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

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

Zoom Meeting, for remote participation
Tuesday, November 29, 2022 9:00 am – 5:00 pm, eastern time (ET)

8:45 am, ET:
• Zoom meeting login:
https://cms.zoomgov.com/webinar/register/WN_v9r9lfW_QZimHUNq__AXrg
• Additional information regarding participation in the public meeting will be sent to participants after they register to attend the meeting.

9:00 am, ET:
• Welcome
• Background and purpose of meeting
• Meeting format and ground rules

Provided for each agenda item is a written overview of the applicant's request, CMS' preliminary coding recommendation, as well as CMS' preliminary benefit category and payment determination, if applicable. Preliminary recommendations are not final or binding upon any payer, and are subject to change. Meeting participants will hear presentations about each agenda item from the registered primary speaker and any registered 5-minute speakers. Speaker presentations will be followed by an opportunity for questions regarding that particular agenda item. The public meeting provides an opportunity for stakeholders and interested parties to provide additional input related to requests to modify the HCPCS code set. Final decisions are not made at the public meeting. CMS' final coding, benefit category, and payment decisions will be published on CMS' HCPCS website at: https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Prior-Years-CMS-HCPCSLevelII-Coding-Decisions-Narrative-Summary around January 2023 and will be effective April 1, 2023, unless otherwise specified.

This agenda includes a summary of each HCPCS code application being presented on Tuesday, November 29, 2022. The information provided in each summary reflects claims made by the applicant and should not be construed as a statement of fact or an endorsement by the federal government.

Table of Contents

Preliminary decisions for the HCPCS Virtual Public Meeting on November 29, 2022.

Agenda Item # 1
Cue Health Monitoring System and Accessories - HCP220705DDRJK

Topic/Issue

Request to establish a new HCPCS Level II code to identify Cue Cartridge Reader and accessories (also called the Cue Reader, and commercially known as the Cue Health Monitoring System.)

Applicant's suggested language: EXXXX, "Molecular diagnostic test reader, for self-administered and self-collected samples, FDA approved, authorized, or cleared"

Applicant's Summary

Cue Health submitted a request to establish a new HCPCS Level II code to identify the Cue Cartridge Reader and accessories. The Cue Reader received Emergency Use Authorization by the Food and Drug Administration (FDA) for COVID-19 testing. However, patients will be able to use the Cue Reader with other test cartridges, for example influenza or respiratory syncytial virus (RSV), when those test cartridges receive marketing authorization from the FDA. The Cue Reader is an in vitro diagnostic medical device that activates the Nucleic Acid Amplification Test (NAAT) process with test-specific Cue Cartridges and interfaces with the Cue Health Mobile Application installed on a mobile smart device. This coding request is for the Cue Reader and its packaged accessories, which include the Cue Power Adapter, the Cue Charging Cable, and additional power sources manufactured specifically for this device. The Cue COVID-19 Test is an at-home molecular NAAT and is not equivalent to the at-home antigen tests commonly available on the market. The Cue Reader is a required device that can be used multiple times for analyzing specimens collected with the single-use Cue COVID-19 Test Cartridges. To complete a Cue COVID-19 Test, the Cue COVID-19 Test Cartridge is inserted into the Cue Reader. Next, a Cue Sample Wand is used to collect a direct nasal swab specimen. Then, the wand is inserted into the Cue COVID-19 Test Cartridge (which was already inserted into the Cue Reader in the previous step). When the wand is inserted into the Cue COVID-19 Test Cartridge, the NAAT begins automatically and provides a test result in 20 minutes. Test results are available in the Cue Health Mobile Application that can be accessed by patients and healthcare professionals (HCP). Based upon the test results, the HCP can determine the most appropriate treatment pathway based on the patient's conditions and symptoms.

CMS Preliminary HCPCS Coding Recommendation

Establish new HCPCS Level II code KXXXX, "Molecular diagnostic test reader, nonprescription self-administered and self-collected use, fda approved, authorized or cleared"

Preliminary Medicare Benefit Category Determination

No Medicare DMEPOS benefit category

Please note that the Cue Cartridge Reader and accessories are not considered by Medicare to be durable medical equipment (DME). 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. It is further described 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). DME is defined as 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. With respect to the first and second conditions, given that DME is a benefit for rental of equipment for use in the home, the equipment must be able to withstand repeated use by successive patients. While the manufacturer has indicated that the Cue Cartridge Reader and accessories have an expected life of at least 3 years, it also indicates that they are not intended for use by successive patients.

In addition, with respect to the third condition the item must be useful to a person for the treatment of an illness or injury, and be expected to make a meaningful contribution to the treatment of the individual's illness or injury. The Cue Cartridge Reader and accessories are used to diagnose whether an individual is infected with the COVID-19 virus, not to treat an individual with COVID-19. CMS considers diagnostic equipment such as the Cue Cartridge Reader and accessories to be an extension of or incident to a clinical service, and not DME. For example, prothrombin time home testing systems (HCPCS Code G0249) are diagnostic and not considered DME.

Agenda Item # 1
Cue COVID-19 Test Cartridge Pack - HCP2207052C281

Topic/Issue

Request to establish a new HCPCS Level II code to identify Cue Cartridge for its COVID-19 at-home test to be used with the Cue Reader.

Applicant's suggested language: AXXXX, "Specimen sample cartridge, sterile, each, for use with COVID-19 molecular diagnostic test reader"

Applicant's Summary

Cue Health submitted a request to establish a new HCPCS Level II code to identify Cue Cartridge for its COVID-19 at-home test to be used with the Cue Reader. As a component of the Cue Health Monitoring System, the COVID-19 Test Cartridge is used with the Cue Reader, an in-vitro diagnostic medical device. The Cue Cartridge and the Cue Reader work with the proprietary Cue Health Mobile Application, which is accessed on a mobile smart device. This HCPCS request is for the Cue Cartridge with the Cue Sample Wand, used for collection of the sample to be analyzed for the presence of COVID-19 using Nucleic Acid Amplification Test (NAAT) technology. For the current Emergency Use Authorization indication of COVID-19 testing, a direct nasal swab specimen is collected from an individual using the Cue Sample Wand and then is inserted into the Cue COVID-19 Test Cartridge and run on the Cue Cartridge Reader. When the cartridge is inserted into the Cue Reader, the NAAT automatically begins and provides a positive or negative result within 20 minutes, and is transmitted to the Cue Health Mobile Application, to which the patient and the patient's healthcare professional (HCP) both have access. The HCP then determines the most appropriate treatment pathway for the patient's condition and symptoms.

CMS Preliminary HCPCS Coding Recommendation

Existing HCPCS Level II code K1034, "Provision of COVID-19 test, nonprescription self-administered and self-collected use, fda approved, authorized or cleared, one test count" describes Cue Cartridge.

Preliminary Medicare Benefit Category Determination

No Medicare DMEPOS benefit category

Please note that the Cue Cartridge is not considered by Medicare to be durable medical equipment (DME). 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. It is further described 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). DME is defined as 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. With respect to the first and second conditions, given that DME is a benefit for rental of equipment for use in the home, the equipment must be able to withstand repeated use by successive patients. The Cue Cartridge is a single use product and is not intended for use by successive patients.

In addition, with respect to the third condition the item must be useful to a person for the treatment of an illness or injury, and be expected to make a meaningful contribution to the treatment of the individual's illness or injury. The Cue Cartridge is used to diagnose whether an individual is infected with the COVID-19 virus, not to treat an individual with COVID-19. CMS considers diagnostic equipment such as the Cue Cartridge to be an extension of or incident to a clinical service, and not DME. For example, prothrombin time home testing systems (HCPCS Code G0249) are diagnostic and not considered DME.

Agenda Item # 2
Koya Dayspring® - HCP2207039VEAR

Topic/Issue

Request to establish a new HCPCS Level II code to identify Koya Dayspring® trunk garment.

Applicant's suggested language: EXXXX, "Non-pneumatic sequential compression garment, trunk"

Applicant's Summary

Koya Medical, Inc. submitted a request to establish a new HCPCS Level II code to identify Koya Dayspring® trunk garment. As a reference, E0656, "Segmental pneumatic appliance for use with pneumatic compressor, trunk" currently exists. This code description specifically limits the method of compression appliance to "pneumatic." The applicant stated that the Dayspring® non-pneumatic garments, including the trunk, perform the same clinical functions as the segmental pneumatic appliances and all Dayspring® garments work with both calibrated gradient and non-calibrated gradient Dayspring® controllers. Both segmental pneumatic and non-pneumatic appliances only work in conjunction with their respective compressors and have identical clinical indications for use, intended for the same patient populations, and perform the same clinical functions delivering the same ranges of therapeutic pressure ranges. In operation, both systems use a controller and a segmental appliance or garment and are similar in its function and clinical use.

CMS Preliminary HCPCS Coding Recommendation

Establish new HCPCS Level II code EXXXX, "Non-pneumatic sequential compression garment, trunk"

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) section 414.202, and means equipment, furnished by a supplier or a home health agency that meets the five conditions listed in the below table. All five of these conditions must be met in order for equipment to be classified as DME.

The final benefit category determinations for HCPCS applications numbers 21.032 Koya Dayspring® System and HCP210903LPG21 Koya Dayspring® Lite System established that these sequential compression devices meet the definition of DME found in 42 CFR §414.202.

Also, the Koya sequential compression devices' garment accessories were reviewed for HCPCS application numbers 21.070 (full arm), HCP210903PMKF3 (full leg) and HCP210903WBEG8 (half leg). The final determinations established that the garment accessories met the requirement of Section 110.3 of the Medical Benefit Policy Manual (CMS Pub. 100-03) which indicates 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.

Similar to the garment accessories discussed above, as shown in the below table, the Koya Dayspring® non-pneumatic trunk garment meets all five DME classification conditions, and therefore is DME.

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

Preliminary Medicare Payment Determination

In accordance with Medicare regulations at 42 CFR § 414.238, 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 new HCPCS code EXXXX for this particular garment is to establish the fee schedule amounts using the existing fee schedule amounts for comparable items described by HCPCS code E0656 ("segmental pneumatic appliance for use with pneumatic compressor, trunk").

The Koya Dayspring® System consists of a segmental calibrated gradient compression device that provides compression comparable to existing pneumatic pump (K1025) and garments (e.g., E0656) 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's garment trunk accessory are the same as those under the code for related pneumatic pump garment accessories (e.g., E0656). 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).

	E0656	Koya Dayspring® non-pneumatic sequential compression garment, trunk
Physical Components	-Segmented garment with tubing to allow filling of pneumatic air. -Air bladders in select number of chambers. -Tubing to connect pump to appliance (used for air flow).	-Fabric shell composed of polyester and spandex. -Multiple compressive segments made of durable plastic nylon frames interlaced with Nickel-Titanium (Ni-Ti) shape-memory alloy.
Mechanical Components	-Pressure ranges from 0 – 100 mmHg. -Air flows through tubing, inflating bladders until they are exerting the desired pressure range for treatment.	-Controller activates segments to exert desired programmed calibrated pressure gradient sequentially in distal to proximal direction.
Electrical Components	-None. All electrical components are in pump.	-Receiver to expand/contract segments to attain desired pressure.
Function and Intended Use	-To move excess fluid in a rhythmic, distal to proximal manner and return it to the bloodstream. -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 and return it to the bloodstream. -Uses segmental sections that expand/contract to exert intended pressure onto applied body area. -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	None	None

Payment for the equipment described by HCPCS code EXXXX would be made on a capped rental basis in accordance with 42 CFR 414.229. It would be established using the fee schedule amounts for HCPCS code E0656, with the 2022 rental fee schedule amount for months 1 through 3 equaling $70.70, and the rental fee schedule amount for months 4 through 13 equaling approximately $53.02 for all areas except Puerto Rico. For Puerto Rico, the 2022 rental fee schedule amount for months 1 through 3 would be equal to $84.83, and the rental fee schedule amount for months 4 through 13 would equal approximately $63.62.

Pricing Indicator = 36

Agenda Item # 3
PainShield® Supplies - HCP220616GR6A0

Topic/Issue

Request to establish a new HCPCS Level II code to identify PainShield® disposable supply kit.

Applicant's suggested language: XXXXX, “Disposable supply kit (1 transducer, 30 adhesive bandages) for use with the PainShieldMD, HCPCS K1004”

Applicant’s Summary

Nanovibronix submitted a request to establish a new HCPCS Level II code to identify the disposable supply kit for use with the PainShield® (HCPCS K1004). Each supply kit includes an ultrasound actuator (lasts 30 days) and 30 adhesive bandages. The PainShield® provides pain management using low frequency, ultrasonic diathermy. The ultrasound actuator included with the PainShield® durable handheld, battery-operated device is effective for 30 days, after which it must be replaced to maintain effective therapeutic action. The PainShield® is intended to apply ultrasonic energy, warming the tissues for the purpose of pain control, muscle spasms, and joint contractures. The mechanism of action is a warming of the skin for a period of 6.5 hours and as needed, as prescribed.

CMS Preliminary 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 disposable supply kit (1 transducer and 30 adhesive bandages) for use with the PainShield®. This follows our prior decision (published September 26, 2022) that the PainShield® device does not have a durable medical equipment, prosthetics, orthotics, and supplies Medicare benefit category. With regard to Medicare, we do not have a benefit category for PainShield®, a low-frequency ultrasonic diathermy treatment device for home use, as it does 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.

Agenda Item # 4
Steri-Lift Kit - HCP220406X5KJQ

Topic/Issue

Request to establish a new HCPCS Level II code to identify Steri-Lift Kit.

Applicant's Summary

L.A.D. Medical Innovations, LLC submitted a request to establish a new HCPCS Level II code to identify Steri-Lift Kit. Steri-Lift Kit is to be used as a drape to cover the floor or overhead lifts in sterile settings and to allow the lift to be used during surgery as a safe patient handling and movement tool. It is applied pre-op by the surgical team nurse and removed by the post-op personnel. Steri-Lift Kit is sterile and packaged individually for one-time use only. Steri-Lift Kit is exempt from the premarket notification procedures by the Food and Drug Administration.

CMS Preliminary HCPCS Coding Recommendation

Our understanding is that the Steri-Lift Kit 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.

Agenda Item # 5
Doula Birth Worker - HCP220323830N1, HCP220323U8HVV, HCP220323DP0KP

Topic/Issue

Request to establish a new HCPCS Level II code to identify doula birth worker prenatal visits, attendance at labor and delivery, and postpartum visits.

Applicant's suggested language:

1. XXXXX, “Doula birth worker prenatal visit”

2. XXXXX, “Doula birth worker attendance at labor and delivery”

3. XXXXX, “Doula birth worker postpartum visit”

Applicant’s Summary

Maryland Department of Health submitted a request to establish three new HCPCS Level II codes to identify doula birth worker prenatal visits, attendance at labor and delivery, and postpartum visits. According to the applicant, one of the new requested codes would cover doula birth worker prenatal visits, usually occurring at the birth parent's home, but could also include accompaniment to medical appointments. In these visits, doula birth workers and birth parents would discuss topics such as: anatomy and physiology of labor, birth, maternal postpartum, neonatal transition, and breastfeeding; labor coping strategies, comfort measures and non-pharmacological techniques for pain management; the reasons for, procedures of, and risks and benefits of common medical interventions, medications, and Cesarean birth; the role of the doula with members of the birth team; communication skills, including active listening, cross-cultural communication, and interprofessional communication; self-advocacy and empowerment techniques; perinatal mental health; family adjustment and dynamics; evidence-informed educational and informational strategies; and community resource referrals. According to the applicant, another new requested code would cover birth worker attendance and services during birth, 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. According to the applicant, a third new requested code would cover doula birth worker postpartum visits, usually occurring at the birthing parent's home, but could also include accompaniment to medical appointments. In these visits, doula birth workers and birth parents would discuss topics such as: anatomy and physiology of labor, birth, maternal postpartum, neonatal transition, and breastfeeding; labor coping strategies, comfort measures and non-pharmacological techniques for pain management; the reasons for, procedures of, and risks and benefits of common medical interventions, medications, and Cesarean birth; the role of the doula with members of the birth team; communication skills, including active listening, cross-cultural communication, and interprofessional communication; self-advocacy and empowerment techniques; perinatal mental health; family adjustment and dynamics; evidence-informed educational and informational strategies; and community resource referrals.
According to the applicant, many states are now reimbursing doula birth workers through Medicaid for physical, emotional and psychosocial support throughout the perinatal period.

Upon further analysis of HCPCS codes, the applicant 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.

CMS Preliminary HCPCS Coding Recommendation

CMS recently established codes that can be used in a multi-purpose manner for services performed by a doula birth worker. Existing HCPCS Level II codes describe the doula birth worker doula birth worker prenatal visits, attendance at labor and delivery, and postpartum visits:

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

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

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. These modifiers offer each state's Medicaid program the opportunity to define the level of care (e.g., prenatal visits, active labor and delivery, postpartum visits).

Agenda Item # 6
Feelix Stethoscope - HCP220701D69QJ

Topic/Issue
Request to establish a new HCPCS Level II code to identify digital stethoscope that collects high-fidelity recordings in any environment and transmit data wirelessly.

Applicant's suggested language: XXXXX, "Smart wireless digital platform with recording device and LED indicators"

Applicant's Summary

Sonavi Labs submitted a request to establish a new HCPCS Level II code to identify Feelix Device. Feelix Stethoscope received the Food and Drug Administration's (FDA's) 510(k) clearance on September 14, 2020. Feelix Stethoscope is a digital stethoscope that collects high-fidelity recordings in any environment and transmit data wirelessly. Feelix collects recordings of patient body sounds including cough and allows clinicians to review, store and share recordings via a HIPAA-compliant cloud. Feelix hardware is designed to run diagnostic and prognostic algorithms for specific respiratory diseases such as chronic obstructive pulmonary disease (COPD), pneumonia, asthma and cystic fibrosis. These algorithms will be separate Software as a Medical Device (SAMD) devices and will be downloaded to the hardware by prescription. According to the applicant, no code exists to define devices used to telemeter, analyze and diagnose body sound recordings. According to the applicant, a new code should be created to incorporate the use of recording devices for the management and treatment of respiratory patients remotely. Feelix is a prescription only device. The Feelix Stethoscope is intended for the detection, amplification and recording of sounds from the heart, lungs, anterior and posterior chest, abdomen, neck, limbs, arteries, veins and other internal organs with selective frequency ranges. It can be used on any person undergoing a physical examination.

CMS Preliminary HCPCS Coding Recommendation

This is a repeat application, previously submitted in B1 2021, application 21.066. It is our understanding that the item that is the subject of this application could be used in furnishing remote monitoring HCPCS Level I (CPT®) codes 99453, "Remote monitoring of physiologic parameters, initial set up and patient education on use of equipment," 99454, "Remote monitoring of physiologic parameters, supply with daily recordings or programmed alert transmission, each 30 days," and 99457, "Remote physiologic monitoring treatment management services, 20 minutes or more of clinical staff/physician/other qualified healthcare professional time in calendar month requiring interactive communication with the patient/caregiver during the month". CMS continues to believe that HCPCS Level I (CPT®) is the appropriate code set for the Feelix Device.

Agenda Item # 7
Cochlear™ Osia® 2 System - HCP220705GRQ19

Topic/Issue

Request to establish a new HCPCS Level II code to identify Cochlear™ Osia® 2 System.

Applicant's suggested language: LXXXX, "Active, auditory osseointegrated device, including implanted transducer/actuator with digital link to external sound processor"

Applicant's Summary

Cochlear Americas submitted a request to establish a new HCPCS Level II code to identify the Osia® 2 System. The Cochlear Osia® 2 System is an active, auditory osseointegrated implant with transcutaneous attachment to external system components. The Osia® 2 System is intended for patients 12 years-of-age or older who have conductive or mixed hearing loss, or single-sided deafness and still can benefit from sound amplification. The Osia® 2 System is a prosthetic that replaces the functioning of the middle ear. The Osia® 2 System is surgically implanted during an outpatient procedure. According to applicant, unlike the passive osseointegrated devices recognized by the current HCPCS Level II code set in which sound is converted to mechanical vibrations in the external sound processor/actuator then transmitted to the internal components, the Osia® 2 System converts the sound to mechanical vibrations after it has reached the internal components. The active, piezoelectric design of the OSI200 Implant, which is one component of the Osia® 2 System, thereby allows for an efficient delivery of the sound from the external environment to the cochlea (inner ear). The Osia® 2 System mechanically vibrates the skull bone, and subsequently the cochlea, acting as a prosthetic to replace the functioning of the middle ear. What is unique about the Osia® 2 System is that it uses a magnetic coupling to transfer the sound received by the external processor to the implanted component via a digital link (e.g., transcutaneous pathway) where it is then transformed into mechanical vibrations by the (active) OSI200 implant, transferred directly to the BI300 Implant, and then to the cochlea via the skull bone. The Osia® 2 System improves upon passive percutaneous systems by eliminating issues associated with the skin penetrating abutment, and solves for the sound diminution issues of passive transcutaneous systems due to the active design of the implant and generation of vibrations under the scalp. According to the applicant, when HCPCS Level II code L8690, "Auditory osseointegrated device, includes all internal and external components" was created, the technology to fully implant the transducer/actuator and thereby transform sound into mechanical vibrations directly at the bone implant did not exist. This technology transforms the functioning of the external sound processor and internal components of active auditory osseointegrated implants because the mechanism of action is entirely different from the passive systems of the past. According to applicant, for these reasons, and as acknowledged by CMS in the 2022 Hospital Outpatient Prospective Payment System (OPPS) final rule (86 Fed. Reg. 63,458, 63,591 and 63,605 (Nov. 16, 2021)), existing HCPCS Level II code L8690 does not describe active osseointegrated systems, like the Osia® 2 System, and a new HCPCS Level II code should be created to specifically describe them. The Cochlear™ Osia® 2 Sound Processor received the Food and Drug Administration's (FDA's) 510(k) clearance on November 15, 2019.

CMS Preliminary HCPCS Coding Recommendation

The Calendar Year 2022 Hospital Outpatient Prospective Payment System (OPPS) Final Rule (86 FR 63458) determination was that the Cochlear™ Osia® 2 Sound Processor does not meet the substantial clinical improvement criterion. Though the mechanism of action with comparable devices may differ, the vibratory stimulation of the skull to stimulate the receptors in the cochlea (inner ear) is the same. CMS did not find any new evidence in the HCPCS Level II application to establish a significant therapeutic distinction. CMS, as an agency, continues to believe that our decision in the 2022 OPPS Final Rule remains accurate. As such, existing HCPCS Level II code L8690, "Auditory osseointegrated device, includes all internal and external components" describes the Cochlear™ Osia® 2 System.

Preliminary Medicare Benefit Category Determination

The Osia® 2 system meets the criteria to be considered a prosthetic device as it is an osseointegrated implant in the skull bone that provides mechanical energy to the cochlea via a mechanical transducer per §411.15(d)(2)(i). As such, it is not subject to the hearing aid exclusion at §411.15(d)(1).

The current Medicare policy and prior established benefit category determination for code L8690 apply to this item.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing code L8690 apply to this product, if covered. The current average fee schedule amount for L8690 is $5,004.81.

The average fee schedule amount is the average of the 2022 fee schedule amounts for the code for each of the 50 states, Washington D.C., Puerto Rico, and the Virgin Islands. Fee schedules are updated annually.

Pricing Indicator = 38

Agenda Item # 7
Cochlear™ Osia® 2 Sound Processor - HCP22070522MTY

Topic/Issue

Request to establish a new HCPCS Level II code to identify to Cochlear™ Osia® 2 Sound Processor.

Applicant's suggested language: LXXXX, "Active, auditory osseointegrated device, external sound processor with digital link to implanted transducer/actuator; replacement only, each"

Applicant's Summary

Cochlear Americas submitted a request to establish a new HCPCS Level II code to identify replacements for the Osia® 2 External Sound Processor. The Osia® 2 System is an active, auditory osseointegrated implant with transcutaneous attachment to external system components that are surgically placed in the temporal bone posterior to the pinna. The Osia® 2 Sound Processor is worn off-the-ear and picks up sound from the environment. After processing sound, the Osia® 2 Sound Processor sends the information to the OSI200 Implant via a transcutaneous inductive link (also referred to as a radiofrequency link). The Osia® 2 Sound Processor houses the microphones that pick-up sound, the battery that powers the microphones as well as the implanted components of the Osia® 2 System, and the magnet that transcutaneously links the external sound processor to the internal transducer/actuator. The Osia® 2 Sound Processor does not contain the actuator/transducer, which is implanted as part of the active Osia® System. The Osia® 2 System is intended for patients 12 years-of-age or older who have conductive or mixed hearing loss, or single-sided deafness and still can benefit from sound amplification. The Osia® 2 Sound Processor is a prosthetic supply. It has a warranty period of two years after which time it may need to be replaced. According to the applicant, unlike the passive osseointegrated devices recognized by the current HCPCS Level II code set in which sound is converted to mechanical vibrations in the external sound processor/actuator then transmitted to the internal components, the Osia® 2 System converts the sound to mechanical vibrations after it has reached the internal components. This innovative technology has made it possible for there to be a single external component of the auditory osseointegrated implant (AOI) system, the sound processor. Passive AOIs all have external sound processors, which include a processing unit and a transducer/actuator. Those external sound processors may contain both the processing unit and transducer/actuator within a single unit or may consist of both pieces separated but connected via a physical wire. Because the Osia® 2 System's transducer/actuator is implanted, the technology in the Osia® 2 Sound Processor itself also is different from passive sound processors because the device must incorporate a digital link to communicate the sounds transcutaneously to the internal components. According to applicant, CMS acknowledged in the 2022 Hospital Outpatient Prospective Payment System (OPPS) final rule that existing HCPCS code L8690 (Auditory osseointegrated device, includes all internal and external components) does not describe the Osia® 2 System. For the same reason, HCPCS Level II code L8691, "Auditory osseointegrated device, external sound processor; excludes transducer/actuator; replacement only, each" does not describe the Osia® 2 Sound Processor. The Cochlear™ Osia® 2 Sound Processor received the Food and Drug Administration's (FDA's) 510(k) clearance on November 15, 2019.

CMS Preliminary HCPCS Coding Recommendation

The Calendar Year 2022 Hospital Outpatient Prospective Payment System (OPPS) Final Rule (86 FR 63458) determination was that the Cochlear™ Osia® 2 Sound Processor does not meet the substantial clinical improvement criterion. Though the mechanism of action with comparable devices may differ, the vibratory stimulation of the skull to stimulate the receptors in the cochlea (inner ear) is the same. CMS did not find any new evidence in the HCPCS Level II application to establish a significant therapeutic distinction. CMS, as an agency, continues to believe that our decision in the 2022 OPPS Final Rule remains accurate. As such, existing HCPCS Level II code L8691, "Auditory osseointegrated device, external sound processor, excludes transducer/actuator, replacement only, each" describes the Cochlear™ Osia® 2 Sound Processor.

Preliminary Medicare Benefit Category Determination

The sound processor is an external component of the implanted Osia® 2 System. The Osia® 2 system meets the criteria to be considered a prosthetic device as it is an osseointegrated implant in the skull bone that provides mechanical energy to the cochlea via a mechanical transducer per §411.15(d)(2)(i). As such, it is not subject to the hearing aid exclusion at §411.15(d)(1).

The current Medicare policy and prior established benefit category determination for code L8691 apply to this item.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing code L8691 apply to this product, if covered. The current average fee schedule amount for L8691 is $1,811.79.

The average fee schedule amount is the average of the 2022 fee schedule amounts for the code for each of the 50 states, Washington D.C., Puerto Rico, and the Virgin Islands. Fee schedules are updated annually.

Pricing Indicator = 38

Agenda Item # 8
SWIK™ - HCP2205316LKRL

Topic/Issue

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

The applicant did not submit any suggested language.

Applicant's Summary

Saliva Systems submitted a request to establish a new HCPCS Level II code to identify the SWIK™ Oral Suction System. SWIK™ is a class 1 device, exempt from the premarket notification procedures by the Food and Drug Administration. SWIK™ is a single-use, disposable device to manage secretions in the oral cavity. The device includes a mouthpiece attached to tubing with a custom molded connector. The tubing then connects to a negative pressure pump with a universal connector. SWIK™ is installed in the mouth and remains in place, for up to 12 hours at a time, while connected to negative pressure. The device does not require intervention during use; only installation and removal of the device. According to the applicant, the current assigned code, A4628, describes a device that requires human intervention to operate and is used intermittently rather than continuously.

CMS Preliminary HCPCS Coding Recommendation

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

1. How does the SWIK™ Oral Suction System compare to some of the other products in this space or those that currently fall under A4628, "Oropharyngeal suction catheter, each" (such as, materials, componentry, etc.)?

2. Who is the patient population utilizing the SWIK™ Oral Suction System?

3. In what clinical setting would a patient use this for 12 hours?

4. Are there any data that show the SWIK™ Oral Suction System is preferable to other oral secretion devices, provides better health outcomes, offers statistically significant improvements in care, etc.?

Agenda Item # 9
NEURO SWING, Cup Disc Spring Force Unit - HCP220705GH052

Topic/Issue

Request to establish a new HCPCS Level II code to identify a cup disc spring force unit.

Applicant's suggested language: XXXXX, "Addition to lower extremity, exchangeable, pre-compressed cup disc spring force unit with integrated range of motion control feature"

Applicant's Summary

FIOR & GENTZ submitted a request to establish a new HCPCS Level II code to identify a pre-compressed cup disc spring force unit in an ankle foot orthosis (AFO). The NEURO SWING is a class 1 device, exempt from the premarket notification procedures by the Food and Drug Administration. According to the applicant, this innovative device not only allows adjustable range of motion in an AFO, but provides more therapeutic benefit than either a coil or helical spring due to a pre-compressed cup disc spring force unit's ability to generate a higher magnitude force capacity than ever previously available in an orthotic joint. The pre-compressed cup disc spring force units are incorporated into the NEURO SWING ankle joint system so that not only can adequate resistance forces be applied, but also an assistive force can be generated that is sufficient to assist the leg with a magnitude of force necessary to return the leg to a proper starting position during gait. The applicant believes the NEURO SWING pre-compressed cup disc spring force unit is therapeutically distinct due to the capability to assist the leg and control the heel strike and return to a proper starting position in the fourth rocker of gait cycle. According to the applicant, other joint devices from competitors do not use pre-compressed springs (helical/coil or cup disc). This feature allows even severely impacted limbs to be moved back into the correct starting position in normal gait cycle.

CMS Preliminary HCPCS Coding Recommendation

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

1. Can you explain the difference from the NEURO SWING pre-compressed cup disc spring force unit within the ankle joint system current application and previous HCPCS Level II application 16.016?

2. What are the principal elements and functions of L2220 versus NEURO SWING pre-compressed cup disc spring force unit?

3. What is the therapeutic distinction of the NEURO SWING pre-compressed cup disc spring force unit compared to existing joints? Specifically, those described by L2220.

4. How does the NEURO SWING pre-compressed cup disc spring force unit anterior and posterior adjustment channel differ from L2220's anterior and posterior channels?

5. Do you think the NEURO SWING pre-compressed cup disc spring force unit’s spring mechanism is a completely new product over the springs and pins included in the L2220 product notwithstanding the reported range of spring dynamics?

Agenda Item # 9
NEURO SWING, System Ankle Joint - HCP220705UQPHF

Topic/Issue

Request to establish a new HCPCS Level II code to identify a system ankle joint.

Applicant's suggested language: XXXXX, "Addition to lower extremity, custom dynamic ankle joint, independently adjustable shank angle (sagittal) alignable system, independently adjustable range of motion, independently and simultaneously adjustable control of resistance and assistance forces of plantar/dorsiflexion"

Applicant's Summary

FIOR & GENTZ submitted a request to establish a new HCPCS Level II code to identify a system ankle joint. According to the applicant, the NEURO SWING system ankle joint is an entirely new class of ankle joints that differ from the existing code L2220 (Addition to lower extremity, dorsiflexion and plantar flexion assist/resist, each joint). The applicant stated, the reason for developing this new class of ankle joints is because of the additional capabilities not previously available in Ankle Foot Orthosis (AFO)/Knee Ankle Foot Orthosis (KAFO). This class of joint is independently adjustable in shank angle alignment and in the dorsi/plantar assist/resist control. The adjustment of one parameter will not affect the adjustment of the other. According to the applicant, this is in contrast to the dual action L2220 joints which affect the other parameter when the orthotist makes a single separate adjustment. These joints interconnect with a spring system that offers an independent repeatedly adjustable range of motion control. This class of joint can simultaneously control both the dorsiflexion and plantarflexion. With an ankle joint that qualifies under L2220, the practitioner must choose between adjusting either dorsi- or plantarflexion, whereas with this new class, adjustments in dorsi- or plantarflexion can be selected independently. According to the applicant, this improved ankle joint is an advancement to the current level of care because it does not block the physiological movement of the joint as occurs with traditional L2220 ankle joints. This class of joint can be adjusted after the device has been fully fabricated whereas a traditional L2220 AFO can only be adjusted in the sagittal plane after finalization and adjustments in this way cause immediate loss of mobility. The applicant asserts, that this new class of joint offers a therapeutic distinction in that its infinite adjustability allows for the accommodation of progress or decline of each individual patient during their specific rehabilitation process.

CMS Preliminary HCPCS Coding Recommendation

Existing HCPCS Level II code L2220, "Addition to lower extremity, dorsiflexion and plantar flexion assist/resist, each joint" describes the NEURO SWING System Ankle Joint.

Preliminary Medicare Benefit Category Determination

The current Medicare policy and prior established benefit category determination for code L2220 apply to this item.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing code L2220 apply to this product, if covered. The current average fee schedule amount for L2220 is $91.78.

The average fee schedule amount is the average of the 2022 fee schedule amounts for the code for each of the 50 states, Washington D.C., Puerto Rico, and the Virgin Islands. Fee schedules are updated annually.

Pricing Indicator = 38

Agenda Item # 10
ULTepap - HCP220628D8N92

Topic/Issue

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

Applicant's suggested language: XXXXX, “EPAP device, reusable, capable of use with multiple size nasal pillows”

Applicant’s Summary

BRYGGS Medical, LLC submitted a request to establish a new HCPCS Level II code to identify ULTepap system. It is a single-patient, reusable Expiratory Positive Airway Pressure (EPAP) device for the treatment of mild to moderate obstructive sleep apnea marketed as ULTepap. The ULTepap system received the Food and Drug Administration’s (FDA’s) 510(k) clearance on January 24, 2020. The device is comprised of a pair of bi-resistance cartridges which are designed and warrantied for a 3-year expected service life. The ULTepap system includes a headgear and appropriate size nasal pillow for the patient. These accessory items are similar in design and performance to currently available products. As such, the applicant requests the following existing codes to be assigned for billing replacement accessories when needed: A7033 "Pillow for use on nasal cannula type interface, replacement only, pair" and A7035 "Headgear used with positive airway pressure device”.

CMS Preliminary HCPCS Coding Recommendation

This application for the ULTepap system is a subsequent application to application number 21.056. Information in this application adequately demonstrates that changes have been made to extend the lifetime of the ULTepap device. As such, CMS will establish a new HCPCS Level II code AXXXX, “Expiratory positive airway pressure intranasal resistance valve” to describe the ULTepap system. Existing code A9270, “Non-covered item or service” is available for billing replacement accessories to the Medicare program such as nasal pillows and headgear.

Preliminary Medicare Benefit Category Determination

No Medicare DMEPOS 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 five conditions listed in the below table. All five of these conditions must be met in order for equipment to be classified as DME. As explained in the below table, the ULTepap expiratory positive airway pressure intranasal resistance valve does not meet all five conditions, and therefore would not fall under a DMEPOS benefit category.

In addition, the pillow and headgear are accessories for the ULTepap expiratory positive airway pressure intranasal resistance valve. The ULTepap expiratory positive airway pressure intranasal resistance valve does not fall under the DME benefit category and thus the pillow and headgear accessories also do not fall under the DME benefit category. For coding

guidance for other payors, 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.

Condition Met?	**Conditions that Must be Met for Equipment to be Classified as DME**
No	1. Can withstand repeated use. 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 ULTepap expiratory positive airway pressure intranasal resistance valve is intended for single patient use and therefore cannot withstand repeated use.
Yes	2. Effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years.
Yes	3. Is primarily and customarily used to serve a medical purpose.
Yes	4. Generally, is not useful to an individual in the absence of an illness or injury.
Yes	5. Is appropriate for use in the home.

Preliminary Medicare Payment Determination

No Medicare Payment. Pricing = 00

Agenda Item # 11
Canvas Dx - HCP220705YK09X

Topic/Issue

Request to establish a new HCPCS Level II code to identify Canvas Dx.

Applicant's suggested language: AXXXX: "Prescription digital diagnostic device for neurodevelopmental/behavioral disorders, FDA authorized, per diagnostic assessment"

Applicant's Summary

Cognoa, Inc. submitted a request to establish a new HCPCS Level II code to identify Canvas Dx. Canvas Dx received the Food and Drug Administration's (FDA's) De Novo classification on June 2, 2021. Canvas Dx is a prescription-only digital diagnostic product that aids healthcare professionals in diagnosing or ruling out Autism Spectrum Disorder (ASD) in children aged 18 months through 72 months. According to the applicant, existing HCPCS Level II code A9291 does not adequately describe Canvas Dx because Canvas Dx is a prescription-only diagnostic. The applicant believes a unique HCPCS Level II code to describe Canvas Dx is necessary because most payors have pushed Canvas Dx to be adjudicated under the medical benefit given that any observed healthcare cost offsets for ASD resulting from earlier diagnosis of ASD are typically observed under the medical benefit. Digital diagnostic devices have a different and unique use and cost profile that warrants different coding from therapeutics. Whereas therapeutics are typically prescribed for the ongoing or episodic treatment of chronic conditions, diagnostic digital devices like Canvas Dx are ordered at a singular point in time to aid a health care provider in assessing the presence or absence of a condition. For both private and public payors, the ability to accurately monitor the cost of, and evaluate holistically, each of the two distinct categories of emerging digital solutions will be of critical importance as the digital health field expands exponentially in the coming years. Assessing the cost of a "one and done" digital diagnostic device compared to ongoing spend for digital therapeutics would be extremely challenging under a single digital therapeutic umbrella code. Cognoa, Inc.'s Canvas Dx is intended for use by healthcare providers as an aid in the diagnosis of Autism Spectrum Disorder for patients aged 18 months through 72 months who are at risk for developmental delay based on concerns of a parent, caregiver, or healthcare provider. This device is not intended as a stand-alone diagnostic, but as an adjunct to the diagnostic process.

CMS Preliminary HCPCS Coding Recommendation

Our understanding is that the Canvas Dx 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.

Agenda Item # 12
OxyBand™ Wound Dressing Matrix - HCP22070507T93

Topic/Issue

Request to establish a new HCPCS Level II code to identify Oxyband™ wound dressing matrix.

The applicant did not submit any suggested language.

Applicant's Summary

Oxyband submitted a request to establish a new HCPCS Level II code to identify Oxyband™ wound dressing matrix. Oxyband™ received the Food and Drug Administration's (FDA's) 510(k) clearance on March 24, 2005. Oxyband™ is a multi-layer wound dressing matrix that provides a moist oxygen rich environment to protect, maintain, and facilitate the wound healing process including supporting cellular repair and regeneration. Its advanced matrix technology provides transdermal delivery of 100% oxygen to both acute wounds and chronic ulcers and delivers oxygen continuously via sustained release over an extended period of time directly from the proprietary reservoir as long as the Oxyband™ wound dressing matrix cover remains intact and secure around the perimeter frame. OxyBand™ wound dressing matrix is designed to provide a framed structure with a cover and border to keep out contaminants that compromise healing and cause infection. The number of days between Oxyband™ wound dressing matrix changes depends upon the size and metabolic characteristics of the wound, and can be applied as either a primary, or secondary therapeutic utilized with skin grafts or other advanced technologies and dressings (alginate, foam, collagen, hydro fiber, hydrocolloid, etc.) Provided in a pouch as a single use sterile device, Oxyband™ wound dressing matrix is FDA cleared to cover and protect wounds and catheter sites or used as a secondary dressing for other wounds such as gauze, alginates, hydrogels, debridement facilitators, or a protective cover over at-risk skin. The Oxyband™ wound dressing matrix is indicated for: clean closed surgical incisions, skin graft donor sites, Stage 1 and II pressure ulcers, pressure sores, superficial wounds such as abrasions, skin tears, and blisters, lacerations, first- and second-degree burns, chafed skin, skin continuously exposed to moisture, secondary dressing over gauzes, alginates and hydrogels.

CMS Preliminary HCPCS Coding Recommendation

Existing HCPCS Level II code A6204, "Composite dressing, sterile, pad size more than 16 sq. in. but less than or equal to 48 sq. in., with any size adhesive border, each dressing" describes Oxyband™ wound dressing matrix.

Preliminary Medicare Benefit Category Determination

The current Medicare policy and prior established benefit category determination for code A6204 apply to this item.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing code A6204 apply to this product, if covered. The current average fee schedule amount for A6204 is $7.68.

The average fee schedule amount is the average of the 2022 fee schedule amounts for the code for each of the 50 states, Washington D.C., Puerto Rico, and the Virgin Islands. Fee schedules are updated annually.

Pricing Indicator = 35

Agenda Item # 13
CloudCath Peritoneal Dialysis Drain Set Monitoring System - HCP220701PTF4P

Topic/Issue

Request to establish a new HCPCS Level II code to identify CloudCath Peritoneal Dialysis Drain Set Monitoring System (CloudCath System).

Applicant's suggested language: "Peritoneal dialysate effluent turbidity monitoring system, including sensor, drain set, computer algorithm/software and user interface that processes, communicates and transmits the information, and all required supplies"

Applicant's Summary

Hull Associates LLC submitted a request to establish a new HCPCS Level II code to identify CloudCath Peritoneal Dialysis Drain Set Monitoring System (CloudCath System). The CloudCath System received the Food and Drug Administration's (FDA's) 510(k) clearance on February 9, 2022.The CloudCath System is a complete peritoneal dialysate effluent turbidity monitoring system, inclusive of all required supplies and equipment. The CloudCath System is a tabletop passive drainage system used as an attachment during a peritoneal dialysis treatment and indicated for use by patients with acute and chronic end-stage renal disease (ESRD) undergoing peritoneal dialysis. The system contains an optical sensor that measures turbidity, reported as a turbidity score, of patient's peritoneal dialysate effluent as a supplement to visual examination of cloudiness in the dialysate drain line. According to the applicant, there is no existing HCPCS Level II code describing a peritoneal dialysate effluent turbidity monitoring system.

CMS Preliminary HCPCS Coding Recommendation

After consideration of all the public comments received for the Calendar Year 2023 ESRD Prospective Payment System Proposed Rule (87 FR 38505), CMS has determined that the evidence and public comments submitted are not sufficient to demonstrate that the CloudCath System meets all eligibility criteria to qualify for the Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES). As a result, the CloudCath System will not be paid for under TPNIES per § 413.236(d). Therefore, we are denying this applicant's request to establish a new HCPCS Level II code for the CloudCath System.

Agenda Item # 14
Theranova 400/500 - HCP2207048YCGW

Topic/Issue

Request to establish a new HCPCS Level II code to identify Theranova 400/500.

Applicant's suggested language: AXXXX, "Dialyzer (artificial kidneys), Theranova, for expanded hemodialysis, each"

Applicant's Summary

Baxter Healthcare submitted a request to establish a new HCPCS Level II code to identify Theranova 400/500 (Theranova). The applicant believes, in the absence of a new code, end-stage renal disease (ESRD) hemodialysis providers will use HCPCS Level II code A4690, "Dialyzer (artificial kidneys), all types, all sizes, for hemodialysis, each." According to the applicant, this code does not adequately describe Theranova. Theranova is an innovative dialyzer intended to treat renal failure by Expanded Hemodialysis (HDx). It features a unique 3-layer membrane structure that offers a higher permeability than regular high-flux dialyzers, with improved removal of large middle molecules while selectively maintaining essential proteins such as albumin. Theranova has the potential to transform in-center hemodialysis by allowing patients, including Medicare beneficiaries, with renal failure to benefit from HDx, the process of blood purification that includes the clearance of small and large middle molecular uremic toxins with existing hemodialysis infrastructure without the need for external infusion of replacement fluid. According to the applicant, a new code is needed to differentiate Theranova from other dialyzers. Baxter Healthcare has submitted a Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES) application for Theranova as well. A product-specific HCPCS Level II code is a requirement for the TPNIES program. The Food and Drug Administration (FDA) authorized Theranova under the de novo pathway on August 28, 2020.

CMS Preliminary HCPCS Coding Recommendation

After consideration of all the public comments received for Calendar Year 2023 ESRD Prospective Payment System Proposed Rule (87 FR 38505), CMS has determined that the evidence and public comments submitted are not sufficient to demonstrate that Theranova meets all eligibility criteria to qualify for the TPNIES. As a result, Theranova will not be paid for under TPNIES per § 413.236(d). Therefore, we are denying this applicant's request to establish a new HCPCS Level II code for Theranova.

Agenda Item # 15
SunWrap™ System Dialysis Access Guard - HCP220131BGMBQ

Topic/Issue

Request to establish a new HCPCS Level II code to identify SunWrap™ System Dialysis Access Guard.

Applicant's suggested language: XXXXX, "Reusable Compression wrap for post-dialysis bleeding control consisting of Patient enabled velcro-secured application, custom compression control with transparent inflatable bolster window to enable visualization of dialysis needle sites"

Applicant's Summary

Sun Scientific submitted a request to establish a new HCPCS Level II code to identify SunWrap™ System Dialysis Access Guard. The SunWrap™ System is a single-patient reusable compression wrap with a transparent window that incorporates compression directly over the wound sites while simultaneously allowing visibility of potential bleeding following hemodialysis via arm access (fistula or graft). The SunWrap™ System Dialysis Access Guard is class 1 device, exempt from the premarket notification procedures by the Food and Drug Administration. The SunWrap™ System is secured by Velcro which accommodates variability of arm circumference. It also incorporates patient controlled adjustable static compression across the transparent window, providing consistent pressure to needle sites post-dialysis, while offering visibility of the wound sites through the transparent static compression window, allowing real time visualization and ability to manage any bleeding. This design enables more consistent and autonomous application of wrap and compression to reduce the need for additional personnel and manual compression immediately following hemodialysis. According to applicant, existing codes do not adequately describe the product and specific service because they are supply codes designed to cover the cost of disposable single patient use supplies that are used and disposed of per hemodialysis event. The SunWrap™ System is a reusable compression wrap that is warrantied for 6 months of normal use, and as a result, is not a typical supply covered under current coding.

CMS Preliminary HCPCS Coding Recommendation

After consideration of all the public comments received for the Calendar Year 2023 ESRD Prospective Payment System Proposed Rule (87 FR 38505), CMS has determined that the evidence and public comments submitted are not sufficient to demonstrate that the SunWrap™ System meets all eligibility criteria to qualify for the Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES). As a result, the SunWrap™ System will not be paid for under TPNIES per § 413.236(d). Therefore, we are denying this applicant's request to establish a new HCPCS Level II code.

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.