated products in 2022 and the Calendar Year 2022 Physician Fee Schedule Final Rule (86 FR 64996), Medicare payment for this product will be determined by the Medicare Administrative Contractors.

CMS has a long-standing convention to assign dose descriptors in the smallest amount that could be billed in multiple units to accommodate a variety of doses and support streamlined billing. This long-standing policy makes coding more robust, and facilitates accurate payment and reporting of the exact dose administered, as only 999 units can appear on a claim line for Medicare fee-for-service using the CMS-1500 form.

Summary of Public Feedback

No verbal or written comments were provided in response to CMS' published preliminary HCPCS Level II coding recommendation.

CMS Final HCPCS Coding Decision

Based on the information provided in the application to establish a new HCPCS Level II code and considering that no comments were received, CMS is finalizing its preliminary recommendation to:

Establish new HCPCS Level II code A2014, "Omeza collagen matrix, per 100 mg" to describe Omeza® Collagen Matrix.

In accordance with HCPCS Level II codes CMS effectuated for similarly situated products in 2022 and the Calendar Year 2022 Physician Fee Schedule Final Rule (86 FR 64996), Medicare payment for this product will be determined by the Medicare Administrative Contractors.

Agenda Item # 6

OrthoNovis Connect - HCP220204GQMWK

Topic/Issue

Request to revise existing HCPCS Level II code Q4161 “Bio-connekt wound matrix, per square centimeter” to include OrthoNovis Connect product in the code descriptor.

Applicant’s Summary

MLM Biologics, Inc. submitted a request to revise an existing HCPCS Level II code Q4161, “Bio-connekt wound matrix, per square centimeter.” Medicare and a few private payers cover bio-ConneKt®, therefore MLM Biologics, Inc. is requesting that existing HCPCS Level II code Q4161 is revised to include the OrthoNovis Connect product, in order to be eligible for claims submission and reimbursement. The private label OrthoNovis Connect and its five different sizes of product offerings will be manufactured exactly the same as bio-ConneKt® Wound Matrix with the same existing FDA 510(k) cleared indications. Nothing will change except for the name on the private label, and MLM Biologics, Inc. will continue to market existing bio-ConneKt® Wound Matrix product to healthcare professionals. All raw material, chemical processing, and manufacturing of OrthoNovis Connect is exactly the same as bio-ConneKt® Wound Matrix. Bio-ConneKt® Wound Matrix is an FDA 510(k) cleared product. As a bioengineered skin substitute, the FDA 510(k) cleared bio-ConneKt® Wound Matrix is clinically indicated for the local management of moderately to heavily exuding wounds, including: partial and full thickness wounds, draining wounds, tunneling wounds, pressure sores/ulcers, venous ulcers, chronic vascular ulcers, diabetic ulcers, trauma wounds and surgical wounds. It is an all-biologic, xenograft collagen-based scaffold that is supplied sterile and subject to proprietary processing to withstand challenges of wound micro-environment. bio-ConneKt® Wound Matrix is fully absorbed into the wound bed where it is vascularized by healing tissue. The product is covered by secondary wound dressings to help keep the wound site clean and protected from infections. Clinical testing indicates no need for product removal of bio-ConneKt® Wound Matrix and one-time application for most conditions.

Preliminary CMS HCPCS Coding Recommendation

CMS could not identify information in the application confirming that bio-ConneKt® Wound Matrix and OrthoNovis are identical products. The bio-ConneKt® Wound Matrix product has received 510(k) clearance from the FDA, which was included as part of its HCPCS Level II application. CMS would expect OrthoNovis to receive similar clearance from the FDA. As a result, we are unable to revise existing HCPCS Level II code Q4161 “Bio-connekt wound matrix, per square centimeter” to include OrthoNovis in the code descriptor.

Summary of Public Feedback

MLM Biologics, Inc. respectfully disagreed with CMS’ published preliminary recommendation and requested that the HCPCS code Q4161 with the descriptor “bio-ConneKt Wound Matrix, per sq. cm.” be modified to include a private label product that is produced for an outside company. The private label OrthoNovis Connect is manufactured exactly the same as bio-ConneKt® with the same existing FDA 510(k) cleared indications.

According to the applicant, all raw material, chemical processing, and manufacturing of OrthoNovis Connect is exactly the same as bio-ConneKt®. If CMS changes the descriptor of Q4161, nothing will change except for the name on the private label, and MLM Biologics, Inc. will continue to market the existing bio-ConneKt® Wound Matrix product.

CMS Final HCPCS Coding Decision

We appreciate the comments provided in response to CMS' published preliminary recommendation. Based on the information provided in the application to revise an existing HCPCS Level II code, and after consideration of the comments we received, CMS has determined that device listings should include all of the current proprietary names that are used to market the devices in the United States. As a result, CMS is denying the request to revise existing code Q4161. The applicant is encouraged to review the FDA's requirements for device distributions in the United States. The applicant is welcome to submit a new HCPCS Level II coding application in a subsequent biannual coding cycle.

Agenda Item # 7

Vapro Intermittent Catheter - HCP2112177QWUE

Topic/Issue

Request to establish a new HCPCS Level II code to identify Vapro Intermittent Catheter.

Applicant's suggested language: XXXXX, "Intermittent urinary catheter; straight tip, with or without coating (teflon, silicone, silicone elastomer, or hydrophilic, etc.), fully enclosed, without collection bag, each"

Applicant's Summary

Hollister Incorporated submitted a request to establish a new HCPCS Level II code for Intermittent Urinary Catheters that are fully enclosed. Urinary tract infections (UTI) are a complication of catheterization that can lead to serious health issues, including hospitalization and even death. Common causes of catheter associated UTIs include urinary catheter contamination, such as touch transfer from contaminated surfaces prior to insertion of the catheter into the urethra (e.g., the user's hands) and/or transfer from a contaminated meatus during insertions. Fully enclosed products are differentiated in that they protect users from both of these types of catheter contamination. First, the presence of a full sleeve protects from accidental touch or bacterial contamination while catheterizing, which is especially critical for patients with limited dexterity, who may not have full control over the catheter while inserting. Catheters with sleeve protection are different from products with other protective features that do not protect the catheter from the environment, such as products with a gripper. Second, catheters with an introducer tip enable the catheter to 'bypass' the distal end of the urethra which is a heavy bacterial zone. This bypass reduces the bacterial transfer to the urethra, thus improving patient outcomes by lowering the risk of UTIs. VaPro Straight and VaPro Pocket Intermittent Catheters are hydrophilic-coated catheters that are fully enclosed with both an introducer tip and protective sleeve but do not include an integrated collection bag. They offer full protection from touch contamination and bypass the bacterial zone of the distal urethra like other A4353 products but do not include the collection chamber, which is not always needed. Existing HCPCS codes identify catheters with insertion supplies (A4353) and without insertion supplies (A4351 and A4352). The DME MACs have determined that "no-touch" catheter systems are described by A4353 but only systems that include a collection tray or bag can be reported under this code. There is no code to describe fully enclosed, protective catheter systems that do include all necessary insertion supplies but which do not include a collection tray or bag. We request a new code to represent the significant difference in level of protection and therapeutic benefit offered by intermittent catheters without a collection bag, but are enclosed the full length of the catheter (from tip to funnel).

Preliminary CMS HCPCS Coding Recommendation

Existing HCPCS Level II code A4353, "Intermittent urinary catheter, with insertion supplies" describes the Vapro intermittent urinary catheter, fully enclosed and without collection bag. The applicant referred to the following sentence in the Policy Article (A52487), "Systems that do not have a collection chamber or otherwise are not functionally equivalent in performing a sterile-technique catheter insertion must be coded as an intermittent catheter,

A4351 or A4352, depending upon the catheter configuration." However, Policy Article A52487 for Ostomy Supplies does not refer to existing HCPCS Level II code A4353, meaning the reference to a collection chamber does not apply.

Policy Article A52521 for Urological Supplies states, "an intermittent urinary catheter with insertion supplies (A4353) is a kit, which includes a catheter and all supplies necessary for a single, sterile insertion (see below). Code A4353 may be used if any of the following 1, 2 or 3 is supplied:

1. A single sterile package containing both an intermittent urinary catheter and all necessary insertion/collection supplies; or
2. A sterile intermittent urinary catheter plus a separately-packaged sterile kit containing all necessary insertion/collection supplies; or
3. A sterile "no-touch" type of catheter system."

"The product described in #3 is a single-catheter system that is functionally equivalent to a complete sterile insertion kit (A4353) containing a catheter and the additional components as described in the previous paragraph. In order to be coded as A4353, a "no-touch" type of catheter system must be a sterile, all-inclusive, self-contained system capable of accomplishing intermittent catheterization with sterile technique without the use of additional supplies such as gloves, lubricant, collection chamber, etc. Additional individual components must not be separately billed. Separate billing of additional supply items is considered as unbundling." The Vapro Intermittent Urinary Catheter would be comparable to a sterile "no-touch" type of catheter system. These "no-touch" systems must be sterile and self-contained, similar to the Vapro Intermittent Urinary Catheter, allowing for insertion with minimal risk of contamination.

Additionally, CMS has conducted a clinical review, which indicates no differences in the incidence of asymptomatic bacteriuria or catheter-associated urinary tract infection have been found between sterile versus clean technique for intermittent catheterization, coated versus uncoated catheters, or single use versus multi-use catheters. If proper application technique is used, other intermittent catheters described by HCPCS Level II code A4353 offer the same clinical benefit.

Preliminary Medicare Benefit Category Determination

The current Medicare policy and prior established benefit category determination for A4353 apply to this item.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing code A4353 apply to this product, if covered.

Pricing = 37

Summary of Public Feedback

The primary speaker agreed with CMS' HCPCS preliminary recommendation to use existing HCPCS Level II code A4353 "Intermittent urinary catheter, with insertion supplies" to

describe the Vapro intermittent urinary catheter. However, the speaker disagreed with the current Medicare eligibility criteria for accessing A4353 category catheters. The speaker and other supporting organizations believed the criteria are too restrictive and potentially a disadvantage to certain patient populations.

The speaker referenced Local Coverage Determination (LCD) L33803, stating that criteria 1-4, address a small percentage of the overall population of intermittent catheter users and is centered on prevention. However, eligibility criteria #5 seems to be more of a reactive qualification versus a preventative one, and patients become eligible only after they have experienced two urinary tract infections in one year. The speaker expressed particular concern regarding criteria #5 and is asking CMS to reassess the coverage criteria for A4353 to ensure it does not disproportionately discriminate access. The speaker enumerated that those with spinal cord injury are at greater risk for Urinary Tract Infections (UTIs). UTIs are also associated with hospitalizations and are also listed as a leading cause of mortality in this population. The speaker also stated, treating UTIs are costly, as such preventing urinary tract infection is better than reacting to an infection.

The speaker stated that the CMS' Office of Minority Health works to ensure that people with disabilities receive equal access to quality health care information and service and released the CMS Framework for Health Equity to address health disparities as a foundational element across all our work in every program and across every community.

CMS Final HCPCS Coding Decision

We appreciate the comments provided in response to CMS' published preliminary recommendation. Based on the information provided in the application and after consideration of the comments we received, CMS is finalizing its preliminary recommendation to assign:

Existing HCPCS Level II code A4353 "Intermittent urinary catheter, with insertion supplies" to describe the Vapro intermittent urinary catheter.

We understand that the applicant agrees with CMS' preliminary recommendation to use existing code A4353. However, the speaker and other supporting organizations believe the coverage criteria for LCD L33803 are too restrictive and are potentially a disadvantage to certain patient populations. Particularly, criterion #5, which states, "the beneficiary has had distinct, recurrent urinary tract infections, while on a program of sterile intermittent catheterization with A4351/A4352 and sterile lubricant A4332, twice within the 12-month prior to the initiation of sterile intermittent catheter kits." In reference to the coverage criteria, CMS refers the applicant to the Durable Medical Equipment Administrative Contractors (DME MAC) for LCD reconsideration.

Final Medicare Benefit Category Determination

The current Medicare policy and prior established benefit category determination for A4353 apply to this item.

Final Medicare Payment Determination

The payment rules and pricing associated with the existing code A4353 apply to this product, if covered.

Pricing = 37

Agenda Item # 8

Repose Contur Overlay - HCP2112200N9K8

Topic/Issue

Request to establish a new HCPCS Level II code to identify Repose Contur Overlay.

Applicant's suggested language: XXXXX, "Reactive air pressure relief overlay for reclining chair, Length 69" Width 21""

Applicant's Summary

Frontier Therapeutics submitted a request to establish a new HCPCS Level II code to identify the Repose Contur Overlay. The Repose Contur Overlay is a pressure redistribution and reduction support surface that reduces peak and average pressures and consistently delivers low levels of pressure ulcer incidence. The Repose Contur Overlay is indicated for the prevention of pressure ulcers for patients at all levels of risk and treatment of all categories of pressure ulcer when used as part of a protocol of care. The Repose Contur Overlay is designed to provide full body pressure relief for a high risk patient when sitting in a chair.

Preliminary CMS HCPCS Coding Recommendation

Existing HCPCS Level II code E0190, "Positioning cushion/pillow/wedge, any shape or size, includes all components and accessories" describes the Repose Contur Overlay.

Preliminary Medicare Benefit Category Determination

The current Medicare policy and prior established benefit category determination for E0190 apply to this item.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing code E0190 apply to this product. Items or services described by HCPCS code E0190 are not covered under Medicare Part B.

Pricing = 00

Summary of Public Feedback

No verbal or written comments were provided in response to CMS' published preliminary HCPCS Level II coding recommendation.

CMS Final HCPCS Coding Decision

Based on the information provided in the application and considering that no comments were received, CMS is finalizing its preliminary recommendation to assign:

Existing HCPCS Level II code E0190, "Positioning cushion/pillow/wedge, any shape or size, includes all components and accessories" to describe the Repose Contur Overlay.

Final Medicare Benefit Category Determination

The current Medicare policy and prior established benefit category determination for E0190 apply to this item.

Final Medicare Payment Determination

The payment rules and pricing associated with the existing code E0190 apply to this product. Items or services described by HCPCS code E0190 are not covered under Medicare Part B.

Pricing = 00

Agenda Item # 9

Electro Flo 6 Airway Clearance System - HCP220104QRKLN

Topic/Issue

Request to establish a new HCPCS Level II code to identify Electro Flo 6 Airway Clearance system.

Applicant's suggested language: XXXXX, "Chest wall compression impact vibrator"

Applicant's Summary

Med Systems Inc. submitted a request to establish a new HCPCS Level II code to identify Electro Flo 6 Airway Clearance System. The Pricing, Data Analysis and Coding (PDAC) contractor has coded the Electro Flo in E0480. This coding decision effectively denies patient access to the Electro Flo because the payment for E0480 does not cover the cost of the device. The proposed new HCPCS "E" code recognizes the Electro Flo's technological and therapeutic distinctions from other "powered percussor" airway clearance systems, and it would enable the PDAC to price it appropriately. The Electro Flo Airway Clearance System's operating principle is actual percussion because it employs a "hammer and anvil" striking mechanism: the hammer is the handheld body of the power head; the anvil is the surface of the power head that is held in contact with the chest. The force from the therapist's hand drives the hammer through a gap until it strikes the anvil and delivers its accumulated momentum in a robust mechanical impact to the chest. The frequency of the impulse train can be varied between about 4 and 20 Hz. An included self-administration strap enables the patient to position the device anywhere on the front or back of the chest without assistance. Because the Electro Flo provides true percussion (striking impact) to targeted areas of the chest wall, it is the only powered percussor that accomplishes all the airway clearance functions of manual percussion: Powerful impulse waves that radiate into the chest and generate mass airflow in the lungs with cephalad airflow bias and deliver high-frequency vibrations that loosen secretions. HCPCS codes E0480, "Percussor, electric or pneumatic, home model" and E0483, "High frequency chest wall oscillation system, includes all accessories and supplies, each" are used for airway clearance devices. The terminology of HCPCS code E0480 is vague and does not differentiate devices by their mechanism of action, clinical utility, device complexity, or cost. The PDAC has created a local coverage policy with a very restrictive definition E0483 that is independent of the HCPCS descriptions. However, no such policy defines E0480, which serves as a catch-all for any device that does not include a vest. The Electro Flo meets all the requirements for E0483 described in the policy, except that it achieves high-frequency chest wall compression without the need for a vest. Nevertheless, the PDAC has placed the Electro Flo impact percussor with two acoustic vibrator devices in E0480. However, they are very different technologies with different therapeutic characteristics, complexity, and cost. Because of the vast difference in payments in E0480 and E0483, the PDAC coding decisions deny Medicare beneficiaries and the beneficiaries of other health plans access to this therapeutically distinct technology.

Preliminary CMS HCPCS Coding Recommendation

Existing HCPCS Level II code E0480, "Percussor, electric or pneumatic, home model" describes the Electro Flo 6 Airway Clearance System. According to the applicant, "The

Electro Flo Airway Clearance System's operating principle is actual percussion because it employs a "hammer and anvil" striking mechanism: the hammer is the handheld body of the power head; the anvil is the surface of the power head that is held in contact with the chest." The Electro Flo allows for a single area of percussion that is controlled by the patient, similar to those devices in existing HCPCS Level II code E0480. Items that fall under HCPCS Level II code E0483 include percussors that provide oscillations and compression to the chest, back and torso simultaneously.

Preliminary Medicare Benefit Category Determination

The current Medicare policy and prior established benefit category determination for E0480 apply to this item.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing code E0480 apply to this product, if covered.

Pricing = 36

Summary of Public Feedback

The primary speaker disagreed with CMS' HCPCS preliminary recommendation to use existing HCPCS Level II code E0480 "Percussor, electric or pneumatic, home model" to describe the Electro Flo 6 Airway Clearance System. The speaker referenced that bronchiectasis is due to the production of excessive and abnormal mucus in the airways, resulting in repeated infections and tissue damage. Impaired clearance of mucus necessitates the need to augment natural mucociliary clearance from the lungs.

The speaker referenced guidelines by the British Thoracic Society and the European Respiratory Society that advocate for two principles in selecting methods of airway clearance:

1. That the means are selected to meet the patients' needs to optimize adherence.
2. That they are personalized to the patient for optimal, individual efficacy.

The speaker commented that there are no guidelines, to date, that have shown any level of evidence to make a recommendation of "best" mechanical means to clear the airways, due to lack of studies. Therefore, the field has settled on a personalized approach based on the above principles. However, the guidelines recommend that mechanically optimized airway clearance be offered and adjusted to each patient based on factors of adherence, independence, and efficacy. Accordingly, clinical experts advocate for a variety of options for each patient that is selected with advice from clinicians in a shared decision-making model.

The speaker mentioned that HCPCS Level II code E0483 "High frequency chest wall oscillation system, includes all accessories and supplies, each" would better describe the Electro Flo 6 Airway Clearance System. The Electro Flo is equally capable of delivering strong compressive forces to all areas of the front and back of the chest, without the need for an assistant, as devices that employ a vest. The speaker commented that the criterion that the

DME MACs use to classify airway clearance devices related to the number of contact points with the body, does not appear in the medical literature, and no evidence supports this criterion as clinically meaningful.

Other commenters stated the "percussor" descriptor for E0480 is imprecise because FDA and CMS have described various airway clearance devices as "percussors," even though they employ different physical principles than manual percussion therapy, which delivers compressive forces described by the impulse-momentum theorem of physics.

CMS Final HCPCS Coding Decision

We appreciate the comments provided in response to CMS' published preliminary recommendation. Based on the information provided in the application and after consideration of the comments we received, CMS is finalizing its preliminary recommendation to assign:

Existing HCPCS Level II code E0480, "Percussor, electric or pneumatic, home model" to describe the Electro Flo 6 Airway Clearance System.

In effort to help distinguish and further define devices that would fall under E0483, CMS is also finalizing a decision to:

Revise existing HCPCS Level II code E0483, "High frequency chest wall oscillation system, includes all accessories and supplies, each" to now read "High frequency chest wall oscillation system, with full anterior and/or posterior thoracic region receiving simultaneous external oscillation, includes all accessories and supplies, each."

According to the applicant, the Electro Flo Airway Clearance System's operating principle is actual percussion because it employs a "hammer and anvil" striking mechanism: the hammer is the hand-held body of the power head; the anvil is the surface of the power head that is held in contact with the chest. The Electro Flo allows for a single area of percussion that is controlled by the patient, similar to devices in existing HCPCS Level II code E0480.

Items that fall under HCPCS Level II code E0483 include percussors that provide oscillations and compression simultaneously to the full anterior and/or posterior thoracic region. Patients that are using a high frequency chest wall oscillation system do not need to assume numerous positions and all external areas of the chest can be treated simultaneously.

CMS recognizes that treatment may need to be customized to the patient based on clinical circumstances. HCPCS Level II codes are typically intended to describe distinctions between products – in this case, based on the simultaneous external oscillation coverage area of the products. The clinical utility of which product brand is most appropriate for a particular patient is beyond the scope of the coding decision.

Final Medicare Benefit Category Determination

The current Medicare policy and prior established benefit category determination for E0480 apply to this item.

Final Medicare Payment Determination

The payment rules and pricing associated with the existing code E0480 apply to this product, if covered.

Pricing = 36

Agenda Item # 10

VibraLung® Acoustical Percussor (VAP) - HCP22010483DKP

Topic/Issue

Request to establish a new HCPCS Level II code to identify the VibraLung® Acoustical Percussor (VAP).

Applicant's suggested language: XXXXX, "Intrapulmonary Acoustical Airway Clearance, electric pertaining to devices generating variable frequency sound (acoustical) waves directed to pulmonary airways via a mouthpiece to facilitate the mobilization of mucus secretions, debris, and physical obstructions, and to open and relax airways"

Applicant's Summary

VibraLung Inc. submitted a request to establish a new HCPCS Level II code to identify the VAP, which is an intrapulmonary (direct to airways) acoustical airway clearance device that generates, using a transducer, a wide range of frequencies. With a significantly different mechanism, the VAP facilitates the mobilization of mucus secretions, and debris, opens and relaxes airways. Existing code E0480 is inadequate for "Intrapulmonary Acoustical Airway Clearance" (IAAC) therapy devices. Other devices operate by mechanical thumping, which transmits vibration through a patient's chest wall. They have the same FDA classification 868.5665. Note the VAP is intrapulmonary, transmitting sound waves, or acoustical oscillatory vibrations directly into the respiratory system via a mouthpiece, and not the chest wall in any manner. A study conducted in 2017 had 20 patients who had discharge diagnosis of either COPD or pneumonia. They were followed for a 90-day period, and only one patient was readmitted for the same diagnosis. Two other studies found readmission rates of 2 to 4.5 (5) patients. For 1 to 4 patients, readmissions cost could be up to $52,800 for a one-night stay, compared to with the cost of the VAP of $2,800 - $4,480 - a huge cost savings to the healthcare system. Due to the low reimbursement of E0480, distributors of the VAP do not accept Medicare assignment, because it barely covers the manufacturing, shipping and handling costs. It does not cover commissions, DME or regulatory costs. The lack of adequate and reasonable reimbursement is discriminatory to those of lower income who are on Medicare/Medicaid, and who cannot afford to private pay for the VAP. Also, doctors are reluctant to prescribe the VAP because their patients cannot easily obtain it. Indications of use: COPD, chronic bronchitis, bronchiectasis, asthma, cystic fibrosis, pneumonia, atelectasis and neuromuscular respiratory disease. Action: Intrapulmonary delivery of sound waves to the respiratory system. Dosage: Generally, two to three treatments per day, starting with Low followed by 2 minutes of Random Noise, then Medium and High clearing larger to smaller airways. Treatments administered through mouthpiece, with patient sitting mostly upright, relaxing and breathing through the device.

Preliminary CMS HCPCS Coding Recommendation

Existing HCPCS Level II code E0480, "Percussor, electric or pneumatic, home model" describes the Vibralung® Acoustical Percussor. The Vibralung® Acoustical Percussor is an electric percussor indicated for airway secretion clearance. According to the applicant, "per FDA 510(k) clearance, the Vibralung® Acoustical Percussor is intended for use in the hospital or home for patient with respiratory diseases and related conditions that involve:

increased mucus production, infection and inspissation of respiratory secretions, and defective mucociliary clearance." To use this device, the patient breathes into a mouthpiece attached to a transducer which is connected to the control unit. The control unit generates sounds waves and controls the treatment. The Vibralung® Acoustical Percussor is for a single area of percussion, similar to devices described by existing HCPCS Level II code E0480, which only allow a single area of percussion at any moment.

Preliminary Medicare Benefit Category Determination

The current Medicare policy and prior established benefit category determination for E0480 apply to this item.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing code E0480 apply to this product, if covered.

Pricing = 36

Summary of Public Feedback

The primary speaker disagreed with CMS' HCPCS preliminary recommendation to use existing HCPCS Level II code E0480 "Percussor, electric or pneumatic, home model" to describe the Vibralung® Acoustical Percussor. According to the speaker, other devices in E0480 apply mechanical or pneumatic force, creating shock waves to the chest wall, allowing a single area of percussion at any moment. The higher frequencies generated are filtered out by the chest wall, which means these devices are effective for the larger and possibly the middle airways only, with being positionally dependent. With extensive research, no hospital readmission studies were found for any of these devices, although some have been around a long time, so any such studies could have been prior to widespread use of the internet. In contrast, the Vibralung® is acoustical that is, it generates sinusoidal oscillatory or vibrational sound waves. It is intrapulmonary or direct to the lungs, and it has the unique feature of random noise. The sound waves provide a gentle form of percussion as the Vibralung® systematically clears sections of the lungs, in dispersed pulmonary branches in both lobes at the same time. Random noise helps to relax and open the airways, providing bronchial dilation. The higher frequencies delivered by the Vibralung® direct to the lungs reach the distal or smaller airways. The speaker recognized that the Frequencer is a comparable device to the Vibralung® based around the mechanism of action and is billed under E0480.

The speaker stated that existing code E0480 does not reimburse enough to cover the cost of the Vibralung®. They indicate that receiving a new HCPCS Level II code, as requested, is the first step to a more reasonable and equitable reimbursement, and would make the Vibralung® available to patients.

CMS Final HCPCS Coding Decision

We appreciate the comments provided in response to CMS' published preliminary recommendation. Based on the information provided in the application and after consideration of the comments we received, CMS is finalizing its preliminary recommendation to assign:

Existing HCPCS Level II code E0480, “Percussor, electric or pneumatic, home model” to describe the Vibralung® Acoustical Percussor.

The Vibralung® Acoustical Percussor is an electric percussor indicated for airway secretion clearance. The Vibralung® Acoustical Percussor generates sinusoidal oscillatory or vibrational sound waves that are controlled by the patient, similar to other devices in existing HCPCS Level II code E0480. No evidence was provided to support that the Vibralung® illustrates significant clinical distinction as a result of its acoustical features from these other devices in existing HCPCS Level II code E0480. One reason the speaker is requesting a new HCPCS Level II code is related to inadequate payment for the Vibralung® under E0480. Cost criteria do not factor into CMS’ decision-making pertaining to the establishment of new HCPCS Level II codes.

Final Medicare Benefit Category Determination

The current Medicare policy and prior established benefit category determination for E0480 apply to this item.

Final Medicare Payment Determination

The payment rules and pricing associated with the existing code E0480 apply to this product, if covered.

Pricing = 36

Agenda Item # 11

EndeavorRx® - HCP220103YXJ32

Topic/Issue

Request to establish a new HCPCS Level II code to identify EndeavorRx®.

Applicant's suggested language: QXXXX, "Prescription digital therapeutic (PDT), for attention deficit hyperactivity disorder, pediatric ages 8-12, strengthens 3 elements of attentional control (interference processing, focus, multitasking) by stimulating specific neural systems in the brain, used as part of a therapeutic program"

Applicant's Summary

Akili Interactive submitted a request to establish a new HCPCS Level II code to identify the EndeavorRx® treatment, a prescription digital therapeutic authorized by the U.S. Food and Drug Administration (FDA) in June 2020 with an indication to improve attention function as measured by computer-based testing in children ages 8-12 years old with primarily inattentive or combined-type attention deficit hyperactivity disorder (ADHD), who have a demonstrated attention issue. Patients who engage with EndeavorRx® demonstrate improvements in a digitally assessed measure, Test of Variables of Attention (TOVA®), of sustained and selective attention and may not display benefits in typical behavioral symptoms, such as hyperactivity. EndeavorRx® should be considered for use as part of a therapeutic program that may include clinician-directed therapy, medication, and/or an educational program, which further address symptoms of the disorder. After a physician prescribes EndeavorRx® to a patient, a specialty pharmacy submits a claim to the patient's health plan for the product and provides an authorization code to the patient. Once the patient downloads EndeavorRx® onto a compatible personal electronic device, they are able to use the prescription digital therapeutic on their own time in their own home. Physicians are not required to pay for or take ownership of the product. Currently, payers adjudicate claims for EndeavorRx® through plan pharmacy benefits, using EndeavorRx®'s unique device identifier (UDI) as a proxy for a national drug code (NDC) number. However, Akili has had conversations with multiple payers that have expressed interest in covering EndeavorRx® through a plan's medical benefit, which would require a HCPCS billing code. Because EndeavorRx® is used by a patient on their own time in their own home, making it most similar to a non-drug, non-biological item that is used outside of a physician's office, Akili Interactive believes that EndeavorRx® should qualify for a Level II HCPCS code. There are currently no Level II (HCPCS) codes that adequately describe the EndeavorRx® treatment.

Preliminary CMS HCPCS Coding Recommendation

Existing HCPCS Level II code A9291, "Prescription digital behavioral therapy, fda cleared, per course of treatment" describes EndeavorRx®.

Preliminary Medicare 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.

Digital therapies or computer software are not devices, equipment, or supplies and therefore would not fall under a DMEPOS benefit category. Whether or not the item could fall under some other Medicare benefit category can be considered, but would not be addressed under the DMEPOS benefit category determination process.

Preliminary Medicare Payment Determination

No Medicare payment. Pricing = 00

Summary of Public Feedback

The primary speaker disagreed with CMS' HCPCS preliminary recommendation to use existing HCPCS Level II code A9291 "Prescription digital behavioral therapy, fda cleared, per course of treatment" to describe EndeavorRx®. The speaker commented that the clinical trials show that this is not considered behavioral therapy for the patient, as it is the only FDA-cleared PDT for ADHD in children between the ages of 8-12 years old. They asserted that existing HCPCS code A9291, as it reads right now, limits the flexibility for payers to cover PDTs for non-behavioral therapies such as pediatric ADHD, and therefore there is an unmet need for specific, discrete HCPCS Level II code. EndeavorRx® is not associated with behavior, and does not train behaviors and/or provide behavior-type therapy, but related to cognitive therapy. Another speaker explained the advancements and pervasiveness of prescription software.

Commenters stated that one generic HCPCS Level II code does not allow payers to efficiently cover several PDTs with different mechanisms of action, price points, benefit categories and utilization management requirements. Thus, manual adjudication of claims would be required, which inherently creates a greater potential for error, and places an administrative burden on the payer.

CMS Final HCPCS Coding Decision

We appreciate the comments provided in response to CMS' published preliminary recommendation. Based on the information provided in the application and after consideration of the comments we received, CMS is revising its preliminary recommendation and finalizing a decision to:

Revise existing HCPCS Level II code A9291, "Prescription digital behavioral therapy, fda cleared, per course of treatment" to now read "Prescription digital cognitive and/or behavioral therapy, fda cleared, per course of treatment." CMS believes that HCPCS Level II code A9291, as revised, describes EndeavorRx®.

EndeavorRx® is a digital therapeutic indicated to improve attention function as measured by computer-based testing in children ages 8-12 years old with primarily inattentive or combined type ADHD, who have a demonstrated attention issue. We understand that the indications for use also state that EndeavorRx® may not display benefits in typical behavioral symptoms, such as hyperactivity. However, it uses the same principles of human learning and development as well as cognitive processing to overcome problem behavior and emotional thinking.

CMS understands the field of prescription digital therapeutics is expanding. However, we do not recognize a need for separate, more specific HCPCS codes to distinguish between items and price points at this time. CMS is not aware of a claims processing need or written policies on the part of other insurers for separately reporting prescription digital therapies; as other payer policies evolve, we expect that will inform future coding actions.

Final Medicare Benefit Category Determination

No DMEPOS 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.

Digital therapies or computer software are not durable devices, equipment, or supplies that would fall under a DMEPOS benefit category. Whether or not the item could fall under some

other Medicare benefit category can be considered, but would not be addressed under the DMEPOS benefit category determination process.

The durable medical equipment benefit is for equipment such as a wheelchair, hospital bed, ventilator, or oxygen concentrator rented to a patient for use in their home. Software that is run on computers would not work unless the patient also has a smartphone, computer or another type of durable device that would enable use of the software. Smartphones and computers are generally useful to individuals in the absence of illness or injury and are therefore not DME. Without the computer or smartphone, the software would not work. Digital therapies or computer software that are housed on non-medical devices like smartphones or computers and the equipment and software, as a whole, are not DME.

Final Medicare Payment Determination

No Medicare payment under a DMEPOS benefit.

Pricing = 00

Agenda Item # 12

Tongueometer™ - HCP2112027WV28

Topic/Issue

Request to establish a new HCPCS Level II code to identify Tongueometer™.

Applicant's suggested language: EXXXX, "Tongue Strength measurement and rehabilitation system"

Applicant's Summary

E2 Scientific submitted a request to establish a new HCPCS Level II code to identify Tongueometer™. Description: Tongueometer™ hand-held device, Tongueometer™ bulb, user manual, powerbank and cable, Tongueometer™ application compatible with Android and iOS with four modules to assess and exercise tongue strength and endurance. Function: used to measure and increase tongue strength and endurance by patients under guidance of their healthcare professional. New code requested as currently there are no codes that adequately describe this device. There are no specific codes for the function of this device. Indications for use: dysphagia, dysarthria, slurring, speech impediment, drooling, oral motor fatigability, strength assessment and rehabilitation.

Preliminary CMS HCPCS Coding Recommendation

Existing HCPCS Level II code A9300, "Exercise equipment" describes Tongueometer™.

Preliminary Medicare Benefit Category Determination

The current Medicare policy and prior established benefit category determination for A9300 apply to this item.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing code A9300 apply to this product. Items or services described by HCPCS code A9300 are not covered under Medicare Part B.

Pricing = 00

Summary of Public Feedback

The primary speaker disagreed with CMS' HCPCS preliminary recommendation to use existing HCPCS Level II code A9300 "Exercise equipment" to describe the Tongueometer™. The speaker stated this product is used extensively by healthcare professionals to assess and treat tongue strength in patients with dysphagia (difficulty swallowing) resulting from many common diseases and disorders (head & neck cancer, stroke, dementia, ALS, multiple sclerosis, Parkinson's disease (and other neuro-degenerative diseases), brain injury, and cerebral palsy, and as well as in aging). Deficient tongue strength and endurance are common causes of dysphagia and require rehabilitation. The Tongueometer™ uses biofeedback to operate. Without treatment, dysphagia leads to serious, sometimes deadly, heath conditions

and costs, including aspiration pneumonia, feeding tube dependence, and modified diets. These conditions result in significant, and in many cases, ongoing, payments. The Tongueometer™ can eliminate, improve, or delay these conditions, resulting in a net reduction in health care costs for millions of Americans. According to the speaker, there are no existing HCPCS Level II codes for a device like this, and asks CMS to reconsider the preliminary HCPCS coding (A9300) coding decision of "Exercise equipment," and create a unique, specific HCPCS Level II code that is covered by both private and public health insurers.

CMS Final HCPCS Coding Decision

We appreciate the comments provided in response to CMS' published preliminary recommendation. Based on the information provided in the application and after consideration of the comments we received, CMS is finalizing its preliminary recommendation to assign:

Existing HCPCS Level II code A9300 "Exercise equipment" to describe the Tongueometer™.

CMS appreciates the positive effects and benefits of the Tongueometer™ to assist people with dysphagia. The Tongueometer™ is a biofeedback device used to measure and help increase tongue strength and endurance by use of exercise modules. The maximum strength module assesses the maximum pressure that the user can produce by pressing an air-filled bulb against the roof of the mouth with the tongue. The maximum tongue endurance is measured by assessing the length of time that a user can maintain a tongue pressure within a set pressure range of the user's maximum pressure. These modules of the Tongueometer™ focus on exercise to increase tongue strength.

Final Medicare Benefit Category Determination

There is not a benefit category under Medicare Part B for exercise therapy equipment used in the home and, as such, it is not payable. The current Medicare policy and prior established benefit category determination for A9300 apply to this item.

Final Medicare Payment Determination

The payment rules and pricing associated with the existing code A9300 apply to this product. Items or services described by HCPCS code A9300 are not covered under Medicare Part B.

Pricing = 00

Agenda Item # 13

NovoPulse® - HCP211224EK2TK

Topic/Issue

Request to establish a new HCPCS Level II code to identify NovoPulse®.

Applicant's suggested language: XXXXX, "Electric Field and Thermal Stimulation Combination Therapy"

Applicant's Summary

BioMagnetic Sciences submitted a request to establish a new HCPCS Level II code to identify NovoPulse®. Existing codes do not support this unique technology of combined electric field and thermal stimulation for pain management. Two recent discoveries created the foundation for this combination therapy: The effect of Electric Field Stimulation on reducing inflammation and long-term pain relief; and the effect of Thermal Stimulation on the regenerative process with short-term pain management. Upregulation of Adenosine A2aR anti-inflammatory pathway by providing local Electric Field Stimulation, which reduces inflammation, provides long-term pain relief via blocking of the Prostaglandin E2, and promotes the restoration of damaged tissues. In NovoPulse® MKX-1, a unique multicoil system is designed to generate appropriate amplitude Electric Field and deliver it to intervertebral discs, facet, and extremity joints with adequate duration, amplitude, orientation, and distribution. In addition to the Electric Field Stimulation, NovoPulse® provides Thermal Stimulation, which is synergistically combined with Electric Field Stimulation. The computer controlled Thermal Stimulation is delivered through heating pads which converts the stored magnetic field energy at the end of each pulse. Thermal Stimulation of the joint increases blood flow around the joint, promotes diffusion of nutrients in and the waste product out of the joint. The most important aspect of using thermal stimulation is the generation of "heat shock proteins" (HSPs). The biological function of HSPs is to preserve cell survival by maintaining the vital functions of proteins. Improved protein function leads to 4-7 fold increase in production of the extracellular cartilage matrix, that significantly accelerates its repair and contributes to long-term pain relief in the joint. Current research, indicates pain reduction and promotion of cartilage tissue regeneration in osteoarthritis. Chronic pain due to wear and tear or pre-existing late-effect injuries or illnesses is mitigated by Electric Field and Thermal Stimulation which reduces inflammation and pain and promotes healing of damaged tissues. The NovoPulse® system is delivered in a carrying case consisting of a wearable applicator, a microprocessor-based controller, a power supply, and a user manual. The device fits on the patient's body region involved and the patient can be in a comfortable position (i.e., sitting, lying, standing) while the therapy is applied to the region for 30 minutes. The system automatically shuts down at the end of the 30-minute session. During operation, the microprocessor-based controller monitors the performance and health status of the device and shuts down the device in the event of any abnormal conditions. Dosage of treatments per day is recommended by the provider based on the patient's condition and response to care.

Preliminary CMS HCPCS Coding Recommendation

Existing HCPCS Level II code E0762, "Transcutaneous electrical joint stimulation device system, includes all accessories" describes NovoPulse®. The thermal stimulation is a

byproduct of the stored magnetic field energy created from the pulsed electromagnetic stimulation. After a pulse, the energy stored in the magnetic field of the coils is converted to heat. CMS does not believe the NovoPulse® provides a clinical benefit beyond the other products in E0762. We welcome the applicant to submit any clinical studies that demonstrate such comparison and distinction.

Preliminary Medicare Benefit Category Determination

The current Medicare policy and prior established benefit category determination for E0762 apply to this item.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing code E0762 apply to this product, if covered.

Pricing = 36

Summary of Public Feedback

CMS received written comment from the applicant in support of the published preliminary HCPCS coding recommendation that existing HCPCS Level II code E0762, describes NovoPulse®.

CMS Final HCPCS Coding Decision

We appreciate the comments provided in response to CMS' published preliminary recommendation. Based on the information provided in the application and after consideration of the comments we received, CMS is finalizing its preliminary recommendation to assign:

Existing HCPCS Level II code E0762 "Transcutaneous electrical joint stimulation device system, includes all accessories" to describe NovoPulse®.

Final Medicare Benefit Category Determination

The current Medicare policy and prior established benefit category determination for E0762 apply to this item.

Final Medicare Payment Determination

The payment rules and pricing associated with the existing code E0762 apply to this product, if covered.

Pricing = 36

Agenda Item # 14

Biobeat – HCP2111231GDB0

Topic/Issue

Request to establish a new HCPCS Level II code to identify Biobeat.

Applicant's suggested language: XXXXX, "Non invasive wearable monitor device for monitoring of vital signs that transmits collected data to any web platform"

Applicant's Summary

Living Well Innovations, Inc. submitted a request to establish a new HCPCS Level II code to identify the Biobeat monitoring solution, which is based on the photoplethysmography (PPG) sensor. Biobeat is designed to allow a clear reading of PPG signal wave, enabling measurement of a wide range of vitals. The Biobeat chest monitor and wrist-monitor each collect and measure 12 parameters from the patient, and the chest-monitor measures a one-lead ECG. The device transmits the measurement data to the Biobeat gateway or cellphone app. All data are uploaded to and stored on the Biobeat Cloud (health insurance portability and accountability act and general data protection regulation compliant). The healthcare provider can then access all data through the Biobeat web platform.

Preliminary CMS HCPCS Coding Recommendation

Existing HCPCS Level II code A9279, "Monitoring feature/device, stand-alone or integrated, any type, includes all accessories, components and electronics, not otherwise classified" describes Biobeat.

Preliminary Medicare Benefit Category Determination

The current Medicare policy and prior established benefit category determination for A9279 apply to this item.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing code A9279 apply to this product. Items or services described by HCPCS code A9279 are not covered under Medicare Part B.

Pricing = 00

Summary of Public Feedback

The primary speaker disagreed with CMS' HCPCS preliminary recommendation to use existing HCPCS Level II code A9279 "Monitoring feature/device, stand-alone or integrated, any type, includes all accessories, components and electronics, not otherwise classified" to describe Biobeat. The speaker stated that Medicare Part B does not cover A9279, thus, consumers will have to pay out of pocket, limiting access. Also, a unique HCPCS code for Biobeat would be consistent with CMS' earlier decisions that virtual health produces better health outcomes. Biobeat allows for users and healthcare providers to identify deteriorating

health before a health crisis occurs, in turn, improving patients' quality of life and providing better patient outcomes.

CMS Final HCPCS Coding Decision

We appreciate the comments provided in response to CMS' published preliminary recommendation. Based on the information provided in the application and after consideration of the comments we received, CMS is finalizing its preliminary recommendation to assign:

Existing HCPCS Level II code A9279, "Monitoring feature/device, stand-alone or integrated, any type, includes all accessories, components and electronics, not otherwise classified" to describe Biobeat.

The speaker commented that CMS should establish a new HCPCS Level II code as existing code A9279 is not covered under Medicare Part B, which will require consumers to pay out of pocket, limiting their access to Biobeat. However, a new HCPCS Level II code does not guarantee a Medicare benefit category or Medicare coverage. Biobeat is a chest or wrist monitor that collects and measures various parameters, similar to other monitoring devices in existing HCPCS Level II code A9279.

Final Medicare Benefit Category Determination

The current Medicare policy and prior established benefit category determination for A9279 apply to this item.

Final Medicare Payment Determination

The payment rules and pricing associated with the existing code A9279 apply to this product. Items or services described by HCPCS code A9279 are not covered under Medicare Part B.

Pricing = 00

Agenda Item # 15

GoSpiro® - HCP2109208A81K

Topic/Issue

Request to revise existing HCPCS Level II code E0487 to identify GoSpiro®.

Applicant's suggested language: XXXXX, "Electronic Spirometer, FDA Product Code BZG cleared for patient self-testing at home. Includes measurement of FVC, SVC and bidirectional flow"

Applicant's Summary

Monitored Therapeutics Inc. submitted a request to revise existing HCPCS Level II code E0487 to identify GoSpiro®, a diagnostic spirometer for physician's offices, clinics, and home settings to conduct basic lung function and spirometry testing. HCPCS code E0487's current language is inadequate. This broad description allows for devices that do not measure lung function with diagnostic accuracy, causing intermediary payors to reject claims even for devices that do provide hospital laboratory quality and actionable data for healthcare providers. "Non- diagnostic" electronic spirometers that fall under HCPCS code E0487 might include Peak Flow Meters or Spirometers that only measure forced expiratory volume in the first second (FEV1) or expiratory flow only. The applicant requested that CMS modify HCPCS code E0487 to include the above language so that its intermediary payors will recognize that they would be paying for true diagnostic devices that provide patient disease management value for the prescribing physician. The intermediary payors already pay for use of these "diagnostic" devices under CPT® codes 99453, 99454, 99457, and 99458 for the labor components of their use for taking lung function measurements. Changing the specification for devices qualifying under E0487 will increase the likelihood that reimbursement will be approved for the device used to take those measurements. The GoSpiro® has been used for several years to provide clinically relevant data to healthcare providers to help guide patient management. The COVID-19 pandemic produced a significant effect, transitioning patient monitoring measurements from hospitals to the home. Collecting more frequent measurements increases the data's statistical power, improving the reliability and usefulness of what is collected when measured by a diagnostic device.

Preliminary CMS HCPCS Coding Recommendation

Existing HCPCS Level II code E0487, "Spirometer, electronic, includes all accessories" describes GoSpiro®. Diagnostic equipment used in the patient's home that provides measurements a physician may use to evaluate the patient's condition and course of treatment does not have a DMEPOS benefit category. For coding guidance, please refer to the insurer(s) in whose jurisdiction(s) claim would be filed. For Medicaid, contact the Medicaid Agency in the state in which the claims would be filed.

Preliminary Medicare Benefit Category Determination

The current Medicare policy and prior established benefit category determination for E0487 apply to this item.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing code E0487 apply to this product. Items or services described by HCPCS code E0487 are not covered under a Medicare Part B DMEPOS benefit.

Pricing = 00

Summary of Public Feedback

The primary speaker disagreed with CMS' HCPCS preliminary recommendation to use existing HCPCS Level II code E0487 "Spirometer, electronic, includes all accessories" to describe GoSpiro®. The speaker stated that Monitored Therapeutics is not requesting revision of the existing HCPCS Level II code E0487 to identify the GoSpiro®. The speaker clarified that Monitored Therapeutics is requesting revision of the existing HCPCS Level II code E0487 to identify a class of spirometers that perform diagnostic measurements. Not all spirometers are the same as there are differences between the classes of spirometers. Spirometers are approved (cleared) by the FDA with two different levels of diagnostic capabilities. Basic spirometers that can measure peak expiratory flow (Peak Flow and FEV1) are considered a Peak Flow Meter and are available without a prescription (e.g., sold on Amazon). These are cleared under FDA Product Code BZH. A more technically sophisticated spirometer that can, in addition, measure the Forced Vital Capacity (FVC), is identified by the FDA as a Diagnostic Spirometer. These require a prescription by a licensed physician and are cleared under FDA product code BZG. The performance standards required by the FDA are significantly different for each product code. There are also different diagnostic and monitoring values of measuring only the FEV1 which is the volume that can be expelled in the first second of a forced exhalation after a maximum inhalation and the FVC, which is the total volume of air that that can be expelled after a maximum inhalation. Without FVC, a physician will not have access to the critical measurements of FEV1/FVC or FVC to monitor disease progression, and devices cleared under BZH do not measure FVC.

CMS Final HCPCS Coding Decision

We appreciate the comments provided in response to CMS' published preliminary recommendation. Based on the information provided in the application and after consideration of the comments we received, CMS is finalizing its preliminary recommendation to not revise existing code E0487 and assign:

Existing HCPCS Level II code E0487, "Spirometer, electronic, includes all accessories" to describe GoSpiro®.

CMS understands that FDA product codes BZH and BZG for spirometers are used to calculate different volumes for a diagnostic purpose. It is our understanding that product code BZH, for a peak flow meter, is commonly used in a physician's office or clinical setting as part of an exam or procedure described by a CPT® code, and is not appropriate for home use. HCPCS Level II codes typically describe devices used in the home environment. We will reconsider if presented with a more clear at home utility of both FDA product codes, or a claims processing need or written policies on the part of other insurers for narrowing the current HCPCS code to specific FDA product code classifications.

Final Medicare Benefit Category Determination

The current Medicare policy and prior established benefit category determination for E0487 apply to this item.

Final Medicare Payment Determination

The payment rules and pricing associated with the existing code E0487 apply to this product. Items or services described by HCPCS code E0487 are not covered under a Medicare Part B DMEPOS benefit.

Pricing = 00

Agenda Item # 16

Eddie® - HCP220511UNGLE

Topic/Issue

Request to establish a new HCPCS Level II code to describe the Eddie® device.

Applicant's suggested language: XXXXX, "External penile rigidity device that mimics the natural physiology of an erection"

Applicant's Summary

Giddy submitted a request to establish a new HCPCS Level II code to identify Eddie®, a new external penile rigidity device. Eddie® is not covered by existing HCPCS codes as it does not utilize a vacuum, inflation, deflation, surgery, or implants, and instead utilizes a first-of-its-kind design that works with the natural physiology of an erection. Eddie® is a wearable, FDA Registered Class II medical device designed to maintain penile rigidity in men with erectile dysfunction (ED). It doesn't require a prescription, vacuum, surgery, or cause any of the side effects of ED pills. Function of the product: Eddie® is designed to be worn at the base of the penis to treat ED. When worn at the base of the penis with a tension band affixed around both ends of the device, Eddie® constricts the veins in the penis, while leaving the arteries and urethra unencumbered, to maintain an erection by optimizing the blood flow in and out of the penis. Reason why existing codes do not adequately describe the product: Below are the current HCPCS codes for ED-related treatments, and explanations why none of these codes are applicable to Eddie®. C1813 - Inflatable Penile Prosthesis; This is a permanent, surgically-implanted penile prosthesis that uses inflation/deflation. This code does not adequately describe Eddie® because Eddie® is a wearable, reusable, external device that doesn't involve surgery. Eddie® is easily added and removed by the user as needed, and uses constriction around the base of the penis, not inflation or deflation, to maintain an erection. C2622 - Non-inflatable Penile Prosthesis; This is another permanent, surgically-implanted prosthesis. The only difference from C1813 is that this is a semi-rigid rod that doesn't use inflation. This code does not adequately describe Eddie® because Eddie® is a wearable, reusable, external device that doesn't involve surgery. Eddie® is easily added and removed by the user as needed, and uses constriction around the base of the penis, not a semi-rigid rod, to maintain an erection. L7900 - Male vacuum erection system + L7902 Accessory Ring; This is a "male vacuum erection system" with a component tension ring. These vacuum erection devices require multiple components to manually pump or pull blood into the penis with a vacuum. This code does not adequately describe Eddie® because Eddie® uses constriction at the base of the penis, not a vacuum, to maintain an erection. Eddie® works with the natural physiology of an erection, optimizing blood flow by constricting the veins, not the arteries or urethra, while L7900 forces the blood into the penis with a manual pump. L7900 is approximately 100 times the size of Eddie®. The applicant stated that certain third party insurers, including TRICARE, Aetna, and Blue Cross Blue Shield provide coverage of treatments for ED.

Preliminary CMS HCPCS Coding Recommendation

This application is a resubmission of an application that CMS reviewed in the B1 2021 coding cycle. In the B1 2021 coding cycle, CMS denied the request to establish a new

HCPCS Level II code to separately identify the Eddie® device because ED devices such as the Eddie® are considered over-the-counter devices and are not typically paid by insurance. In the current submission, the applicant stated that certain insurers provide coverage of treatments for ED; however, they did not provide specific documentation that any insurers provide coverage of the Eddie® device. We invite the applicant to provide documentation to demonstrate that insurers provide coverage of the Eddie® device, such as publicly-available written policies, written correspondence from other insurers that the lack of a unique HCPCS Level II code is the reason for claims denials, or documentation that insurers are allowing the Eddie® device to be billed using an existing HCPCS Level II code(s).

Summary of Public Feedback

The primary speaker disagreed with CMS' HCPCS preliminary recommendation not to establish a new HCPCS Level II code for the external FDA Class II treatment for erectile dysfunction, Eddie® by Giddy™. The speaker said Eddie® is not in the same category as existing HCPCS codes, which are limited to vacuum erection systems and surgically implanted prosthesis. Eddie® is a standalone, wearable device that does not draw/extract blood into the penis using a vacuum system, is not surgically implanted, and does not require inflation/deflation to function. Instead, Eddie® is an external device that allows blood to flow into the penis and works with the natural physiology of an erection by constricting the veins without obstructing the arteries or urethra. According to the speaker, Tricare and most private insurance entities consider the diagnosis and treatment of ED medically necessary. Due to the distinction and uniqueness of Eddie® compared to other existing ED devices, private insurances will not be able to complete the claim processing needs without a new HCPCS Level II code for Eddie®. According to the speaker, Eddie® is being utilized by the Department of Veterans Affairs (VA) and the Department of Defense (DoD) to help men with depression, anxiety, PTSD, pain management, diabetes, and cardiac conditions maintain healthier intimacy in their relationships, which is improving their overall treatment and quality of life. The speaker reiterated that establishing a new unique HCPCS Level II code for Eddie® can save Medicare and Medicaid billions of dollars annually.

CMS Final HCPCS Coding Decision

We appreciate the comments provided in response to CMS' published preliminary recommendation. Based on the information provided in the application and after consideration of the comments we received, CMS is finalizing its preliminary recommendation to deny the request to establish a new HCPCS Level II code to separately identify the Eddie® device.

CMS continues to believe over-the-counter ED devices, such as the Eddie®, are not typically paid by insurance. While the applicant provided policy information from a couple other insurers showing coverage of certain ED devices, CMS did not receive any documentation to demonstrate that insurers provide coverage of the Eddie® device, such as publicly-available written policies pertaining to the Eddie® or devices like it, written correspondence from other insurers that the lack of a unique HCPCS Level II code is the reason for claims denials, or documentation that insurers are allowing the Eddie® device to be billed using an existing HCPCS Level II code(s) or miscellaneous Level II code.

June 10, 2022 Meeting Agenda Items

Agenda Item # 1

Exersides™ Refraint™ System - HCP211227F8TPL

Topic/Issue

Request to establish a new HCPCS Level II code to identify the Exersides™ Refraint™ System.

Applicant's suggested language: XXXXX, "Upper extremity mobility device with medical equipment safety integration"

Applicant's Summary

Healthy Design submitted a request to establish a new HCPCS Level II code to identify the Exersides™ Refraint™ System, which has can be used both in the inpatient setting and at home as durable medical equipment. It is a mobility device for patients who are attached to and at risk for entanglement in vital tubes, lines and catheters such as ventilators, intravenous lines, or feeding tubes. The novel device is intended for people/patients who would otherwise require restraint, be it physical or chemical, to prevent dislodgement of attached vital medical equipment which would then render them immobile. The innovative mobility device significantly differs from physical restraint devices in that it allows and encourages mobility, and in such a way that not only complies with CMS' regulations which require use of 'least restraint necessary' by offering multiple levels of restraint including the proprietary most minimized level within its system, but also entrains tubing and cords to move with the device as the person/patient moves to prevent entanglement during mobility and allows every joint to move while allowing people/patients the ability to move safely while attached to vital tubes, lines, and catheters. The current code which most closely resembles the novel device is a physical restraint code which describes apparatuses that preclude movement of one or more joints and do not entrain lines and cords in such a way as to improve mobilization or maintain safety and mobility for the person/patient attached to vital medical equipment. In short, restraint devices are used to reduce mobility in a (failed) attempt to keep patients safe in the short-term; the Exersides™ Refraint™ System is a never-before-seen mobilization device intended to increase mobility to keep patients safe and functional in the short and long-term.

Preliminary CMS HCPCS Coding Recommendation

Existing HCPCS Level II code E0710, "Restraints, any type (body, chest, wrist or ankle)" describes the Exersides™ Refraint™ System and existing HCPCS Level II code A9300, "Exercise equipment" describes the optional bed straps of the Exersides™ Refraint™ System, when appropriate. Medicare and other payers would not separately pay for the Exersides™ Refraint™ System for inpatient use. For coding guidance, please refer to the insurer(s) in whose jurisdiction(s) claims would be filed. For Medicaid, contact the Medicaid Agency in the state in which the claims would be filed.

Preliminary Medicare Benefit Category Determination

The current Medicare policy and prior established benefit category determination for E0710 and A9300 apply to this item.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing code E0710 and A9300 apply to this product. Items or services described by HCPCS code E0710 and A9300 are not covered under Medicare Part B.

Pricing for E0710 = 57; Pricing for A9300 = 00.

Summary of Public Feedback

The primary speaker disagreed with CMS' HCPCS preliminary recommendation to use existing HCPCS Level II code E0710 "Restraints, any type (body, chest, wrist or ankle)" and A9300 "Exercise equipment" to describe the Exersides™ Refraint™ System. The speaker said that even though the device may be temporarily and optionally used as a restraint, its main function is to be an alternative to restraints and allow more movement. Because the Exersides™ Refraint™ System allows for the patient to participate in activities without the risk of physical harm, the device adheres to §482.13(e)(1)(i)(c). The optional resistance bed strap and possible configurations change the outcome of a patient who would otherwise only have the option of full restraint. According to the speaker, this unique functionality gives the device its compliance with CMS' regulations regarding 'Least Restraint Necessary' with its continual opportunity to reduce restraint level toward the Refraint's™ primary function as a safe mobility device rather than a restraint. Other speakers agreed that the Exersides™ Refraint™ System is the first device to allow at-will freedom of movement for cognitively or physically impaired people. Other devices do not provide a means to avoid entanglement in lines. All commenters requested that CMS assign a new HCPCS code to align with the cost of the Exersides™ Refraint™ System to permit the patient to participate in activities without the risk of physical harm with the least restraint necessary.

CMS Final HCPCS Coding Decision

We appreciate the comments provided in response to CMS' published preliminary recommendation. Based on the information provided in the application and after consideration of the comments we received, CMS is not making final decisions regarding HCPCS coding, Medicare benefit category, or Medicare payment at this time. Instead, we are seeking further information to better understand this device.

In an effort to better understand the clinical distinction and mechanistic parts in terms of how this product varies from other restraint devices, CMS has the following questions for the applicant:

- How does the Exersides™ Refraint™ System compare to some of the other products in this space (such as, soft surgical arm support, wearable medical tubing and cabling containment harness, arm board device, patient positioning device, arm abduction splint, arm rest for IV injections, protective arm and leg restraint, etc.)?

- Are there any data that show the Exersides™ Refraint™ System is preferable to other restraint devices, provides better health outcomes, offers statistically significant improvements in care, results in a reduction in time needing restraint, etc. ?

Agenda Item # 2

SecurAcath - HCP211223CXNXW

Topic/Issue

Request to establish new HCPCS Level II code to identify SecurAcath.

Applicant's suggested language: XXXXX, "Subcutaneous anchoring securement systems"

Applicant's Summary

Interrad Medical, Inc. submitted a request to establish a new HCPCS Level II code to identify SecurAcath. SecurAcath is a single use securement device used to hold percutaneous catheters. The subcutaneous anchoring securement system consists of two components. The base contains two small blunt flexible securement prongs, which are placed subcutaneously at the insertion site of the external catheter or tube. The cover snaps onto the base outside of the body to hold the shaft of the external device according to its specific diameter. The SecurAcath remains with the external device for the duration of need from days to years without the need to replace. External device placement and replacement are coded in the current publication. However, there is no specific code for securement of these external devices. For the most part, temporary adhesive-based or suture-based securement is replaced weekly or used beyond recommendations for use. During care of the external devices temporary securement is removed at which time the device may migrate in or out of its optimal position. Incidental retraction or removal may require replacement of the device. SecurAcath is a system that stabilizes the external device throughout the duration of need. The SecurAcath is similar to external fixation, implanted temporary spacers or interdental fixation. A SecurAcath can withstand repeated dressing changes while maintaining the catheters targeted position. There are some codes for adhesive based securement of ostomy bags. Central venous access devices that are tunneled and cuffed are coded as a higher level for payment based on the increased securement made possible by the cuff that encourages skin to adhere subcutaneously. These cuffs have variable ability to actually secure the device based on the patient's ability to heal. SecurAcath is a more reliable subcutaneous securement not related to the patient's healing rate. SecurAcath is an engineered, FDA approved, securement device.

Preliminary CMS HCPCS Coding Recommendation

Our understanding is that the SecurAcath securement device would generally be used in a procedure reported with a HCPCS Level I (CPT®) code. We have not identified a specific need for this device to be separately paid, since we believe that a particular payer may elect to pay for the service in which this device is used. For instance, Medicare would typically reflect the costs of the device in the payment for the procedure, if it is used, and as such it would not be separately payable.

Summary of Public Feedback

No verbal or written comments were provided in response to CMS' published preliminary HCPCS Level II coding recommendation.

CMS Final HCPCS Coding Decision

Based on the information provided in the application to establish a new HCPCS Level II code and considering that no comments were received, CMS is finalizing its preliminary recommendation. We continue to believe the SecurAcath securement device is not suitable for inclusion in the HCPCS Level II code set because it is used in a procedure reported with a HCPCS Level I (CPT®) code. We have not identified a specific need for this device to be separately paid, since we believe that a particular payer may elect to pay for the service in which this device is used. For instance, Medicare would typically reflect the costs of the device in the payment for the procedure, if it is used, and as such it would not be separately payable.

Agenda Item # 3

Disposable Catheter Guidewire Holder - HCP2112201BUWA

Topic/Issue

Request to establish a new HCPCS Level II code to identify Disposable Catheter Exchange Guidewire Holder.

Applicant's suggested language: XXXXX, "Disposable Catheter Exchange Guidewire Holder (Sterile) for use with CorPath GRX System"

Applicant's Summary

Siemens Healthineers submitted a request to establish a new HCPCS Level II code to identify Disposable Catheter Exchange Guidewire Holder, Sterile (the "Cassette"). It is used with the CorPath GRX system during percutaneous coronary and vascular procedures. The CorPath GRX System is intended for patients with vascular diseases. Specific patient populations vary and are dependent upon the type of interventional devices selected to be used with the system. The cassette functions to facilitate guidance and delivery of interventional devices during coronary and vascular procedures. The cassette is delivered sterile and ready for use. The CorPath GRX System is a combination of durable equipment and disposable supplies that allow for the remote delivery and manipulation of interventional devices in percutaneous coronary, peripheral vascular, and neurovascular procedures. This request for new HCPCS Level II code reflects the disposable component only (the "Cassette"). The CorPath GRX System allows physicians to deliver and manipulate commercially available guidewires, rapid exchange catheters, guide catheters, microcatheters, embolization coils, and coil assist stents during vascular interventional procedures via use of the disposable cassette. During the use of the CorPath GRX System, the physician maneuvers interventional devices using intuitive controls under independent angiographic fluoroscopy. The system allows the physician, seated at the Remote Workspace, to manipulate interventional devices at the patient bedside using joysticks or touch-screen controls on the Control Console. Commercially available interventional devices (guidewires, rapid exchange catheters, guide catheters, embolization coils and or stents) are loaded into the Single Use Cassette, attached to a Robotic Drive. The physician can then control the Robotic Drive to advance, retract, and rotate the guidewire, advance and retract the rapid exchange catheter, embolization coil, and/or coil assist stent, and advance, retract and rotate the guide catheter or microcatheter. The Robotic Drive and Control Console communicate via a single communication cable. The CorPath GRX software ensures that no movement of the commercially available interventional devices can be initiated, except by the controls at the Control Console. The CorPath GRX System is an apparatus intended to be used on human beings for treatment and alleviation of disease states, not intended by pharmacological, immunological, or metabolic means in or on the human body, but may be assisted by such means.

Preliminary CMS HCPCS Coding Recommendation

Our understanding is that the Disposable Catheter Exchange Guidewire Holder would generally be used in a procedure reported with a HCPCS Level I (CPT®) code. We have not identified a specific need for this product to be separately paid, since we believe that a particular payer may elect to pay for the service in which this product is used. For instance,

Medicare would typically reflect the costs of the product in the payment for the procedure, if it is used, and as such it would not be separately payable.

Summary of Public Feedback

No verbal or written comments were provided in response to CMS' published preliminary HCPCS Level II coding recommendation.

CMS Final HCPCS Coding Decision

Based on the information provided in the application to establish a new HCPCS Level II code and considering that no comments were received, CMS is finalizing its preliminary recommendation. We continue to believe the Disposable Catheter Exchange Guidewire Holder is not suitable for inclusion in the HCPCS Level II code set because it is used in a procedure reported with a HCPCS Level I (CPT®) code. We have not identified a specific need for this product to be separately paid, since we believe that a particular payer may elect to pay for the service in which this product is used. For instance, Medicare would typically reflect the costs of the product in the payment for the procedure, if it is used, and as such it would not be separately payable.

Agenda Item # 4

Allura® Vaginal Stent - HCP210920UCYP7

Topic/Issue

Request to establish a new HCPCS Level II code to identify the Allura® Vaginal Stent.

Applicant's suggested language: XXXXX, "Vaginal Stent for use in creating, enlarging or restoring a vagina/vaginal canal"

Applicant's Summary

PMT Corporation submitted a request to establish a new HCPCS Level II code to identify the Allura® Vaginal Stent to cover its use in vaginal procedures, including plastic surgery, gynecological procedures, genitourinary procedures and gender affirmation procedures. The function of the product is to maintain the vaginal canal following radiological or surgical procedures and assist in restoring, enlarging or creating a vagina. Currently, there is no comparable product on the market to the Allura® Vaginal Stent, and currently available codes regarding stents are related to cardiac or other non-applicable procedures and products. There are also no vaginal, gynecological, urological, genitourinary codes currently listed that apply represent the Allura® Vaginal Stent. The intended uses for the Allura® Vaginal Stent are (a) "As a pressure dressing after vaginal surgery to hold pedicle flaps or free skin grafts in close apposition to the receptor site," and (b) "As an obturator or dilator to maintain the vaginal canal and reduce the possibility of contracture and stenosis following vaginal surgery and/or radiological treatment." The Allura® Vaginal Stent is only available through a prescription from a licensed medical professional. The Allura® Vaginal Stent is considered to be a single patient-use product, intended for 90 days of use. The schedule of use is determined by the licensed medical professional. The route of administration is insertion through the vaginal canal, either during surgery or post-op. The Allura® Vaginal Stent is sold sterile, delivered in doubled-packed Tyvek® bags.

Preliminary CMS HCPCS Coding Recommendation

Our understanding is that the Allura® Vaginal Stent would generally be used in a procedure reported with a HCPCS Level I (CPT®) code. We have not identified a specific need for this product to be separately paid, since we believe that a particular payer may elect to pay for the service in which this product is used. For instance, Medicare would typically reflect the costs of the product in the payment for the procedure, if it is used, and as such it would not be separately payable.

Summary of Public Feedback

No verbal or written comments were provided in response to CMS' published preliminary HCPCS Level II coding recommendation.

CMS Final HCPCS Coding Decision

Based on the information provided in the application to establish a new HCPCS Level II code and considering that no comments were received, CMS is finalizing its preliminary

recommendation. We continue to believe the Allura® Vaginal Stent is not suitable for inclusion in the HCPCS Level II code set because it is used in a procedure reported with a HCPCS Level I (CPT®) code. We have not identified a specific need for this product to be separately paid, since we believe that a particular payer may elect to pay for the service in which this product is used. For instance, Medicare would typically reflect the costs of the product in the payment for the procedure, if it is used, and as such it would not be separately payable.

Agenda Item # 5

BandGrip® Micro-Anchor® Skin Closure - HCP2201045HMQY

Topic/Issue

Request to establish a new HCPCS Level II code to identify the BandGrip® Micro-Anchor® Skin Closure.

Applicant's suggested language: XXXXX, "Micro-anchor adhesive strip, more than 2 sq. in. but less than or equal to 16 sq. in., with any size adhesive border, each dressing"

Applicant's Summary

BandGrip Inc. submitted a request to establish a new HCPCS Level II code to identify the BandGrip strips. This skin closure product includes skin microanchors and adhesive binding technology, that through insertion of the strip anchors into the upper skin layers, creates tension required to approximate the skin on opposite sides of wounds of varying sizes and depths. Current wound care product codes describe wound care products that cover, fill, or dress a wound or have separately inserted skin anchors to create the tension necessary for wound closure.

Preliminary CMS HCPCS Coding Recommendation

This application was reviewed in the second biannual (B2) 2021 coding cycle and was included in the public meeting agenda. However, the applicant did not attend the B2 2021 public meeting held on December 1-2, 2021. CMS re-reviewed this application and did not identify new or different information from what was submitted in Bandgrip Inc.'s B2 2021 application. Our understanding is that the BandGrip® Micro-Anchor® Skin Closure would generally be used in a procedure reported with a HCPCS Level I (CPT®) code. We have not identified a specific need for this product to be separately paid, since we believe that a particular payer may elect to pay for the service in which this product is used. For instance, Medicare would typically reflect the costs of the product in the payment for the procedure, if it is used, and as such it would not be separately payable

Summary of Public Feedback

No verbal or written comments were provided in response to CMS' published preliminary HCPCS Level II coding recommendation.

CMS Final HCPCS Coding Decision

Based on the information provided in the application to establish a new HCPCS Level II code and considering that no comments were received, CMS is finalizing its preliminary recommendation. We continue to believe the BandGrip® Micro-Anchor® Skin Closure is not suitable for inclusion in the HCPCS Level II code set because it is used in a procedure reported with a HCPCS Level I (CPT®) code. We have not identified a specific need for this product to be separately paid, since we believe that a particular payer may elect to pay for the service in which this product is used. For instance, Medicare would typically reflect the costs

of the product in the payment for the procedure, if it is used, and as such it would not be separately payable.

Agenda Item # 6

AlertWet® system - HCP211001DP8XX

Topic/Issue

Request to establish a new HCPCS Level II code to identify the AlertWet® system.

Applicant's Summary

AlertWet submitted a request to establish a new HCPCS Level II code to identify the AlertWet® system. The AlertWet® system delivers a high-quality, cost-effective, innovative medical system that helps caregivers know when a disposable moisture-absorbing underpad product is wet and requires changing. The new innovative system alerts caregivers when patients' disposable products are dry, damp, wet, wetter, soaked, and requires attention before scheduled checks to reduce skin wounds, linen changes, and liabilities. Caregivers and patients need and now have available with this system an automated "patients disposable underpads are wet" alert system, critical to keep patients safe from acquiring wounds and reduce care providers' unrecoverable costs. Further, wet patients tend to get out of bed to go to the toilet, leading to unaccompanied falls and injury, extending the care improvement value of our system. The AlertWet® system performs a function that not even manual checking can achieve today. Today, caregivers try to check patients' underpads and diapers regularly (every 2 hours). But, unfortunately, patients often have voids immediately after checking and lie in wetness for long times; while skin is breaking down. Therefore, it is unrealistic and impossible for caregivers to check as often as patients can potentially soil underpads or diapers. Instead, this system checks every ten seconds to ensure patient care occurs on time and when required using a single disposable breathable underpad that moves patients 350 pounds plus and works on airbeds. Most caregivers use washable underpads, large disposable underpads, and a diaper on each patient. The AlertPad replaces all of these products with a single pad accompanying an automated checking and wet-alerting system. Dry patients also reduce the need for ointments while reducing incontinent falls. While there are codes currently for incontinence pads there are no codes that cover the benefits and value and function that AlertWet® provides. It is not coverable under A4520, or T4541 or others like it as it is not just a pad to collect urine, rather a system that allows for the reduction in wounds, and, therefore, a possible shortening of patient stays due to this reduction and improving patient care in multiple areas.

Preliminary CMS HCPCS Coding Recommendation

Our understanding is that the AlertWet® system would generally be used in a procedure reported with a HCPCS Level I (CPT®) code. We have not identified a specific need for this product to be separately paid, since we believe that a particular payer may elect to pay for the service in which this product is used. For instance, Medicare would typically reflect the costs of the product in the payment for the procedure, if it is used, and as such it would not be separately payable.

Based on the reported settings of use for the AlertWet® System, CMS believes existing HCPCS Level II codes A4520, "Incontinence garment, any type, (e.g., brief, diaper), each" or T4541, "Incontinence product, disposable underpad, large, each" could be used to describe the disposable moisture-absorbing underpad component of the AlertWet® System in

conjunction with existing HCPCS Level II code A9280, “Alert or alarm device, not otherwise classified” to describe the alert/alarm component of the AlertWet® System. These codes are available for assignment by insurers if they deem it appropriate.

We welcome information from the applicant explaining why the referenced HCPCS codes do not work for Medicaid or other insurers and demonstrating the need for a new HCPCS Level II “T” code to identify an incontinence pad that incorporates wetness sensor monitoring technology, compatible with AlertWet® system.

Preliminary Medicare Benefit Category Determination

The current Medicare policy and prior established benefit category determinations for T4541, A4520 and A9280 apply to this item.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing codes T4541, A4520 and A9280 apply to this product. Items or services described by HCPCS code T4541, A4520 and A9280 are not covered under Medicare Part B.

Pricing = 00

Summary of Public Feedback

The primary speaker disagreed with CMS’ HCPCS preliminary recommendation to use existing HCPCS Level II code A4520 “Incontinence garment, any type, (e.g., brief, diaper), each”, T4541 “Incontinence product, disposable underpad, large, each” or A9280 “Alert or alarm device, not otherwise classified” to describe the AlertWet® System. The speaker said the AlertWet® System is not a single incontinent product, garment or medical supply, nor is it an alarm. The AlertWet® System monitors patients’ AlertPads™ volume of wetness (urine and feces) in real-time, improves patient care and safety, and improves care organizations’ star rating and PSIs (falls/wound care). According to the speaker, caregivers immediately know when patients need changing and are able to respond quickly. The AlertWet® System provides a schedule for patient toilet training and delivers volume estimates to validate diuretics and bodily functions. The speaker acknowledged that the AlertWet® System does alert and monitor, but emphasized that the AlertWet® System is much more.

According to the speaker, three successful clinical trials have been conducted with outstanding outcomes including: caregiver accountability, quick soiled patient changes, fewer patient disruptions, reports of patients utilizing the toilet more often, knowledge of patient volume output estimates, confirmation diuretics are working, no incontinent falls and no new skin wounds during the study, improved patient care with a happier family, reduced laundry and the use of many misused incontinent products, and reduced ointment use.

The speaker commented that other incontinent products are very different from incontinent monitoring. Underpads require manual checking, diapers reduce skin breathability, catheters often lead to urinary tract infections, urine collection systems reduce patient checking and can lead to wounds and tissue damage, and no incontinent products monitor the patient in real-time to ensure quick changing from soiled to dry. The AlertWet® System is a proactive

approach before skin wounds develop versus a reactive approach to patient suffering and costs.

CMS Final HCPCS Coding Decision

We appreciate the comments provided in response to CMS' published preliminary recommendation. Based on the information provided in the application and after consideration of the comments we received, CMS is revising its preliminary recommendation and finalizing the following decision:

Existing HCPCS Level II codes A4554 "Disposable underpads, all sizes" and A9280 "Alert or alarm device, not otherwise classified" together describe the AlertWet® System.

CMS appreciates the positive effects and benefits of the AlertWet® System. After further consideration and review, we no longer believe T4541 or A4520 appropriately describe the AlertWet® System. The AlertWet® System is a disposable underpad that alerts caregivers when a set amount of urine is collected in or onto the pad. The AlertWet® System is similar to those devices in existing HCPCS Level II codes A4554 and A9280. Existing HCPCS Level II code A4554 describes a disposable pad with embedded moisture sensors; and existing HCPCS Level II code A9280 describes the AlertClip™ that wirelessly communicates to the software and alerts caregivers when the AlertPads™ become wet.

Final Medicare Benefit Category Determination

The current Medicare policy and prior established benefit category determinations for A4554 and A9280 apply to this item.

Final Medicare Payment Determination

The payment rules and pricing associated with the existing codes A4554 and A9280 apply to this product. Items or services described by HCPCS code A4554 and A9280 are not covered under Medicare Part B.

Pricing = 00

Agenda Item # 7

Magtrace® - HCP211224JJ1BQ

Topic/Issue

Request to establish a new HCPCS Level II code to identify Magtrace®.

Applicant's suggested language: QXXXX, "Carboxydextran-coated superparamagnetic iron oxide particles in water containing 0.3% w/v sodium chloride, diagnostic, 2ml study dose"

Applicant's Summary

Endomag submitted a request to establish a new HCPCS Level II code to identify the single use 2ml vial of Magtrace®. Magtrace® is a non-radioactive combination device/drug product and assists in localizing lymph nodes draining a breast cancer tumor site as part of a sentinel lymph node biopsy in patients with breast cancer undergoing a mastectomy. Magtrace® is a solution of iron nanoparticles coated with a carboxydextran shell which maps lymphatic drainage to the axilla. It is injected subcutaneously into interstitial breast tissue days or weeks before, or during, the surgery. Magtrace® use eliminates radiation exposure by replacing the use of the radioisotope and the blue dye that may cause severe allergic reactions. Magtrace® consists of a sterile aqueous suspension of carboxydextran-coated superparamagnetic iron oxide particles in water for injection (WFI) containing 0.3% w/v sodium chloride. Magtrace® does not quickly decay and is retained in the sentinel node, which allows injection from 20 minutes, to weeks before surgery. Injection may occur prior to the surgery in the physician practice, including freestanding radiology centers, and in the hospital outpatient setting, by a radiologist or surgeon. There is no HCPCS code to report Magtrace®. The codes for non-radioactive, non-contrast visualization adjuncts (Q9968) or nonradioactive contrast imaging material, not otherwise classified, per study (A9698) are not appropriate. Magtrace® is not a visualization adjunct or contrast agent. Magtrace® should not be included in Current Procedural Terminology (CPT®) coding (as suggested by CMS in the prior HCPCS application). This request is only to establish a unique HCPCS code for Magtrace® just as radioisotopes (Technetium/Lymphoseek) have a unique product code for separate reporting from the administration procedure.

Preliminary CMS HCPCS Coding Recommendation

Our understanding is that Magtrace® would generally be used in a procedure reported with a HCPCS Level I (CPT®) code. We have not identified a specific need for Magtrace® to be separately paid, since we believe that a particular payer may elect to pay for the service in which Magtrace® is used. For instance, Medicare would typically reflect the costs of Magtrace® in the payment for the procedure, if it is used, and as such it would not be separately payable.

Summary of Public Feedback

The primary speaker disagreed with CMS' HCPCS preliminary recommendation that Magtrace® would generally be used in a procedure reported with a HCPCS Level I (CPT®) code. The applicant stated Magtrace® is a non-radioactive combination device/drug product and assists in localizing lymph node drainage as part of a sentinel lymph node biopsy in

patients with breast cancer undergoing a mastectomy. The speaker requested a unique code to identify the single use 2ml vial of Magtrace®. Magtrace® is a solution of iron nanoparticles coated with a carboxydextran shell which maps lymphatic drainage to the axilla injected subcutaneously into interstitial breast tissue. Magtrace® does not quickly decay and is retained in the sentinel node, which allows injections to occur from twenty minutes to weeks before surgery. According to the speaker, the injection may occur prior to the surgery in the physician practice, including freestanding radiology centers, or in the hospital outpatient setting by a radiologist or surgeon. The speaker noted that the codes for non-radioactive, non-contrast visualization adjuncts (Q9968) or nonradioactive contrast imaging material, not otherwise classified, per study (A9698) are not appropriate because Magtrace® is not a visualization adjunct or contrast agent. The speaker noted that Magtrace® could be bundled and include in a CPT® code if injected during the time of the procedure; however, since Magtrace® can be administered days or weeks before the time of the procedure, a separate code is warranted. The speaker suggested the descriptor of "carboxydextran-coated superparamagnetic iron oxide particles in water containing 0.3% w/v sodium chloride, diagnostic, 2ml study dose."

CMS Final HCPCS Coding Decision

We appreciate the comments provided in response to CMS' published preliminary recommendation. Based on the information provided in the application and after consideration of the comments we received, CMS requires additional time to consider Endomag's request to establish a new HCPCS Level II code to identify Magtrace®. As a result, CMS is deferring this application to the next biannual coding cycle.

Agenda Item # 8

Social Determinants of Health (SDOH) Assessment - HCP22010430R11

Topic/Issue

Request to establish a new HCPCS Level II code to identify Social Determinants of Health (SDOH) assessment.

Applicant's suggested language: QXXXX, "Social determinants of health (SDOH)"

Applicant's Summary

The American Psychological Association (APA) submitted a request to establish a new HCPCS Level II code to identify SDOH assessment (e.g., education/history, employment/unemployment, occupational exposure, housing/economic circumstances, social environment, upbringing, family support group/family circumstance, psychosocial), with scoring and documentation. An assessment provides a vital opportunity for qualified healthcare providers to assess the needs of patients, on an ongoing basis, in order to promote emotional, behavioral and medical health. The age-appropriate SDOH assessment is administered, scored and documented by the qualified healthcare professional. SDOH assessments include the following areas of interest, education/history, employment/unemployment, occupational exposure, housing/economic circumstances, social environment, upbringing, family support group/family circumstance and psychosocial. While SDOH ICD-10 diagnosis codes exist, a universally recognized HCPCS code does not exist to report an assessment of SDOH by a qualified healthcare professional. HCPCS code H0025 "Behavioral health prevention education service (delivery of services with target population to affect knowledge, attitude and/or behavior)" is recognized by some payers, as are SDOH ICD-10 codes, but HCPCS code H0025 has a Medicare Status I "Not Valid for Medicare Purposes." Physicians may include their time for SDOH screening in evaluation and management (E/M) CPT® Codes (i.e. 99212-99215). However, qualified health care professionals, other than Doctors of Medicine and Doctors of Osteopathic Medicine, cannot report E/M CPT® Codes 99212-99215.

Preliminary CMS HCPCS Coding Recommendation

CMS believes the work done by qualified health care professionals to perform SDOH assessments is consistent with the type of provider services described by HCPCS Level I (CPT®) codes. CMS refers this applicant to the American Medical Association (AMA) CPT® Editorial Panel for coding guidance on reporting SDOH assessments.

Summary of Public Feedback

The primary speaker disagreed with CMS' HCPCS preliminary recommendation that Social Determinants of Health assessments would generally be used in a procedure reported with a HCPCS Level I (CPT®) code. The speaker stated the American Psychological Association respects the recommendation to work with the AMA HCPCS Level I (CPT®) Panel; however, the existing coding options (HCPCS Level I (CPT®) and HCPCS Level II), do not provide a mechanism for capturing standardized assessment of SDOH on a routine basis.

Also, the speaker stated the current HCPCS Level I (CPT®) codes are inaccessible to many qualified healthcare professionals.

CMS Final HCPCS Coding Decision

We appreciate the comments provided in response to CMS' published preliminary recommendation. At the HCPCS public meeting, the applicant stated that the APA would be engaging with the AMA's CPT Editorial Panel on this topic to request a new CPT® code specific to SDOH assessments. HCPCS Level I (CPT®) codes generally describe the work of healthcare professionals, and to the extent that SDOH assessments are conducted by healthcare professionals as part of patient care, we believe HCPCS Level I (CPT®) codes could be developed to describe this activity. CMS is interested in hearing the outcome of that conversation.

CMS is committed to building solutions that will help close gaps in healthcare quality, access, and outcomes. Accordingly, in the Calendar Year 2023 Physician Fee Schedule Proposed Rule (87 FR 45860), we included a Request for Information (RFI) on Medicare Part B Payment for Services Involving Community Health Workers (CHWs) (https://www.govinfo.gov/content/pkg/FR-2022-07-29/pdf/2022-14562.pdf). Discussion of the CHW RFI begins on page 45940. We are reviewing the comments and intend to continue to engage on this broader issue.

Agenda Item # 9

Chaplain Services - HCP220103QGVN8

Topic/Issue

Request to revise existing HCPCS Level II code Q9001 to remove "department of veterans affairs."

Applicant's suggested language: Q9001, which currently reads "Assessment by department of veterans affairs chaplain services" to instead read "Assessment by chaplain services"

Applicant's Summary

HealthCare Chaplaincy Network submitted a request to revise HCPCS Level II code Q9001 to remove "department of veterans affairs." Chaplain spiritual care provides in-depth specialist spiritual and pastoral care and counseling, which is integrated into the total care and treatment program. Chaplains provide a full range of spiritual and pastoral care and counseling that is characterized by in-depth assessment, evaluation and treatment of patients with many different spiritual and religious needs. As part of an integrated and comprehensive bio-psycho-social-spiritual approach, ascertaining a patient's spiritual preference and practices and how they wish those integrated into their care, and developing appropriate goals and outcomes of spiritual care. The chaplain also provides consultation, counseling and support to family members and staff. Professional chaplains are clinically trained to provide this care. The existing codes only apply to hospice and /or chaplaincy services in the Veterans Health Administration (VHA). However, the need for standardized data for budgeting and quality purposes that was identified by the VHA as a justification for the original codes also applies to all US health care institutions. Emerging objectives of care such as the needs to drive accountable care and advance health equity as proposed in the Strategy Refresh of the Center for Medicare and Medicaid Innovation (CMMI) can benefit from chaplaincy care and thus require the collection of standardized data. At present, there are no standardized chaplaincy care data sets essential to this data collection.

Preliminary CMS HCPCS Coding Recommendation

This application from the HealthCare Chaplaincy Network is a repeat from 2021 and did not contain any new information in response to the previous HCPCS Level II coding decision. CMS continues to understand the desire for HCPCS Level II codes to assist with the collection of standardized data for chaplain spiritual care. However, CMS is still not aware of a claims processing need on the part of other insurers for reporting chaplain activity other than the Department of Veterans Affairs. CMS' recommendation is to maintain the existing HCPCS Level II chaplain codes for use by the Department of Veterans Affairs.

Summary of Public Feedback

The primary speaker disagreed with CMS' HCPCS preliminary recommendation to not revise existing HCPCS Level II codes Q9001 "Assessment by department of veterans affairs chaplain services", Q9002 "Counseling, individual, by department of veterans affairs chaplain services", and Q9003 "Counseling, group, by department of veterans affairs chaplain services." The request was to remove the term "department of veterans affairs." The

speaker expressed appreciation for CMS affirming the need for codes to assist with the collection of standardized data for chaplain spiritual care.

According to the speaker, CMS' reason to exclude chaplains from HCPCS Level II coding is that chaplain visits are not captured in claims data. However, CMS is currently seeking endorsement from the National Quality Forum (NQF) for a quality measure that seeks to address the lack of visits from hospice staff in the last days of life by having the hospice report visits by staff in the last three days of life. The speaker referenced that CMS noted that there is no standard way to collect data on chaplain visits. Thus, hospices will be incentivized to substitute a nurse or social work visit for a chaplain visit even when the chaplain visit is clinically indicated or preferred. The speaker asserted that CMS suggested chaplains cannot be included in a quality measure because chaplain visits cannot be tracked. On the other hand, CMS did not approve the HCPCS Level II code request that would provide that standard measure needed. Revising Q9001, Q9002, and Q9003 will provided the mechanism for gathering data on chaplain visits and open the door for inclusion of chaplains in quality measures such as NQF 3645. Through this measure and other measures, the Chaplain services will improve the quality of whole person care that every beneficiary deserves.

Ascension submitted comments to support the request to revise existing HCPCS Level II codes to identify Chaplain services. It is one of the leading non-profit and Catholic health systems in the United States. Ascension currently offers Medicare Advantage (MA) coverage through a joint venture (JV) – Ascension Complete (AC) – across eight states. Ascension functions as an insurer directly and through JVs with other insurance providers. Their products include ACA Marketplace plans, Medicaid, and Medicare Advantage (MA). Ascension specifically highlighted Ascension Complete (AC) plan for which CMS recently authorized the offering of Spiritual Care using chaplain services as a primarily health related optional supplemental benefit. In other words, the Ascension Complete MA plan covers members' use of chaplain services, primarily as offered by in-network Ascension chaplains through a dedicated Spiritual Care program.

Ascension also indicated that based on their experience to date with the Special Supplemental Benefits for the Chronically Ill (SSBCI) offering, they anticipate that this expanded supplemental benefits offering will lead to more of their ACJV members utilizing the spiritual care benefit as part of the healthcare they obtain through in-network Ascension providers and facilities, which in turn, will require Ascension chaplains to submit claims for services provided.

CMS Final HCPCS Coding Decision

We appreciate the comments provided in response to CMS' published preliminary recommendation. Based on the information provided in the application and after consideration of the comments we received from another insurer indicating a claims processing need for reporting chaplain activity, CMS is revising its preliminary recommendation and finalizing the decision to:

Revise HCPCS Level II code Q9001 to read "Assessment by chaplain services"

Agenda Item # 9

Chaplain Services - HCP2201036JBC9

Topic/Issue

Request to revise existing HCPCS Level II code Q9002 to remove "department of veterans affairs."

Applicant's suggested language: Q9002, which currently reads "Counseling, individual, by department of veterans affairs chaplain services" to instead read "Counseling, individual, by chaplain services"

Applicant's Summary

HealthCare Chaplaincy Network submitted a request to revise HCPCS Level II code Q9002 to remove "department of veterans affairs." Chaplain spiritual care provides in-depth specialist spiritual and pastoral care and counseling, which is integrated into the total care and treatment program. Chaplains provide a full range of spiritual and pastoral care and counseling that is characterized by in-depth assessment, evaluation and treatment of patients with many different spiritual and religious needs. As part of an integrated and comprehensive bio-psycho-social-spiritual approach, ascertaining a patient's spiritual preference and practices and how they wish those integrated into their care, and developing appropriate goals and outcomes of spiritual care. The chaplain also provides Feedback, counseling and support to family members and staff. Professional chaplains are clinically trained to provide this care. The existing codes only apply to hospice and /or chaplaincy services in the Veterans Health Administration (VHA). However, the need for standardized data for budgeting and quality purposes that was identified by the VHA as a justification for the original codes also applies to all US health care institutions. Emerging objectives of care such as the needs to drive accountable care and advance health equity as proposed in the Strategy Refresh of the Center for Medicare and Medicaid Innovation (CMMI) can benefit from chaplaincy care and thus require the collection of standardized data. At present, there are no standardized chaplaincy care data sets essential to this data collection.

Preliminary CMS HCPCS Coding Recommendation

This application from the HealthCare Chaplaincy Network is a repeat from 2021 and did not contain any new information in response to the previous HCPCS Level II coding decision. CMS continues to understand the desire for HCPCS Level II codes to assist with the collection of standardized data for chaplain spiritual care. However, CMS is still not aware of a claims processing need on the part of other insurers for reporting chaplain activity other than the Department of Veterans Affairs. CMS' recommendation is to maintain the existing HCPCS Level II Chaplain codes for use by the Department of Veterans Affairs.

Summary of Public Feedback

The primary speaker disagreed with CMS' HCPCS preliminary recommendation to not revise existing HCPCS Level II codes Q9001 "Assessment by department of veterans affairs chaplain services", Q9002 "Counseling, individual, by department of veterans affairs chaplain services", and Q9003 "Counseling, group, by department of veterans affairs

chaplain services." The request was to remove the term "department of veterans affairs." The speaker expressed appreciation for CMS affirming the need for codes to assist with the collection of standardized data for chaplain spiritual care.

According to the speaker, CMS' reason to exclude chaplains from HCPCS Level II coding is that chaplain visits are not captured in claims data. However, CMS is currently seeking endorsement from the National Quality Forum (NQF) for a quality measure that seeks to address the lack of visits from hospice staff in the last days of life by having the hospice report visits by staff in the last three days of life. The speaker referenced that CMS noted that there is no standard way to collect data on chaplain visits. Thus, hospices will be incentivized to substitute a nurse or social work visit for a chaplain visit even when the chaplain visit is clinically indicated or preferred. The speaker asserted that CMS suggested chaplains cannot be included in a quality measure because chaplain visits cannot be tracked. On the other hand, CMS did not approve the HCPCS Level II code request that would provide that standard measure needed. Revising Q9001, Q9002, and Q9003 will provided the mechanism for gathering data on chaplain visits and open the door for inclusion of chaplains in quality measures such as NQF 3645. Through this measure and other measures, the Chaplain services will improve the quality of whole person care that every beneficiary deserves.

Ascension submitted comments to support the request to revise existing HCPCS Level II codes to identify Chaplain services. It is one of the leading non-profit and Catholic health systems in the United States. Ascension currently offers Medicare Advantage (MA) coverage through a joint venture (JV) – Ascension Complete (AC) – across eight states. Ascension functions as an insurer directly and through JVs with other insurance providers. Their products include ACA Marketplace plans, Medicaid, and Medicare Advantage (MA). Ascension specifically highlighted Ascension Complete (AC) plan for which CMS recently authorized the offering of Spiritual Care using chaplain services as a primarily health related optional supplemental benefit. In other words, the Ascension Complete MA plan covers members' use of chaplain services, primarily as offered by in-network Ascension chaplains through a dedicated Spiritual Care program.

Ascension also indicated that based on their experience to date with the Special Supplemental Benefits for the Chronically Ill (SSBCI) offering, they anticipate that this expanded supplemental benefits offering will lead to more of their ACJV members utilizing the spiritual care benefit as part of the healthcare they obtain through in-network Ascension providers and facilities, which in turn, will require Ascension chaplains to submit claims for services provided.

CMS Final HCPCS Coding Decision

We appreciate the comments provided in response to CMS' published preliminary recommendation. Based on the information provided in the application and after consideration of the comments we received from another insurer indicating a claims processing need for reporting chaplain activity, CMS is revising its preliminary recommendation and finalizing the decision to:

Revise HCPCS Level II code Q9002 to read "Counseling, individual, by chaplain services"

Agenda Item # 9

Chaplain Services - HCP2201034JRL4

Topic/Issue

Request to revise existing HCPCS Level II code Q9003 to remove "department of veterans affairs."

Applicant's suggested language: Q9003, which currently reads "Counseling, group, by department of veterans affairs chaplain services" to instead read "Counseling, group, by chaplain services"

Applicant's Summary

HealthCare Chaplaincy Network submitted a request to revise HCPCS Level II code Q9003 to remove "department of veterans affairs." Chaplain spiritual care provides in-depth specialist spiritual and pastoral care and counseling, which is integrated into the total care and treatment program. Chaplains provide a full range of spiritual and pastoral care and counseling that is characterized by in-depth assessment, evaluation and treatment of patients with many different spiritual and religious needs. As part of an integrated and comprehensive bio-psycho-social-spiritual approach, ascertaining a patient's spiritual preference and practices and how they wish those integrated into their care, and developing appropriate goals and outcomes of spiritual care. The chaplain also provides consultation, counseling and support to family members and staff. Professional chaplains are clinically trained to provide this care. The existing codes only apply to hospice and /or chaplaincy services in the Veterans Health Administration (VHA). However, the need for standardized data for budgeting and quality purposes that was identified by the VHA as a justification for the original codes also applies to all US health care institutions. Emerging objectives of care such as the needs to drive accountable care and advance health equity as proposed in the Strategy Refresh of the Center for Medicare and Medicaid Innovation (CMMI) can benefit from chaplaincy care and thus require the collection of standardized data. At present, there are no standardized chaplaincy care data sets essential to this data collection.

Preliminary CMS HCPCS Coding Recommendation

This application from the HealthCare Chaplaincy Network is a repeat from 2021 and did not contain any new information in response to the previous HCPCS Level II coding decision. CMS continues to understand the desire for HCPCS Level II codes to assist with the collection of standardized data for chaplain spiritual care. However, CMS is still not aware of a claims processing need on the part of other insurers for reporting chaplain activity other than the Department of Veterans Affairs. CMS' recommendation is to maintain the existing HCPCS Level II Chaplain codes for use by the Department of Veterans Affairs.

Summary of Public Feedback

The primary speaker disagreed with CMS' HCPCS preliminary recommendation to not revise existing HCPCS Level II codes Q9001 "Assessment by department of veterans affairs chaplain services", Q9002 "Counseling, individual, by department of veterans affairs chaplain services", and Q9003 "Counseling, group, by department of veterans affairs

chaplain services." The request was to remove the term "department of veterans affairs." The speaker expressed appreciation for CMS affirming the need for codes to assist with the collection of standardized data for chaplain spiritual care.

According to the speaker, CMS' reason to exclude chaplains from HCPCS Level II coding is that chaplain visits are not captured in claims data. However, CMS is currently seeking endorsement from the National Quality Forum (NQF) for a quality measure that seeks to address the lack of visits from hospice staff in the last days of life by having the hospice report visits by staff in the last three days of life. The speaker referenced that CMS noted that there is no standard way to collect data on chaplain visits. Thus, hospices will be incentivized to substitute a nurse or social work visit for a chaplain visit even when the chaplain visit is clinically indicated or preferred. The speaker asserted that CMS suggested chaplains cannot be included in a quality measure because chaplain visits cannot be tracked. On the other hand, CMS did not approve the HCPCS Level II code request that would provide that standard measure needed. Revising Q9001, Q9002, and Q9003 will provided the mechanism for gathering data on chaplain visits and open the door for inclusion of chaplains in quality measures such as NQF 3645. Through this measure and other measures, the Chaplain services will improve the quality of whole person care that every beneficiary deserves.

Ascension submitted comments to support the request to revise existing HCPCS Level II codes to identify Chaplain services. It is one of the leading non-profit and Catholic health systems in the United States. Ascension currently offers Medicare Advantage (MA) coverage through a joint venture (JV) – Ascension Complete (AC) – across eight states. Ascension functions as an insurer directly and through JVs with other insurance providers. Their products include ACA Marketplace plans, Medicaid, and Medicare Advantage (MA). Ascension specifically highlighted Ascension Complete (AC) plan for which CMS recently authorized the offering of Spiritual Care using chaplain services as a primarily health related optional supplemental benefit. In other words, the Ascension Complete MA plan covers members' use of chaplain services, primarily as offered by in-network Ascension chaplains through a dedicated Spiritual Care program.

Ascension also indicated that based on their experience to date with the Special Supplemental Benefits for the Chronically Ill (SSBCI) offering, they anticipate that this expanded supplemental benefits offering will lead to more of their ACJV members utilizing the spiritual care benefit as part of the healthcare they obtain through in-network Ascension providers and facilities, which in turn, will require Ascension chaplains to submit claims for services provided.

CMS Final HCPCS Coding Decision

We appreciate the comments provided in response to CMS' published preliminary recommendation. Based on the information provided in the application and after consideration of the comments we received from another insurer indicating a claims processing need for reporting chaplain activity, CMS is revising its preliminary recommendation and finalizing the decision to:

Revise HCPCS Level II code Q9003 to read "Counseling, group, by chaplain services"

Agenda Item # 10

VibraCool - HCP220103PBVLQ

Topic/Issue

Request to establish a new HCPCS Level II code to identify a vibrating motor for focal mechanical stimulation, capable of applying torque perpendicular to skin surface directly under compression or indirectly when attached to a rigid brace, with frequency 80-300 Hz.

Applicant's suggested language: XXXXX, "Vibrating motor for focal mechanical stimulation, capable of applying torque perpendicular to skin surface directly under compression or indirectly when attached to a rigid brace, with frequency 80-300 Hz, each"

Applicant's Summary

Pain Care Labs submitted a request to establish a new HCPCS Level II code to identify a vibrating motor for focal mechanical simulation, capable of applying torque perpendicular to skin surface directly under compression or indirectly when attached to a rigid brace, with frequency 80-300 Hz. The code would describe a mechanical simulation (m-stim) motor used for focal mechanical stimulation, usually in conjunction with cold or heat packs. To be effective, the motor must vibrate at a high rate (80 - 300 Hz) and at a non-traumatic amplitude, and the vibration energy must be applied perpendicularly, conforming continuously to the skin overlaying the affected area (i.e., not at a single point). Pocketed compression accessories are used to ensure vibrations travel perpendicularly in the target area; alternatively, if the patient is using a rigid brace for joint stabilization, the motor may be attached to the brace. The effect of using the motor is supported and amplified by reusable cold or heat pack accessories configured for use with the motor, as needed. (The accessories are subject to separate applications.) Pain Care Labs currently distributes its patented motor configuration, which vibrates at 200 HZ, under the trade name VibraCool. With respect to function, studies support use of m-stim for treatment of (1) joint instability or weakness, with or without pain (resulting from, e.g., tendinopathies, inactivity, stroke, osteoarthritis, post-operative weakness, post-ligamentous injury, or muscular or bony injury); (2) chronic pain or spasms (osteoarthritis, stroke, or post-operative spasms); (3) acute pain (post-operative inflammation, post-operative skin disruption, itching from healing, or physical therapy); or (4) inflammatory pain (injury or rheumatoid arthritis). Under a National Institutes of Health grant, Pain Care Labs is extending research to the effectiveness of its m-stim configuration in decreasing opioid use for lower-back pain.

No existing codes describe this item. Indications for use as cleared by FDA relevant to this application are for the temporary relief of minor injuries (muscle or tendon aches) and to treat myofascial pain caused by trigger points, restricted motion and muscle tension. The method of action is to apply high-frequency low-amplitude mechanical stimulation to a target body part, accompanied as appropriate by application of heat or cold. Application perpendicular to the skin surface ensures mechanical energy penetrates the muscles, stimulating production of growth and repair hormones by muscle and bone cells while mechanically separating muscle fibers contracted by energy or spasm, facilitating increased mobility. Vibratory energy transmitted in conformity to a contiguous surface area stimulates deep Pacinian mechanoreceptors, overring the A-Delta pain signal transmission in the spine (gate control).

Heat aids in central and peripheral pain and spasm reduction, while cold acts centrally and locally to reduce pain and inflammation.

Preliminary CMS HCPCS Coding Recommendation

CMS has not identified a program operating need for Medicare or other payers for a new HCPCS Level II code to describe a vibrating motor for focal mechanical simulation, capable of applying torque perpendicular to skin surface directly under compression or indirectly when attached to a rigid brace, with frequency 80-300 Hz. With regard to Medicare, we do not have a benefit category for massage devices such as VibraCool, as they do not meet the definition of durable medical equipment. We welcome information from the applicant and other insurers who are currently paying for this product to demonstrate a claims processing need for a unique HCPCS Level II code.

Summary of Public Feedback

The primary speaker disagreed with CMS' HCPCS preliminary recommendation of no program operating need for the VibraCool System. According to the speaker, there is an operating need for codes, in particular, for workers' compensation. The speaker commented that in multiple situations, clinical decision makers wanted the VibraCool for their patients but were turned down by their leadership due to lack of a unique HCPCS code.

The speaker commented that VibraCool is not a massage device, but a focal stimulation device. VibraCool vibrates at 200 Hz, with action constrained by compression accessories to deliver energy perpendicularly to the skin surface so that it penetrates the deep underlying tissues and activates particular neural structures useful for pain control. The heat and cool packs have been designed to remain solid while in use. Massager devices, in contrast, typically vibrate at 30 to 80 Hz and do not involve sustained compression. Massage devices must be placed over the affected area, which may be painful because of injury or surgery, while VibraCool can be placed along the neural pathway between the source of the pain and the brain. The sensation when using the VibraCool is intense and not likely to be tolerated unless the patient is in pain or suffering from joint weakness/instability. The speaker claimed that VibraCool meets the characteristics for durable medical equipment.

The speaker stated the because the device is considered minimal risk, the manufacturer does not need to file a new 510(k) for new iterations of the device. The predicate iteration of VibraCool is classified as a massager from the FDA. The speaker commented that terms have changed and they do not want to be considered a massager device, but a mechanical stimulator.

CMS Final HCPCS Coding Decision

We appreciate the comments provided in response to CMS' published preliminary recommendation. Based on the information provided in the application and after consideration of the comments we received, CMS is finalizing its preliminary recommendation. CMS has not identified a program operating need for Medicare or other payers for a new HCPCS Level II code to describe a vibrating motor for focal mechanical simulation, capable of applying torque perpendicular to skin surface directly under compression or indirectly when attached to a rigid brace, with frequency 80-300 Hz.

Medicare Benefit Category Determination

With regard to Medicare, we do not have a benefit category for massage devices, such as VibraCool, as they do not meet the definition of durable medical equipment (DME). Per section 280.1 of chapter 1, part 4 of the Medicare National Coverage Determinations Manual (CMS Pub. 100-03), massage devices 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.

Agenda Item # 10

VibraCool - HCP220103PAHMY

Topic/Issue

Request to establish a new HCPCS Level II code to identify a cold pack accessory used in conjunction with a vibrating motor for focal mechanical stimulation.

Applicant's suggested language: XXXXX, "Cold pack accessory capable of transmitting vibration when frozen, configured for use with vibrating motor for focal mechanical stimulation, reusable, each"

Applicant's Summary

Pain Care Labs submitted a request to establish a new HCPCS Level II code to identify a cold pack accessory used in conjunction with a vibrating motor for focal mechanical stimulation. (This vibrating motor is subject to a separate application.) The code sought in this application would be used to describe a cold pack accessory designed to apply cryotherapy to a specific target area subject to focal mechanical stimulation. This item is frozen solid to be used, so that it transmits rather than dampens the transmission of mechanical energy to the target area. The accessory is configured to fit the footprint of the vibrating motor and to be held in place between the vibrating motor and the skin surface when the motor is activated. With respect to function, mechanical stimulation with cold may be used for treatment of (1) weakness with or without pain due to stroke, or pain due to tendinopathies, rheumatoid arthritis or osteoarthritis, post-operative pain, post-ligamentous injury, or muscular or bony injury); (2) chronic pain (osteoarthritis, stroke,); (3) acute pain (post-operative inflammation, post-operative skin disruption, itching from healing, or physical therapy); or (4) inflammatory pain (injury or rheumatoid arthritis). Cold acts centrally and locally to reduce pain and inflammation, and the physiological effects of mechanical stimulation are synergistically maximized by simultaneous application of cold. An existing code could describe this item, but the items it describes are not covered by Medicare. This accessory is a critical element of the vibrating motor's system for pain or inflammation, and to be able to provide coverage, payers must be able to distinguish this item from other, non-covered items. Indications for use as cleared by FDA relevant to this application are for temporary relief of minor injuries (muscle or tendon aches) and to treat myofascial pain caused by trigger points, restricted motion and muscle tension. The method of action is application of cryotherapy in conjunction with vibration; the transmission of vibration requires that the cold pack accessory be rigid when applied, to ensure that vibrations are transmitted effectively rather than dampened by the accessory. The system is usually applied to the target area for 20 minutes; the accessory thaws after that time. Pain Care Labs makes the item available as part of a kit with the motor and other accessories or separately as needed for replacement.

Preliminary CMS HCPCS Coding Recommendation

CMS has not identified a program operating need for Medicare or other payers for a new HCPCS Level II code to describe a cold pack accessory used in conjunction with a vibrating motor for focal mechanical simulation. With regard to Medicare, we do not have a benefit category for massage devices such as VibraCool, as they do not meet the definition of durable medical equipment. We welcome information from the applicant and other insurers who are

currently paying for this product to demonstrate a claims processing need for a unique HCPCS Level II code.

Summary of Public Feedback

The primary speaker disagreed with CMS' HCPCS preliminary recommendation of no program operating need for the VibraCool System. According to the speaker, there is an operating need for codes, in particular, for workers compensation. The speaker commented that in multiple situations, clinical decision makers wanted the VibraCool for their patients but were turned down by their leadership due to lack of a unique HCPCS code.

The speaker commented that VibraCool is not a massage device, but a focal stimulation device. VibraCool vibrates at 200 Hz, with action constrained by compression accessories to deliver energy perpendicularly to the skin surface so that it penetrates the deep underlying tissues and activates particular neural structures useful for pain control. The heat and cool packs have been designed to remain solid while in use. Massager devices, in contrast, typically vibrate at 30 to 80 Hz and do not involve sustained compression. Massage devices must be placed over the affected area, which may be painful because of injury or surgery, while VibraCool can be placed along the neural pathway between the source of the pain and the brain. The sensation when using the VibraCool is intense and not likely to be tolerated unless the patient is in pain or suffering from joint weakness/instability. The speaker claimed that VibraCool meets the characteristics for durable medical equipment.

The speaker stated the because the device is considered minimal risk, the manufacturer does not need to file a new 510(k) for new iterations of the device. The predicate iteration of VibraCool is classified as a massager from the FDA. The speaker commented that terms have changed and they do not want to be considered a massager device, but a mechanical stimulator.

CMS Final HCPCS Coding Decision

We appreciate the comments provided in response to CMS' published preliminary recommendation. Based on the information provided in the application and after consideration of the comments we received, CMS is finalizing its preliminary recommendation. CMS has not identified a program operating need for Medicare or other payers for a new HCPCS Level II code to describe a cold pack accessory used in conjunction with a vibrating motor for focal mechanical simulation.

Medicare Benefit Category Determination

With regard to Medicare, we do not have a benefit category for massage devices, such as VibraCool, as they do not meet the definition of durable medical equipment (DME). Per section 280.1 of chapter 1, part 4 of the Medicare National Coverage Determinations Manual (CMS Pub. 100-03), massage devices 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.

Agenda Item # 10

VibraCool - HCP220103JC42V

Topic/Issue

Request to establish a new HCPCS Level II code to identify a heat pack accessory used in conjunction with a vibrating motor for focal mechanical stimulation.

Applicant's suggested language: XXXXX, "Heat pack accessory, solid and capable of transmitting vibration when activated, configured for use with vibrating motor for focal mechanical stimulation, reusable, each"

Applicant's Summary

Pain Care Labs submitted a request to establish a new HCPCS Level II code to identify a heat pack accessory used in conjunction with a vibrating motor for focal mechanical stimulation. (This vibrating motor is subject to a separate application.) The code sought in this application would be used to describe a heat pack accessory designed to apply heat to a specific target area subject to focal mechanical stimulation. This item is solid when heated, so that it transmits rather than dampens the transmission of mechanical energy to the target area. The accessory is configured to fit the footprint of the vibrating motor and to be held in place between the vibrating motor and the skin surface when the motor is activated. With respect to function, studies support use of mechanical stimulation with heat for treatment of (1) joint pain (resulting from, e.g., tendinopathies, inactivity, stroke, osteoarthritis, post-operative weakness, post-ligamentous injury, or muscular or bony injury); (2) chronic pain or spasms (osteoarthritis, stroke, or post-operative spasms); (3) acute pain (post-operative skin disruption, itching from healing, or physical therapy); or (4) injury pain after inactivity. Heat aids in central and peripheral pain relief and local spasm reduction, and the physiological effects of mechanical stimulation are synergistically maximized by simultaneous application of heat. An existing code could describe this item, but the items it describes are not covered by Medicare. This accessory is a critical element of the vibrating motor's system, and to be able to provide coverage, payers must be able to distinguish this item from other, non-covered items. Indications for use of the VibraCool system relevant to this application are for temporary relief of minor injuries (muscle or tendon aches) and to treat myofascial pain caused by trigger points, restricted motion and muscle tension. The method of action is application of heat in conjunction with vibration; the transmission of vibration requires that the heat pack accessory be solid when applied, to ensure that mechanical stimulation frequency is transmitted effectively rather than dampened by the accessory. The system is usually applied to the target area for about 20 minutes. Pain Care Labs makes the item available as part of a kit with the motor and other accessories or separately as needed for replacement, both reusable and disposable packs.

Preliminary CMS HCPCS Coding Recommendation

CMS has not identified a program operating need for Medicare or other payers for a new HCPCS Level II code to describe a heat pack accessory used in conjunction with a vibrating motor for focal mechanical simulation. With regard to Medicare, we do not have a benefit category for massage devices such as VibraCool, as they do not meet the definition of durable medical equipment. We welcome information from the applicant and other insurers who are

currently paying for this product to demonstrate a claims processing need for a unique HCPCS Level II code.

Summary of Public Feedback

The primary speaker disagreed with CMS' HCPCS preliminary recommendation of no program operating need for the VibraCool System. According to the speaker, there is an operating need for codes, in particular, for workers compensation. The speaker commented that in multiple situations, clinical decision makers wanted the VibraCool for their patients but were turned down by their leadership due to lack of a unique HCPCS code.

The speaker commented that VibraCool is not a massage device, but a focal stimulation device. VibraCool vibrates at 200 Hz, with action constrained by compression accessories to deliver energy perpendicularly to the skin surface so that it penetrates the deep underlying tissues and activates particular neural structures useful for pain control. The heat and cool packs have been designed to remain solid while in use. Massager devices, in contrast, typically vibrate at 30 to 80 Hz and do not involve sustained compression. Massage devices must be placed over the affected area, which may be painful because of injury or surgery, while VibraCool can be placed along the neural pathway between the source of the pain and the brain. The sensation when using the VibraCool is intense and not likely to be tolerated unless the patient is in pain or suffering from joint weakness/instability. The speaker claimed that VibraCool meets the characteristics for durable medical equipment.

The speaker stated the because the device is considered minimal risk, the manufacturer does not need to file a new 510(k) for new iterations of the device. The predicate iteration of VibraCool is classified as a massager from the FDA. The speaker commented that terms have changed and they do not want to be considered a massager device, but a mechanical stimulator.

CMS Final HCPCS Coding Decision

We appreciate the comments provided in response to CMS' published preliminary recommendation. Based on the information provided in the application and after consideration of the comments we received, CMS is finalizing its preliminary recommendation. CMS has not identified a program operating need for Medicare or other payers for a new HCPCS Level II code to describe a heat pack accessory used in conjunction with a vibrating motor for focal mechanical simulation.

Medicare Benefit Category Determination

With regard to Medicare, we do not have a benefit category for massage devices, such as VibraCool, as they do not meet the definition of durable medical equipment (DME). Per section 280.1 of chapter 1, part 4 of the Medicare National Coverage Determinations Manual (CMS Pub. 100-03), massage devices 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.

Agenda Item # 10

VibraCool - HCP220103RYF4M

Topic/Issue

Request to establish a new HCPCS Level II code to identify a pocketed compression accessory used in conjunction with a vibrating motor for focal mechanical stimulation.

Applicant's suggested language: XXXXX, "Pocketed compression accessory for use with vibrating motor for focal mechanical stimulation, each"

Applicant's Summary

Pain Care Labs submitted a request to establish a new HCPCS Level II code to identify a pocketed compression accessory for use with vibrating motor for focal mechanical stimulation. The code sought in this application would be used to describe a pocketed compression accessory appropriately configured for the target therapeutic area and designed to hold in place a vibrating motor and a cold pack accessory or heat pack accessory (as used), while compressing them against the skin surface on or near the target area to ensure that mechanical energy is transmitted perpendicularly to the skin without loss of force. With respect to function, studies support use of mechanical stimulation for treatment of (1) joint instability or weakness, with or without pain (resulting from, e.g., tendinopathies, inactivity, stroke, osteoarthritis, post-operative weakness, post-ligamentous injury, or muscular or bony injury); (2) chronic pain or spasms (osteoarthritis, stroke, or post-operative spasms); (3) acute pain (post-operative inflammation, post-operative skin disruption, itching from healing, or physical therapy); or (4) inflammatory pain (injury or rheumatoid arthritis). No existing codes describe this item. The pocketed compression accessory would be used for any of these conditions. Indications for use as cleared by FDA relevant to this application are for temporary relief of minor injuries (muscle or tendon aches) and to treat myofascial pain caused by trigger points, restricted motion and muscle tension. The method of action of the pocketed compression accessory is to compress the vibrating motor and heat pack accessory or cold pack accessory (as used) to a target body part. Pain Care Labs makes the item available as part of a kit with the motor and other accessories or separately as needed for replacement.

Preliminary CMS HCPCS Coding Recommendation

CMS has not identified a program operating need for Medicare or other payers for a new HCPCS Level II code to describe a pocketed compression accessory for use with vibrating motor for focal mechanical stimulation. With regard to Medicare, we do not have a benefit category for massage devices such as VibraCool, as they do not meet the definition of durable medical equipment. We welcome information from the applicant and other insurers who are currently paying for this product to demonstrate a claims processing need for a unique HCPCS Level II code.

Summary of Public Feedback

The primary speaker disagreed with CMS' HCPCS preliminary recommendation of no program operating need for the VibraCool System. According to the speaker, there is an

operating need for codes, in particular, for workers compensation. The speaker commented that in multiple situations, clinical decision makers wanted the VibraCool for their patients but were turned down by their leadership due to lack of a unique HCPCS code.

The speaker commented that VibraCool is not a massage device, but a focal stimulation device. VibraCool vibrates at 200 Hz, with action constrained by compression accessories to deliver energy perpendicularly to the skin surface so that it penetrates the deep underlying tissues and activates particular neural structures useful for pain control. The heat and cool packs have been designed to remain solid while in use. Massager devices, in contrast, typically vibrate at 30 to 80 Hz and do not involve sustained compression. Massage devices must be placed over the affected area, which may be painful because of injury or surgery, while VibraCool can be placed along the neural pathway between the source of the pain and the brain. The sensation when using the VibraCool is intense and not likely to be tolerated unless the patient is in pain or suffering from joint weakness/instability. The speaker claimed that VibraCool meets the characteristics for durable medical equipment.

The speaker stated the because the device is considered minimal risk, the manufacturer does not need to file a new 510(k) for new iterations of the device. The predicate iteration of VibraCool is classified as a massager from the FDA. The speaker commented that terms have changed and they do not want to be considered a massager device, but a mechanical stimulator.

CMS Final HCPCS Coding Decision

We appreciate the comments provided in response to CMS' published preliminary recommendation. Based on the information provided in the application and after consideration of the comments we received, CMS is finalizing its preliminary recommendation. CMS has not identified a program operating need for Medicare or other payers for a new HCPCS Level II code to describe a pocketed compression accessory used in conjunction with a vibrating motor for focal mechanical simulation.

Medicare Benefit Category Determination

With regard to Medicare, we do not have a benefit category for massage devices, such as VibraCool, as they do not meet the definition of durable medical equipment (DME). Per section 280.1 of chapter 1, part 4 of the Medicare National Coverage Determinations Manual (CMS Pub. 100-03), massage devices 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.

Agenda Item # 11

Zipline - HCP21122159KTB

Topic/Issue

Request to establish a new HCPCS Level II code to identify transportation of laboratory specimens from point of care to an appropriate laboratory via automated unmanned aerial vehicle.

Applicant's suggested language: XXXXX, "Stat lab request, specimen delivery by automated unmanned aerial vehicle"

Applicant's Summary

Zipline International Inc. submitted a request to establish a new HCPCS Level II code to identify transportation of laboratory specimens from point of care to an appropriate laboratory via automated unmanned aerial vehicle. This service uses small, electric, fixed-wing airplanes with vertical take-off and landing capabilities to automatically transport lab samples from patient facilities to laboratory facilities. This functionality provides two significant clinical benefits beyond services covered by existing codes: 1) dramatically improved speed to result in time-critical cases and 2) access to test results that are otherwise unavailable in remote or underserved care settings. Existing codes (e.g. S3600) do not adequately describe this service in the same way that non-emergency transportation codes do not adequately describe air ambulance services.

Preliminary CMS HCPCS Coding Recommendation

CMS does not believe there is a claims processing need for a new HCPCS Level II code to identify the transportation of laboratory specimens from point of care to an appropriate laboratory via automated unmanned aerial vehicle. Existing HCPCS Level II code S3600 "Stat laboratory request (situations other than s3601)" was established to describe all urgent laboratory requests outside of those described under code S3601. The timeframe for STAT deliveries will vary from by situation, regardless of the mechanism of delivery, due to the associated circumstances (e.g., travel distance between point of care and laboratory), and code S3600 is intended to account for a broad range of expedited timeframes.

Summary of Public Feedback

No verbal or written comments were provided in response to CMS' published preliminary HCPCS Level II coding recommendation.

CMS Final HCPCS Coding Decision

Based on the information provided in the application to establish a new HCPCS Level II code and considering that no comments were received, CMS is finalizing its preliminary recommendation. We continue to believe that there is not a claims processing need for a new HCPCS Level II code to identify the transportation of laboratory specimens from point of care to an appropriate laboratory via automated unmanned aerial vehicle.

Existing HCPCS Level II code S3600 “Stat laboratory request (situations other than s3601)” was established to describe all urgent laboratory requests outside of those described under code S3601. The timeframe for STAT deliveries will vary from by situation, regardless of the mechanism of delivery, due to the associated circumstances (e.g., travel distance between point of care and laboratory), and code S3600 is intended to account for a broad range of expedited timeframes.

Agenda Item # 12

Dynasplint - HCP2201030HELW

Topic/Issue

Request to establish two new modifiers to be used with existing HCPCS Level II code E1810.

Applicant's suggested language: "XT" for (extension) and "FL" for (flexion)

Applicant's Summary

Dynasplint Systems, Inc. submitted a request to establish two new HCPCS modifiers to be used with E1810. Currently, the short description of E1810 is as follows: "Adjust knee ext/flex device" and the long description is as follows: "Dynamic adjustable knee extension / flexion device, includes soft interface material." The knee is a hinge joint which is a type of synovial joint. Hinge joints can only allow for one plane of motion, i.e., either extension or flexion, but not both. The E1810 code is an inadequate and confusing description. The short and long E1810 descriptions create the assumption that one E1810 device can work both extension and flexion for a hinge joint. However, the applicant states that is untrue. The proposed two modifiers are as follows: XT = Extension and FL = Flexion. There is room on the current CMS/HCFA 1500 Claim Form to use the requested modifiers. For example, with the modifier, a patient who has been prescribed a knee extension device and a knee flexion device for the left knee would be submitted on the CMS/HCFA 1500 Form as follows: E1810 RR LT XT FL. These modifiers would accurately and adequately describe the E1810 that was serviced.

Preliminary CMS HCPCS Coding Recommendation

Per the HCPCS Level II Coding Procedures, "HCPCS code modifiers are established internally by CMS to facilitate accurate Medicare claims processing. Modifiers are assigned for use when the information provided by a HCPCS code descriptor needs to be supplemented to identify specific circumstances that may apply to an item or service."

In an effort to better understand the clinical issue(s) in terms of access to care and why the referenced HCPCS codes are problematic, CMS has the following questions for the applicant:

- Under what clinical circumstances would a patient require both an extension device and a flexion device to simultaneously treat the same condition?
- Are patients being denied access to obtaining both an extension device and flexion device due to a billing scenario where claims are being denied? If so, please provide examples.
- The descriptor language for HCPCS codes E1800, E1805, E1810, E1815, E1825, and E1830 all describe "extension / flexion device[s]." To clarify, CMS' intention in these code descriptors was to identify devices that provide extension and/or flexion. Are there devices currently on the market that fall under the referenced HCPCS codes that allow for both extension and flexion?

Summary of Public Feedback

The primary speaker disagreed with CMS' HCPCS preliminary recommendation to not establish modifiers for HCPCS Level II code E1800, E1805, E1810, E1815, E1825, and E1830. The speaker commented that there is no way to distinguish between a flexion or extension device for the same joint, or body part based on the current HCPCS Level II codes.

Dynasplint is a 3-point of contact, spring-loaded, bilateral tension device that applies a low load, prolonged duration stretch to tight connective tissue as part of a patient's home passive range of motion program. Dynasplint is not a continuous passive motion (CPM) device. Dynasplint is used for patients that are lacking range of motion due to surgery, trauma, or disease. Dynasplint focuses on terminal end range time which is proven to promote remodeling of dense connective tissue for permanent range of motion (ROM) improvement. Dynasplint is ideal for most patients that lack ROM and are released by their physician for passive range of motion therapy, and is also used as the stretching component of home exercise programs. According to the speaker, local manufacturer representatives fit the splint on a patient adjusting it for length and circumference for an individual fit.

The speaker stated that, based on the current code descriptions, CMS only recognizes one code for flexion and/or extension per joint. The speaker asserted that a patient cannot properly stretch a hinged joint or a joint that has a primary motion plane of flexion and extension with only one splint. In some cases, both a flexion and an extension device are required by a patient's post-injury and post-surgical interventions. The speaker noted that both flexion and extension devices are most often needed by patients that have undergone either a total knee replacement, tendon repairs, or ligament repairs. The speaker claimed that patients are being denied access to obtaining both flexion and extension devices to aid in a full range of motion recovery causing longer rehabiliation intervention. The speaker stated that providing both a flexion and extension device, when needed, would help reduce the amount of time required to regain full range of motion in a joint and improve the patient's functional outcomes, reducing the need for rehospitalization, longer therapy intervention, or further surgical intervention. The speaker recognized that there are other devices that provide both extension and flexion capabilities.

CMS Final HCPCS Coding Decision

We appreciate the comments provided in response to CMS' preliminary recommendation. Based on the information provided in the application and after consideration of the comments we received, CMS does not recognize a need to create a modifier to identify "extension" and a modifier to identify "flexion."

The current code descriptors for HCPCS Level II codes E1800, E1805, E1810, E1815, E1825, and E1830 identify devices that provide extension and/or flexion of the applicable anatomical joint, and the current code set provides an adequate description to treat either flexion or extension when clinically necessary. To clarify, CMS' intention in these code descriptors was to identify devices that provide extension and/or flexion.

CMS requested, but did not receive, denial claims for patients who need both flexion and extension devices described by HCPCS Level II codes E1800, E1805, E1810, E1815, E1825, and E1830. CMS is unaware of clinical scenarios where patients require two devices to

concurrently perform different functions (i.e., one for flexion and one for extension) and are being denied for the number of device units that they need.

Agenda Item # 12

Dynasplint - HCP220103LMW31

Topic/Issue

Request to establish two new modifiers to be used with existing HCPCS Level II code E1800.

Applicant's suggested language: "XT" for (extension) and "FL" for (flexion)

Applicant's Summary

Dynasplint Systems, Inc. submitted a request to establish two new HCPCS modifiers to be used with E1800. Currently, the short description of E1800 is as follows: "Adjust elbow ext/flex device" and the long description is as follows: "Dynamic adjustable elbow extension / flexion device, includes soft interface material." The elbow is a hinge joint which is a type of synovial joint. Hinge joints can only allow for one plane of motion, i.e., either extension or flexion, but not both. The E1800 code is an inadequate and confusing description. The short and long E1800 descriptions create the assumption that one E1800 device can work both extension and flexion for a hinge joint. However, the applicant states that is untrue. The proposed two modifiers are as follows: XT = Extension and FL = Flexion. There is room on the current CMS/HCFA 1500 Claim Form to use these requested modifiers. For example, with the modifier, a patient who has been prescribed an elbow extension device and an elbow flexion device for the left elbow would be submitted on the CMS/HCFA 1500 Form as follows: E1800 RR LT XT FL. These modifiers would accurately and adequately describe the E1800 that was serviced.

Preliminary CMS HCPCS Coding Recommendation

Per the HCPCS Level II Coding Procedures, "HCPCS code modifiers are established internally by CMS to facilitate accurate Medicare claims processing. Modifiers are assigned for use when the information provided by a HCPCS code descriptor needs to be supplemented to identify specific circumstances that may apply to an item or service."

In an effort to better understand the clinical issue(s) in terms of access to care and why the referenced HCPCS codes are problematic CMS has the following questions for the applicant:

- Under what clinical circumstances would a patient require both an extension device and a flexion device to simultaneously treat the same condition?
- Are patients being denied access to obtaining both an extension device and flexion device due to a billing scenario where claims are being denied? If so, please provide examples.
- The descriptor language for HCPCS codes E1800, E1805, E1810, E1815, E1825, and E1830 all describe "extension / flexion device[s]." To clarify, CMS' intention in these code descriptors was to identify devices that provide extension and/or flexion. Are there devices currently on the market that fall under the referenced HCPCS codes that allow for both extension and flexion?

Summary of Public Feedback

The primary speaker disagreed with CMS' HCPCS preliminary recommendation to not establish modifiers for HCPCS Level II code E1800, E1805, E1810, E1815, E1825, and E1830. The speaker commented that there is no way to distinguish between a flexion or extension device for the same joint, or body part based on the current HCPCS Level II codes.

Dynasplint is a 3-point of contact, spring-loaded, bilateral tension device that applies a low load, prolonged duration stretch to tight connective tissue as part of a patient's home passive range of motion program. Dynasplint is not a continuous passive motion (CPM) device. Dynasplint is used for patients that are lacking range of motion due to surgery, trauma, or disease. Dynasplint focuses on terminal end range time which is proven to promote remodeling of dense connective tissue for permanent range of motion (ROM) improvement. Dynasplint is ideal for most patients that lack ROM and are released by their physician for passive range of motion therapy, and is also used as the stretching component of home exercise programs. According to the speaker, local manufacturer representatives fit the splint on a patient adjusting it for length and circumference for an individual fit.

The speaker stated based on the current code descriptions, CMS only recognizes one code for flexion and/or extension per joint. The speaker asserted that a patient cannot properly stretch a hinged joint or a joint that has a primary motion plane of flexion and extension with only one splint. In some cases, both a flexion and an extension device are required by a patient's post-injury and post-surgical interventions. The speaker noted that both flexion and extension devices are most often needed by patients that have undergone either a total knee replacement, tendon repairs, or ligament repairs. The speaker claimed that patients are being denied access to obtaining both flexion and extension devices to aid in a full range of motion recovery causing longer rehabiliation intervention. The speaker stated that providing both a flexion and extension device, when needed, would help reduce the amount of time required to regain full range of motion in a joint and improve the patient's functional outcomes, reducing the need for rehospitalization, longer therapy intervention, or further surgical intervention. The speaker recognized that there are other devices that provide both extension and flexion capabilities.

CMS Final HCPCS Coding Decision

We appreciate the comments provided in response to CMS' preliminary recommendation. Based on the information provided in the application and after consideration of the comments we received, CMS does not recognize a need to create a modifier to identify "extension" and a modifier to identify "flexion."

The current code descriptors for HCPCS Level II codes E1800, E1805, E1810, E1815, E1825, and E1830 identify devices that provide extension and/or flexion of the applicable anatomical joint, and the current code set provides an adequate description to treat either flexion or extension when clinically necessary. To clarify, CMS' intention in these code descriptors was to identify devices that provide extension and/or flexion.

CMS requested, but did not receive, denial claims for patients who need both flexion and extension devices described by HCPCS Level II codes E1800, E1805, E1810, E1815, E1825, and E1830. CMS is unaware of clinical scenarios where patients require two devices to

concurrently perform different functions (i.e., one for flexion and one for extension) and are being denied for the number of device units that they need.

Agenda Item # 12

Dynasplint - HCP220104VM3VW

Topic/Issue

Request to establish two new modifiers to be used with existing HCPCS Level II code E1805.

Applicant's suggested language: "XT" for (extension) and "FL" for (flexion)

Applicant's Summary

Dynasplint Systems, Inc. submitted a request to establish two new HCPCS modifiers to be used with E1805. Currently, the short description of E1805 is as follows: "Adjust wrist ext/flex device" and the long description is as follows: "Dynamic adjustable wrist extension / flexion device, includes soft interface material." The wrist and metacarpals are hinge joints which is a type of synovial joint. Hinge joints can only allow for one plane of motion, i.e., either extension or flexion, but not both. The E1805 code is an inadequate and confusing description. The short and long E1805 descriptions create the assumption that one E1805 device can work both extension, flexion, and metacarpal extension and flexion for a hinge joint. However, the applicant states that is untrue. The proposed two modifiers are as follows: XT = Extension and FL = Flexion. There is room on the current CMS/HCFA 1500 Claim Form to use these requested modifiers. For example, with the modifier, a patient who has been prescribed a wrist extension device and a wrist flexion device for the left wrist would be submitted on the CMS/HCFA 1500 Form as follows: E1805 RR LT XT FL. These modifiers would accurately and adequately describe the E1805 that was serviced.

Preliminary CMS HCPCS Coding Recommendation

Per the HCPCS Level II Coding Procedures, "HCPCS code modifiers are established internally by CMS to facilitate accurate Medicare claims processing. Modifiers are assigned for use when the information provided by a HCPCS code descriptor needs to be supplemented to identify specific circumstances that may apply to an item or service."

In an effort to better understand the clinical issue(s) in terms of access to care and why the referenced HCPCS codes are problematic CMS has the following questions for the applicant:

- Under what clinical circumstances would a patient require both an extension device and a flexion device to simultaneously treat the same condition?
- Are patients being denied access to obtaining both an extension device and flexion device due to a billing scenario where claims are being denied? If so, please provide examples.
- The descriptor language for HCPCS codes E1800, E1805, E1810, E1815, E1825, and E1830 all describe "extension / flexion device[s]." To clarify, CMS' intention in these code descriptors was to identify devices that provide extension and/or flexion. Are there devices currently on the market that fall under the referenced HCPCS codes that allow for both extension and flexion?

Summary of Public Feedback

The primary speaker disagreed with CMS' HCPCS preliminary recommendation to not establish modifiers for HCPCS Level II code E1800, E1805, E1810, E1815, E1825, and E1830. The speaker commented that there is no way to distinguish between a flexion or extension device for the same joint, or body part based on the current HCPCS Level II codes.

Dynasplint is a 3-point of contact, spring-loaded, bilateral tension device that applies a low load, prolonged duration stretch to tight connective tissue as part of a patient's home passive range of motion program. Dynasplint is not a continuous passive motion (CPM) device. Dynasplint is used for patients that are lacking range of motion due to surgery, trauma, or disease. Dynasplint focuses on terminal end range time which is proven to promote remodeling of dense connective tissue for permanent range of motion (ROM) improvement. Dynasplint is ideal for most patients that lack ROM and are released by their physician for passive range of motion therapy, and is also used as the stretching component of home exercise programs. According to the speaker, local manufacturer representatives fit the splint on a patient adjusting it for length and circumference for an individual fit.

The speaker stated based on the current code descriptions, CMS only recognizes one code for flexion and/or extension per joint. The speaker asserted that a patient cannot properly stretch a hinged joint or a joint that has a primary motion plane of flexion and extension with only one splint. In some cases, both a flexion and an extension device are required by a patient's post-injury and post-surgical interventions. The speaker noted that both flexion and extension devices are most often needed by patients that have undergone either a total knee replacement, tendon repairs, or ligament repairs. The speaker claimed that patients are being denied access to obtaining both flexion and extension devices to aid in a full range of motion recovery causing longer rehabiliation intervention. The speaker stated that providing both a flexion and extension device, when needed, would help reduce the amount of time required to regain full range of motion in a joint and improve the patient's functional outcomes, reducing the need for rehospitalization, longer therapy intervention, or further surgical intervention. The speaker recognized that there are other devices that provide both extension and flexion capabilities.

CMS Final HCPCS Coding Decision

We appreciate the comments provided in response to CMS' preliminary recommendation. Based on the information provided in the application and after consideration of the comments we received, CMS does not recognize a need to create a modifier to identify "extension" and a modifier to identify "flexion."

The current code descriptors for HCPCS Level II codes E1800, E1805, E1810, E1815, E1825, and E1830 identify devices that provide extension and/or flexion of the applicable anatomical joint, and the current code set provides an adequate description to treat either flexion or extension when clinically necessary. To clarify, CMS' intention in these code descriptors was to identify devices that provide extension and/or flexion.

CMS requested, but did not receive, denial claims for patients who need both flexion and extension devices described by HCPCS Level II codes E1800, E1805, E1810, E1815, E1825, and E1830. CMS is unaware of clinical scenarios where patients require two devices to

concurrently perform different functions (i.e., one for flexion and one for extension) and are being denied for the number of device units that they need.

Agenda Item # 12

Dynasplint - HCP2201042VU1F

Topic/Issue

Request to establish two new modifiers to be used with existing HCPCS Level II code E1815.

Applicant's suggested language: "XT" for (extension) and "FL" for (flexion)

Applicant's Summary

Dynasplint Systems, Inc. submitted a request to establish two new HCPCS modifiers to be used with E1815. Currently, the short description of E1815 is as follows: "Adjust ankle ext/flex device" and the long description is as follows: "Dynamic adjustable ankle extension / flexion device, includes soft interface material." The ankle is a hinge joint which is a type of synovial joint. Hinge joints can only allow for one plane of motion, i.e., either extension or flexion, but not both. The E1815 code is an inadequate and confusing description. The short and long E1815 descriptions create the assumption that one E1815 device can work both extension and flexion for a hinge joint. However, the applicant states that is untrue. The proposed two modifiers are as follows: XT = Extension and FL = Flexion. There is room on the current CMS/HCFA 1500 Claim Form to use these requested modifiers. For example, with the modifier, a patient who has been prescribed an ankle extension device and an ankle flexion device for the left ankle would be submitted on the CMS/HCFA 1500 Form as follows: E1815 RR LT XT FL. These modifiers would accurately and adequately describe the E1815 that was serviced.

Preliminary CMS HCPCS Coding Recommendation

Per the HCPCS Level II Coding Procedures, "HCPCS code modifiers are established internally by CMS to facilitate accurate Medicare claims processing. Modifiers are assigned for use when the information provided by a HCPCS code descriptor needs to be supplemented to identify specific circumstances that may apply to an item or service."

In an effort to better understand the clinical issue(s) in terms of access to care and why the referenced HCPCS codes are problematic CMS has the following questions for the applicant:

- Under what clinical circumstances would a patient require both an extension device and a flexion device to simultaneously treat the same condition?
- Are patients being denied access to obtaining both an extension device and flexion device due to a billing scenario where claims are being denied? If so, please provide examples.
- The descriptor language for HCPCS codes E1800, E1805, E1810, E1815, E1825, and E1830 all describe "extension / flexion device[s]." To clarify, CMS' intention in these code descriptors was to identify devices that provide extension and/or flexion. Are there devices currently on the market that fall under the referenced HCPCS codes that allow for both extension and flexion?

Summary of Public Feedback

The primary speaker disagreed with CMS' HCPCS preliminary recommendation to not establish modifiers for HCPCS Level II code E1800, E1805, E1810, E1815, E1825, and E1830. The speaker commented that there is no way to distinguish between a flexion or extension device for the same joint, or body part based on the current HCPCS Level II codes.

Dynasplint is a 3-point of contact, spring-loaded, bilateral tension device that applies a low load, prolonged duration stretch to tight connective tissue as part of a patient's home passive range of motion program. Dynasplint is not a continuous passive motion (CPM) device. Dynasplint is used for patients that are lacking range of motion due to surgery, trauma, or disease. Dynasplint focuses on terminal end range time which is proven to promote remodeling of dense connective tissue for permanent range of motion (ROM) improvement. Dynasplint is ideal for most patients that lack ROM and are released by their physician for passive range of motion therapy, and is also used as the stretching component of home exercise programs. According to the speaker, local manufacturer representatives fit the splint on a patient adjusting it for length and circumference for an individual fit.

The speaker stated based on the current code descriptions, CMS only recognizes one code for flexion and/or extension per joint. The speaker asserted that a patient cannot properly stretch a hinged joint or a joint that has a primary motion plane of flexion and extension with only one splint. In some cases, both a flexion and an extension device are required by a patient's post-injury and post-surgical interventions. The speaker noted that both flexion and extension devices are most often needed by patients that have undergone either a total knee replacement, tendon repairs, or ligament repairs. The speaker claimed that patients are being denied access to obtaining both flexion and extension devices to aid in a full range of motion recovery causing longer rehabiliation intervention. The speaker stated that providing both a flexion and extension device, when needed, would help reduce the amount of time required to regain full range of motion in a joint and improve the patient's functional outcomes, reducing the need for rehospitalization, longer therapy intervention, or further surgical intervention. The speaker recognized that there are other devices that provide both extension and flexion capabilities.

CMS Final HCPCS Coding Decision

We appreciate the comments provided in response to CMS' preliminary recommendation. Based on the information provided in the application and after consideration of the comments we received, CMS does not recognize a need to create a modifier to identify "extension" and a modifier to identify "flexion."

The current code descriptors for HCPCS Level II codes E1800, E1805, E1810, E1815, E1825, and E1830 identify devices that provide extension and/or flexion of the applicable anatomical joint, and the current code set provides an adequate description to treat either flexion or extension when clinically necessary. To clarify, CMS' intention in these code descriptors was to identify devices that provide extension and/or flexion.

CMS requested, but did not receive, denial claims for patients who need both flexion and extension devices described by HCPCS Level II codes E1800, E1805, E1810, E1815, E1825, and E1830. CMS is unaware of clinical scenarios where patients require two devices to

concurrently perform different functions (i.e., one for flexion and one for extension) and are being denied for the number of device units that they need.

Agenda Item # 12

Dynasplint - HCP2201044JC64

Topic/Issue

Request to establish two new modifiers to be used with existing HCPCS Level II code E1825.

Applicant's suggested language: "XT" for (extension) and "FL" for (flexion)

Applicant's Summary

Dynasplint Systems, Inc. submitted a request to establish two new HCPCS modifiers to be used with E1825. Currently, the short description of E1825 is as follows: "Adjust finger ext/flex device" and the long description is as follows: "Dynamic adjustable finger extension / flexion device, includes soft interface material." The finger is a hinge joint which is a type of synovial joint. Hinge joints can only allow for one plane of motion, i.e., either extension or flexion, but not both. The E1825 code is an inadequate and confusing description. The short and long E1825 descriptions create the assumption that one E1825 device can work both extension and flexion for a hinge joint. However, the applicant states that is untrue. The proposed two modifiers are as follows: XT = Extension and FL = Flexion. There is room on the current CMS/HCFA 1500 Claim Form to use these requested modifiers. For example, with the modifier, a patient who has been prescribed a finger extension device and a finger flexion device for the left second digit would be submitted on the CMS/HCFA 1500 Form as follows: E1825 RR LT F1 XT FL. These modifiers would accurately and adequately describe the E1825 that was serviced.

Preliminary CMS HCPCS Coding Recommendation

Per the HCPCS Level II Coding Procedures, "HCPCS code modifiers are established internally by CMS to facilitate accurate Medicare claims processing. Modifiers are assigned for use when the information provided by a HCPCS code descriptor needs to be supplemented to identify specific circumstances that may apply to an item or service."

In an effort to better understand the clinical issue(s) in terms of access to care and why the referenced HCPCS codes are problematic CMS has the following questions for the applicant:

- Under what clinical circumstances would a patient require both an extension device and a flexion device to simultaneously treat the same condition?
- Are patients being denied access to obtaining both an extension device and flexion device due to a billing scenario where claims are being denied? If so, please provide examples.
- The descriptor language for HCPCS codes E1800, E1805, E1810, E1815, E1825, and E1830 all describe "extension / flexion device[s]." To clarify, CMS' intention in these code descriptors was to identify devices that provide extension and/or flexion. Are there devices currently on the market that fall under the referenced HCPCS codes that allow for both extension and flexion?

Summary of Public Feedback

The primary speaker disagreed with CMS' HCPCS preliminary recommendation to not establish modifiers for HCPCS Level II code E1800, E1805, E1810, E1815, E1825, and E1830. The speaker commented that there is no way to distinguish between a flexion or extension device for the same joint, or body part based on the current HCPCS Level II codes.

Dynasplint is a 3-point of contact, spring-loaded, bilateral tension device that applies a low load, prolonged duration stretch to tight connective tissue as part of a patient's home passive range of motion program. Dynasplint is not a continuous passive motion (CPM) device. Dynasplint is used for patients that are lacking range of motion due to surgery, trauma, or disease. Dynasplint focuses on terminal end range time which is proven to promote remodeling of dense connective tissue for permanent range of motion (ROM) improvement. Dynasplint is ideal for most patients that lack ROM and are released by their physician for passive range of motion therapy, and is also used as the stretching component of home exercise programs. According to the speaker, local manufacturer representatives fit the splint on a patient adjusting it for length and circumference for an individual fit.

The speaker stated based on the current code descriptions, CMS only recognizes one code for flexion and/or extension per joint. The speaker asserted that a patient cannot properly stretch a hinged joint or a joint that has a primary motion plane of flexion and extension with only one splint. In some cases, both a flexion and an extension device are required by a patient's post-injury and post-surgical interventions. The speaker noted that both flexion and extension devices are most often needed by patients that have undergone either a total knee replacement, tendon repairs, or ligament repairs. The speaker claimed that patients are being denied access to obtaining both flexion and extension devices to aid in a full range of motion recovery causing longer rehabiliation intervention. The speaker stated that providing both a flexion and extension device, when needed, would help reduce the amount of time required to regain full range of motion in a joint and improve the patient's functional outcomes, reducing the need for rehospitalization, longer therapy intervention, or further surgical intervention. The speaker recognized that there are other devices that provide both extension and flexion capabilities.

CMS Final HCPCS Coding Decision

We appreciate the comments provided in response to CMS' preliminary recommendation. Based on the information provided in the application and after consideration of the comments we received, CMS does not recognize a need to create a modifier to identify "extension" and a modifier to identify "flexion."

The current code descriptors for HCPCS Level II codes E1800, E1805, E1810, E1815, E1825, and E1830 identify devices that provide extension and/or flexion of the applicable anatomical joint, and the current code set provides an adequate description to treat either flexion or extension when clinically necessary. To clarify, CMS' intention in these code descriptors was to identify devices that provide extension and/or flexion.

CMS requested, but did not receive, denial claims for patients who need both flexion and extension devices described by HCPCS Level II codes E1800, E1805, E1810, E1815, E1825, and E1830. CMS is unaware of clinical scenarios where patients require two devices to

concurrently perform different functions (i.e., one for flexion and one for extension) and are being denied for the number of device units that they need.

Agenda Item # 12

Dynasplint - HCP2201047DPYK

Topic/Issue

Request to establish two new modifiers to be used with existing HCPCS Level II code E1830.

Applicant's suggested language: "XT" for (extension) and "FL" for (flexion)

Applicant's Summary

Dynasplint Systems, Inc. submitted a request to establish two new HCPCS modifiers to be used with E1830. Currently, the short description of E1830 is as follows: "Adjust toe ext/flexion device" and the long description is as follows: "Dynamic adjustable toe extension / flexion device, includes soft interface material." The toe is a hinge joint which is a type of synovial joint. Hinge joints can only allow for one plane of motion, i.e., either extension or flexion, but not both. The E1830 code is an inadequate and confusing description. The short and long E1830 descriptions create the assumption that one E1830 device can work both extension, flexion, hammertoe, and Varus/Valgus extension and flexion for a hinge joint. However, the applicant states that is untrue. The proposed two modifiers are as follows: XT = Extension and FL = Flexion. There is room on the current CMS/HCFA 1500 Claim Form to use these requested modifiers. For example, with the modifier, a patient who has been prescribed a toe extension device and a toe flexion device for the left great toe would be submitted on the CMS/HCFA 1500 Form as follows: E1830 RR LT XT FL. These modifiers would accurately and adequately describe the E1830 that was serviced.

Preliminary CMS HCPCS Coding Recommendation

Per the HCPCS Level II Coding Procedures, "HCPCS code modifiers are established internally by CMS to facilitate accurate Medicare claims processing. Modifiers are assigned for use when the information provided by a HCPCS code descriptor needs to be supplemented to identify specific circumstances that may apply to an item or service."

In an effort to better understand the clinical issue(s) in terms of access to care and why the referenced HCPCS codes are problematic CMS has the following questions for the applicant:

- Under what clinical circumstances would a patient require both an extension device and a flexion device to simultaneously treat the same condition?
- Are patients being denied access to obtaining both an extension device and flexion device due to a billing scenario where claims are being denied? If so, please provide examples.
- The descriptor language for HCPCS codes E1800, E1805, E1810, E1815, E1825, and E1830 all describe "extension / flexion device[s]." To clarify, CMS' intention in these code descriptors was to identify devices that provide extension and/or flexion. Are there devices currently on the market that fall under the referenced HCPCS codes that allow for both extension and flexion?

Summary of Public Feedback

The primary speaker disagreed with CMS' HCPCS preliminary recommendation to not establish modifiers for HCPCS Level II code E1800, E1805, E1810, E1815, E1825, and E1830. The speaker commented that there is no way to distinguish between a flexion or extension device for the same joint, or body part based on the current HCPCS Level II codes.

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concurrently perform different functions (i.e., one for flexion and one for extension) and are being denied for the number of device units that they need.

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.