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

Centers for Medicare & Medicaid Services' (CMS') Second Biannual 2023 Healthcare Common Procedure Coding System (HCPCS) Public Meeting Agenda

Zoom Meeting - Remote participation
Tuesday, November 28, 2023 9:00 am – 5:00 pm, eastern time (ET)

8:45 am, ET:
• Zoom meeting login:
https://cms.zoomgov.com/webinar/register/WN_spNk4pWiR2Wb2SZ-TMarxQ
• Individuals who plan to speak as a primary or 5-minute speaker must register, through the link above, by the published deadline. All other attendees can access the virtual public meeting through the Zoom link that we will post on the HCPCS website after speaker registration closes.

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 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 February 2024 and will be effective April 1, 2024, unless otherwise specified.

This agenda includes a summary of each HCPCS code application being presented on Tuesday, November 28, 2023. The information provided in each summary reflects claims made by the applicant and should not be construed as a statement of fact or an endorsement by the federal government.

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Preliminary decisions for the HCPCS Virtual Public Meeting on Tuesday, November 28th, 2023.

Agenda Item # 1
KeraStat® Cream - HCP2306273CR3W

Topic/Issue

Request to establish a new HCPCS Level II Code to identify KeraStat® Cream.

Applicant's suggested language: XXXXX, “KeraStat cream, per milliliter”

Summary of Applicant's Submission

KeraNetics, Inc. submitted a request to establish a new HCPCS Level II code to identify KeraStat® Cream. KeraStat® Cream received the Food and Drug Administration’s (FDA’s) 510(k) clearance on July 16, 2020. KeraStat® Cream is indicated for the management of a variety of partial thickness dermal wounds such as first- and second-degree burns, severe sunburns, superficial injuries, cuts, abrasions, incisions, and surgical wounds. KeraStat® cream is also intended to maintain a moist wound environment. KeraStat® Cream also may be used in the management of dry, light, and moderately exuding partial thickness wounds including pressure ulcers (stage I-II), venous stasis ulcers, ulcers caused by mixed vascular etiologies, diabetic ulcers, radiation dermatitis, donor sites, and grafts under the direction of a healthcare professional. By managing the symptoms of radiation dermatitis, KeraStat® Cream can improve patient treatment adherence to their radiotherapy, shown in a clinical study with breast, head, and neck cancer patients. KeraStat® Cream has been compared to Strata XRT Gel and Biafine Emulsion. There are some similarities between the products, however, these products do not contain keratin. Keratin is the primary ingredient in KeraStat® cream. KeraStat® Cream is used at different frequency than Strata XRT Gel and Biafine Emulsion. It can be an important consideration in adjudicating claims for these different products. KeraStat® Cream is a non-sterile, non-implantable wound dressing. KeraStat® Cream is provided in a 1-ounce (29.6 milliliters) screw top tube containing keratin protein incorporated into a cream base. KeraStat® Cream is available by prescription.

CMS Preliminary HCPCS Coding Recommendation

KeraStat® Cream, containing keratin protein, is indicated for radiation dermatitis after radiotherapy as a topical treatment. Therefore, existing HCPCS Level II code A6250, “Skin sealants, protectants, moisturizers, ointments, any type, any size" describes KeraStat® Cream.

The applicant made a claim for clinical therapeutic distinction compared to Biofine. Biofine is the reference product for KeraStat® Cream. Per FDA’s 510(k), “KeraStat® Cream and the reference wound dressing, Biafine®, have the same intended use to provide a moist environment for wound management including wounds caused by radiation dermatitis. Biafine®, has similar technological characteristics as KeraStat® Cream, as both are non-sterile, multi-use cream emulsions composed of a protein/amine, emollients, emulsifiers, thickeners, and preservatives.” Biofine is assigned existing HCPCS Level II code A6250. Also, the applicant did not provide adequate support for the claim of significant therapeutic distinction. The applicant submitted clinical studies designed to evaluate the feasibility of using KeraStat® Cream to manage the symptoms of radiation dermatitis in patients with cancer and assessing compliance of use, safety and tolerability. However, there were no comparisons made with the use of Biafine®.

Agenda Item # 2
Restrata® MiniMatrix - HCP230630JLCVQ

Topic/Issue

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

Applicant's suggested language: XXXXX, “Restrata MiniMatrix, per mg”

Summary of Applicant's Submission

Acera Surgical, Inc. submitted a request to establish a new HCPCS Level II code to identify Restrata® MiniMatrix. Restrata® MiniMatrix received the Food and Drug Administration’s (FDA’s) 510(k) clearance on May 18, 2023. Restrata® MiniMatrix is fragmented, milled and sieved into its dispersible form. The device surface area is not measurable in square centimeters given the fragmented form, rather, it is measured by units of mass (i.e., milligrams). Restrata® MiniMatrix is a sterile, single patient use device intended for the local management of wounds, including partial and full thickness wounds, pressure sores, venous and diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds, (e.g., donor sites, grafts, post-laser surgery, post-Mohs surgery, podiatric, dehisced wounds); trauma wounds, and draining wounds. Restrata® MiniMatrix can be dispersed at the wound site and during application applied to soft tissue areas with irregular or complex topography, which would not readily accommodate a sheet form of the device. Restrata® MiniMatrix is made from synthetic biocompatible materials and was designed to include a fibrous structure with high porosity like native extracellular matrix (ECM). Restrata® MiniMatrix completely degrades via hydrolysis. Restrata® MiniMatrix does not contain any human or animal materials or tissues. Restrata® MiniMatrix is prepared from the same component sheet materials as the primary predicate device Restrata® Matrix. Both devices are manufactured using electrospun, fully resorbable poly (lactic-co-glycolic acid) (PGLA) (10:90) and polydiaxonone (PDO) synthetic polymers. It can be applied dry or hydrated. Post-application, the fibers are gradually hydrolyzed and absorbed over time forming a new tissue. Restrata® MiniMatrix is reapplied if wound is free of infection and necrosis as needed, based on physician or provider discretion. Restrata® MiniMatrix can be shaken or sprinkled over the open, compromised area. It is supplied in a nested pouch configuration, placed within a shelf-box. The product is terminally sterilized.

CMS Preliminary HCPCS Coding Recommendation

Establish a new HCPCS Level II code AXXXX, "Restrata minimatrix, 5 mg"

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. As such, we recommend the dose descriptor of 5 mg based on the largest package size of Restrata® MiniMatrix, which is 2000 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.

Agenda Item # 3
ACEND™ - HCP23070329LQ2

Topic/Issue

Request to establish a new HCPCS Level II code to identify ACEND™ (Advanced Clinical Enteral Nutrition Delivery).

Applicant's suggested language: XXXXX, "Enteral formula, nutritionally incomplete, for special anti-inflammatory needs, includes polyphenol isolates, administered through an enteral feeding tube"

Summary of Applicant's Submission

Trility™, Inc. submitted a request to establish a new HCPCS Level II code to identify ACEND™. ACEND™ is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). ACEND™ is an enteral nutrition product specially formulated and processed for the dietary management of patients with chronic infection and oncology where universal inflammation is established. ACEND™ is enhanced by specific polyphenols intended to adequately address the systemic, chronic inflammation caused by disease-related malnutrition, which represents a unique, anti-inflammatory enteral formula in the form of a powdered drink mix. Because ACEND™ is not a nutritionally complete enteral formula with intact nutrients, it is precluded from coding under HCPCS code B4150. Because ACEND™ is not a nutritionally incomplete enteral formula, but includes what modern research terms "non-nutrients" rather than "specific nutrients including carbohydrates, proteins, and fats," it is precluded from coding under HCPCS code B4155.

CMS Preliminary HCPCS Coding Recommendation

Existing HCPCS Level II code A9153, "Multiple vitamins, with or without minerals and trace elements, oral, per dose, not otherwise specified" describes ACEND™.

Preliminary Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

Medicare provides coverage for enteral nutritional therapy when a feeding tube, the prosthetic device, is used to deliver nutrition to a patient who has an inoperative internal body organ, or the function thereof as cited in National Coverage Determination 180.2. Since the applicant describes the orally administered powder drink as a nutritionally incomplete enteral formula that lacks specific nutrients including carbohydrates, proteins, and fats, ACEND does not fall into the prosthetic device benefit category.

Preliminary Medicare Payment Determination

No Medicare payment. Pricing Indicator = 00

Agenda Item # 4
Cue COVID-19 Molecular Test Cartridge - HCP2306305R33J

Topic/Issue

Request to establish a new HCPCS Level II code to identify COVID-19 molecular test cartridge.

Applicant's suggested language: AXXXX, "Covid-19 molecular test cartridge, sterile, each, FDA fully cleared for use with molecular diagnostic test reader"

Summary of Applicant's Submission

Cue Health submitted a request to establish a new HCPCS Level II code to identify COVID-19 molecular test cartridge with the Cue sample wand, to detect the presence of COVID-19 using molecular Nucleic Acid Amplification Test (NAAT) technology. Cue COVID-19 molecular test received the Food and Drug Administration's (FDA's) De Novo clearance on June 6, 2023. As a component of the Cue Health monitoring system, the Cue COVID-19 molecular test is used with the Cue cartridge reader, an in-vitro diagnostic medical device. The Cue test cartridge and the Cue cartridge reader work with the proprietary Cue health App, which is accessed on a mobile smart device.

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 the Cue Cartridge.

Following the end of the COVID-19 Public Health Emergency, Medicare no longer pays for HCPCS Level II code K1034. CMS is not aware of other insurers potentially paying for this type of at-home COVID-19 test. Please contact non-Medicare payers for coding and payment guidance.

Agenda Item # 5
POGO Automatic® Test Cartridges - HCP2306306L0YM

Topic/Issue

Request to establish a new HCPCS Level II code to identify POGO Automatic® Test Cartridges.

Applicant's Suggested Language: XXXXX, "Test Cartridge with Automated Blood Sampling, 50 tests"

Summary of Applicant's Submission

Intuity Medical submitted a request to establish a new HCPCS Level II code to identify the POGO Automatic® Test Cartridges, which are supplies used with the POGO Automatic® Blood Glucose Monitoring System (ABGMS). POGO Automatic® Blood Glucose Monitoring System (ABGMS) received the Food and Drug Administration's (FDA's) 510(k) clearance on May 18, 2018. POGO ABGMS is currently classified by the Medicare Contractor for Pricing, Data Analysis and Coding (PDAC) as E2101, "Blood glucose monitor with integrated lancing/blood sample." Previously, the POGO Automatic® Test Cartridges were classified by the PDAC as A4253, "Blood glucose/reagent strips, per 50 strips" and A4259, "Lancets per box of 100." However, the POGO ABGMS does not use test strips and lancets. It is not possible for a consumer to insert or use traditional test strips and lancets as supplies for the POGO ABGMS, nor is it possible for suppliers to provide the POGO Automatic® Test Cartridge in quantities associated with the traditional test strip and lancet codes. The test cartridge used to perform the glucose measurement in the POGO ABGMS is significantly different from and not interchangeable with traditional strips and lancets used in existing blood glucose monitor (BGM) systems, all of which are generally similar in design and construction. POGO was given FDA clearance with the product name "POGO Automatic®" because it automates multiple procedural steps in the glucose testing process that must be done manually using a traditional BGM system. Each POGO test is a miniaturized blood acquisition and analysis unit called a "microanalyzer"; the user loads an easy-to-handle foil sealed cartridge containing ten tests into the POGO monitor rather than handling the test strips, lancets, and lancing device necessary to perform a traditional BGM test. The microanalyzer performs the finger prick, acquires the blood sample, transports the blood sample to the reaction zone which then provides an optical signal proportional to the glucose level in the sample, positions the reaction zone at the correct location to allow the monitor optical system to calculate a glucose value, all while the user rests their finger on the test area of the POGO monitor. The design of this cartridge integrates the lancing and testing functions in the cartridge, and is not similar to the separate design and function of a solid lancet and a test strip. Because these features present a distinction from the test strips and lancets used in traditional BGM systems, the payment assigned to a new code for the POGO Automatic® Test Cartridge is also requested to be gap-filled rather than cross walked from the payment amount assigned to a BGM test strip and lancet.

CMS Preliminary HCPCS Coding Recommendation

Establish a new HCPCS Level II code AXXXX, "Integrated lancing and testing cartridge for home blood glucose monitor, 10 tests"

According to the application, the microanalyzer in the cartridge performs the finger prick, acquires the blood sample, transports the blood sample to the reaction zone which then provides an optical signal proportional to the glucose level in the sample. Therefore, the integrated lancing and testing functionality is contained in the cartridge.

Preliminary Medicare Benefit Category Determination

Supply used with Durable Medical Equipment.

The applicant is requesting a new code for the POGO Automatic® Test Cartridges that are supplies used with the POGO Automatic® Blood Glucose Monitoring System. Unlike past devices falling under code E2101 where the integrated lancing/blood sample functionality is contained in the monitor, the integrated lancing/blood sample functionality for the POGO Automatic® Blood Glucose Monitoring System is contained in the POGO Automatic® Test Cartridge. Therefore, the correct code to use for billing the monitor portion of the system is E0607 rather than E2101. According to the application, the microanalyzer in the cartridge performs the finger prick, acquires the blood sample, transports the blood sample to the reaction zone which then provides an optical signal proportional to the glucose level in the sample. Since the POGO Automatic® Testing Cartridges are necessary for the effective use of a blood glucose monitor (DME), the cartridges are DME supplies.

Preliminary Medicare Payment Determination

Existing codes E2101, A4253, and A4259 represent the comparable functions of the POGO Automatic® Blood Glucose Monitoring System with the integrated lancing/blood sample feature incorporated into the test cartridge rather than the blood glucose monitor. The fee schedule amounts for the POGO Automatic® Blood Glucose Monitoring System (blood glucose monitor and integrated lancing/blood sample cartridges), billed using codes E0607 and AXXXX, should be established so that the total payments for this system are equal to the total payments made for other automatic blood glucose monitoring systems billed using codes E2101, A4253, and A4259, as follows:

- One POGO Automatic® Test Cartridge contains 10 tests, and 5 cartridges are delivered at a time (50 tests in total). The 2023 Medicare fee schedule amount for ten reagent strips (A4253) is $1.66 and the 2023 Medicare fee schedule amount for ten lancets (A4259) is $0.14.
- The 2023 Medicare fee schedule amount for a blood glucose monitor (E0607) is $88.86, while the 2023 Medicare fee schedule amount for a blood glucose monitor with integrated lancing/blood sample (E2101) is $250.75, a $161.89 difference. When the difference in cost of $161.89 is divided by sixty (the number of months in the lifetime of the monitor), this produces the monthly cost of $2.70 for the special integrated lancing/blood sample feature. The usual number of tests allowed per month for a beneficiary with type II diabetes is one hundred, so the cost of the special integrated lancing/blood sample feature per ten tests is $0.27.
- Thus, payment for the POGO Automatic® Test Cartridge would be $2.07 ($1.66 + $0.14 + $0.27).

Also, the Medicare payment amount for non-mail order diabetic supplies, including test strips, is required under section 1834(a)(1)(H) of the Social Security Act (The Act) to be equal to the single payment amounts established under the national mail order competitive bidding program for diabetic supplies (as established in section 1847 of The Act). We consider section 1834(a) to be applicable to the POGO Automatic Test Cartridges since they are diabetic supplies used to measure glucose levels.

Therefore, the preliminary payment determination is that the fee schedule amount for the new HCPCS code AXXXX, when covered, would be $2.07. The payment for a monthly supply (ten cartridges) would be $20.70. Claims for the monitor portion of the POGO Automatic® Blood Glucose Monitoring System would be submitted using code E0607.

Pricing Indicator = 34

Agenda Item # 6
Buzzy® Pro Therapeutic Vibrator with Cold Pack - HCP230701T9HT2

Topic/Issue

Request to establish a new HCPCS Level II code to identify the Buzzy® Pro Therapeutic Vibrator with Cold Pack.

Applicant's suggested language: XXXXX, "Vibrating motor for focal mechanical stimulation, capable of applying torque perpendicular to skin surface directly under compression or when attached with a tourniquet, with frequency 100-250 Hz, each"

Summary of Applicant's Submission

Pain Care Labs submitted a request to establish a new HCPCS Level II code to identify Buzzy® Pro Therapeutic Vibrator with Cold Pack. The Buzzy® Pro received the Food and Drug Administration's (FDA's) 510(k) clearance on May 15, 2023. Buzzy® Pro Therapeutic Vibrator is a vibrating motor for focal mechanical stimulation, capable of applying torque perpendicular to the skin surface directly under compression or when attached with a tourniquet, with frequency 100-250 Hz. Buzzy® Pro is designed specifically for dialysis cannulation pain relief. Buzzy® Pro device consists of a mechanical stimulation motor, ice pack, and silicone strap which can be applied by the patient or a caregiver. When attached directly on the skin or proximal within the same dermatome (nerve pathway), Buzzy® Pro delivers mechanical stimulation to control pain from dialysis cannulation or needle procedures. The frequency, amplitude and orientation of the vibration specifically targets pain-blocking motion nerves to override pain transmission. The shape of the device orients vibrations perpendicular to the target area, either directly or on the nerve pathway proximally in the dermatome, while the area of the device covers the entire cannulation field. An ice pack accessory with calculated thermal energy is shaped to match the cannulation field and slows nerve conduction for synergistic pain relief. The identical mechanism of the Buzzy® device in a different shape was cleared to control needle pain by the FDA in 2014 and has been used for needle pain relief for over 45 million procedures. In 2022, CMS did not grant Pain Care Labs' request to establish a code for the Buzzy® pain relief device, designating general needle pain relief for medication injections and vaccination to be out of mandate, and pain relief by therapeutic vibration to be a "comfort item".

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 vibrating motor for focal mechanical stimulation, capable of applying torque perpendicular to the skin surface directly under compression or when attached with a tourniquet.

When Buzzy® Pro is used to control pain associated with needle procedures (e.g., injections, vascular access, cannulation, lab draws, blood donation, dialysis, cosmetic and dental injections), Medicare would typically reflect the costs of it in the payment for the procedure and, as such, it would not be separately payable. Buzzy® Pro, when used at home, is considered to be a personal comfort item that is not primarily medical in nature, and does not meet the Medicare definition of durable medical equipment and would not be payable by Medicare.

Also, CMS took into consideration the Calendar Year 2024 ESRD End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) Final Rule (CMS-1782-F) determination that Buzzy® Pro Therapeutic Vibrator will not be paid for using the Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES) per § 413.236(d).

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.

Preliminary Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

Section 1862(a)(6) of the Social Security Act excludes Medicare coverage of items and services which constitute personal comfort items. Personal comfort items are further defined in Chapter 16, Section 80 of the Medicare Benefit Policy Manual (CMS Pub. 100-02), which says, "Items that do not contribute meaningfully to the treatment of an illness or injury or the functioning of a malformed body member are not covered."

The Buzzy® Pro is used alongside needle procedures. Although the needle procedure itself may be treating an illness or injury, the Buzzy® Pro is not. Based on our understanding of the mechanism of action, it is creating a distraction to make the injection experience easier for the patient. We believe this item is a personal comfort item that is not primarily medical in nature, and it therefore does not fall under a DMEPOS benefit category.

Preliminary Medicare Payment Determination

No Medicare payment. Pricing Indicator = 00

Agenda Item # 6
Buzzy® Pro Ice Pack Accessory - HCP2307032RY8G

Topic/Issue

Request to establish a new HCPCS Level II code to identify Buzzy® Pro Ice Pack Accessory.

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

Summary of Applicant's Submission

Pain Care Labs submitted a request to establish a new HCPCS Level II code to identify Buzzy® Pro Ice Pack Accessory. The Buzzy® Pro Ice Pack Accessory is a cold pack accessory capable of transmitting vibration when frozen, reversible for two temperature options, configured for use with vibrating motor for focal mechanical stimulation. The code request is for a Buzzy® Pro Ice Pack Accessory that is used in conjunction with a vibrating motor for focal mechanical stimulation and describes a cold pack accessory designed to apply cryotherapy to a specific target area that is subject to focal mechanical stimulation. This item is frozen solid with a calculated thermal energy safe for repeated application, so that it transmits rather than dampens the transmission of mechanical energy to the target area without risk of tissue damage. 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. Cold acts centrally and locally via nerve conduction slowing to reduce pain, and the physiological effects of mechanical stimulation are synergistically maximized by simultaneous application of cold. HCPCS Level II code A9273, "Cold or hot fluid bottle, ice cap or collar, heat and/or cold wrap, any type," could describe Buzzy® Pro Ice Pack Accessory, but the items that code A9273 describes are not covered by Medicare, do not freeze solid, and are too large for the device. In an outpatient or inpatient care setting the single-patient ice packs will be discarded. This accessory is a critical element of the Buzzy® Pro's vibrating motor's system for dialysis cannulation pain relief, and to be able to provide coverage, payers must be able to distinguish this item from other, non-covered items. The system is applied topically to the target area (fistula) for up to 2 minutes, then moved proximally during cannulation. It is then removed unless there is ongoing pain; the accessory thaws within 15 minutes. The item is available as part of a kit of five with the motor and other accessories, or separately in 10, 25, and 100 count units as needed for replacement.

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 reusable cold pack accessory capable of transmitting vibration when frozen, reversible for two temperature options, configured for use with vibrating motor for focal mechanical stimulation.

When Buzzy® Pro and Ice Pack Accessory are used to control pain associated with needle procedures (e.g., injections, vascular access, cannulation, lab draws, blood donation, dialysis, cosmetic and dental injections), Medicare would typically reflect the costs of it in the payment for the procedure and, as such, it would not be separately payable. Buzzy® Pro and Ice Pack Accessory, when used at home, is considered to be a personal comfort item that is

not primarily medical in nature, and does not meet the Medicare definition of durable medical equipment and would not be payable by Medicare.

Also, CMS took into consideration the Calendar Year 2024 ESRD End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) Final Rule (CMS-1782-F) determination that Buzzy® Pro Therapeutic Vibrator will not be paid for using the Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES) per § 413.236(d).

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.

Preliminary Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

Section 1862(a)(6) of the Social Security Act excludes Medicare coverage of items and services which constitute personal comfort items. Personal comfort items are further defined in Chapter 16, Section 80 of the Medicare Benefit Policy Manual (CMS Pub. 100-02), which says, “Items that do not contribute meaningfully to the treatment of an illness or injury or the functioning of a malformed body member are not covered.”

The Buzzy Pro Ice Pack Accessory is used alongside needle procedures. Although the needle procedure itself may be treating an illness or injury, the Buzzy Pro Ice Pack Accessory is not. It is creating a distraction to make the injection experience easier for the patient. We believe this item is a personal comfort item that is not primarily medical in nature, and it therefore does not fall under a DMEPOS benefit category.

Preliminary Medicare Payment Determination

No Medicare payment. Pricing Indicator = 00

Agenda Item # 6
VibraCool® Pro - HCP2307036BGBU

Topic/Issue

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

Applicant's suggested language: XXXXX, “Vibrating motor for focal mechanical stimulation, capable of applying torque perpendicular to skin surface under compression or indirectly when attached to a rigid brace, with frequency 100-250 Hz, each”

Summary of Applicant's Submission

Pain Care Labs submitted a request to establish a new HCPCS Level II code to identify VibraCool® Pro. The VibraCool® Pro received the Food and Drug Administration’s (FDA’s) 510(k) clearance on May 15, 2023. VibraCool® Pro is a vibrating motor for focal mechanical stimulation, capable of applying torque perpendicular to the skin surface under compression or indirectly when attached to a rigid brace, with frequency 100-250 Hz. The code will describe a mechanical simulation (m-stim) motor used for focal mechanical vibration, usually in conjunction with thermal packs, to be applied topically directly or adjacent to injury, inflammation, or surgical disruption for pain relief and treatment of musculoskeletal pain. The VibraCool® Pro DME is a 200 Hz motor unit that can be attached to rigid braces. VibraCool® Pro Upper Extremity and VibraCool® Pro Lower Extremity allow for stereotactic positioning by the patient or care provider, with thermal options for increased pain relief. The function of the item is to reduce pain on contact and over time via multiple physiologic mechanisms and multiple modalities. The m-stim devices interrupt pain transmission locally, at the level of the spine (gate control), increase blood flow, and reduce pain perception centrally (inhibitory control, reduction of central sensitization). The frequency, amplitude and orientation of the vibration specifically target pain-blocking motion nerves to override pain transmission. The shape of the device orients vibrations perpendicular to the target area, either directly or on the dermatome nerve pathway. For joint pain or surgery, two of the motors can be configured opposite each other to penetrate, or for a larger surgical field adjacent to each other to block pain proximally in multiple dermatomes. Existing codes do not adequately describe the item for three reasons: new gate control research, and research and development application of these mechanisms have only occurred in the past decade; Transcutaneous Electrical Nerve Stimulation (TENS) post-surgical codes are for electrical stimulation; FDA coding categories do not distinguish m-stim from massage, which CMS calls "comfort items" and excludes these novel devices from coverage. VibraCool® products are "intended for the temporary relief of minor injuries (muscle or tendon aches) and the treatment of myofascial pain post-surgery. It is also indicated for use prior to or during physical therapy to treat myofascial pain caused by trigger points, restricted motion and muscle tension." VibraCool® Pro Upper or Lower Extremity units include two motor units with AAA batteries, hot and cold packs, neoprene compression, an opioid-sparing workbook, Allen wrench, and instructions.

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 vibrating motor for focal mechanical stimulation, capable

of applying torque perpendicular to the skin surface under compression or indirectly when attached to a rigid brace, with frequency 100-250 Hz.

When VibraCool® Pro is used during the physical therapy to treat myofascial pain caused by trigger points, restricted motion and muscle tension, Medicare would typically reflect the costs of it in the payment for the procedure and, as such, it would not be separately payable. VibraCool® Pro, when used at home, is considered to be a personal comfort item that is not primarily medical in nature, and does not meet the Medicare definition of durable medical equipment and would not be payable by Medicare. 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.

Preliminary Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

In the 2022 Biannual 1 HCPCS Level II Coding Cycle, CMS indicated in application HCP220103PBVLQ that VibraCool® did not fall under a DMEPOS benefit category because CMS does not have a benefit category for massage devices as they do not meet the definition of durable medical equipment (DME).

Medicare program guidance at section 280.1 of chapter 1, part 4 of the Medicare National Coverage Determinations Manual indicates that massage devices are personal comfort items excluded from Medicare coverage by section 1862(a)(6) of the Social Security Act. These national Medicare guidelines also indicate that these devices are not primarily medical in nature, which makes them ineligible for classification as DME under current Federal regulations. The VibraCool® Pro device provides mechanical vibration and vibration devices are considered to be massage modalities.

In this current application the applicant, Pain Care Labs, has indicated that it has received a newer FDA 510(k) classification. In an earlier FDA 510(k) classification, VibraCool® was registered as a “therapeutic massager” whereas the current FDA 510(k) classification registers VibraCool® as a “therapeutic vibrator.” However, other than the change in the FDA classification, nothing else appears to have changed with the device, that is, it is still a device with a vibrating motor that stimulates the extremities for pain relief. We do not have any evidence to indicate that the VibraCool® is not a massage device, and therefore it does not fall into a Medicare DMEPOS benefit category.

Preliminary Medicare Payment Determination

No Medicare payment. Pricing Indicator = 00

Agenda Item # 6
VibraCool® Pro Ice Pack Accessory - HCP230703P85V9

Topic/Issue

Request to establish a new HCPCS Level II code to identify VibraCool® Pro Ice Pack Accessory.

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

Summary of Applicant's Submission

Pain Care Labs submitted a request to establish a new HCPCS Level II code to identify VibraCool® Pro Ice Pack Accessory. VibraCool® Pro Ice Pack Accessory is an ice pack accessory capable of transmitting vibration when frozen, reversible for two temperature options, configured for use with a vibrating motor for focal mechanical stimulation. The code is for a VibraCool® Pro Ice Pack Accessory that is used in conjunction with a vibrating motor and neoprene compression cuff for focal mechanical stimulation. This item is frozen solid with a calculated thermal energy safe for tissues, that transmits rather dampens the transmission of mechanical energy to the target area. The accessory is configured to fit the footprint of the vibrating motor and neoprene cuff, to be held in place with a latex-free elastic band next to the skin surface when the motor is activated. Cold acts centrally and locally via nerve conduction slowing to reduce pain, and the physiological effects of mechanical stimulation are synergistically maximized by simultaneous application of cold. HCPCS Level II code A9273, “Cold or hot fluid bottle, ice cap or collar, heat and/or cold wrap, any type,” could describe VibraCool® Pro Ice Pack Accessory, but the primary active ingredient is the mechanical stimulation motor, not the cold. The items that code A9273 describes are not covered by Medicare, do not freeze solid, and are too large for the device. In an outpatient or inpatient care setting the single-patient ice packs will be discarded. This accessory is a critical element of the VibraCool® Pro’s m-stim system for musculoskeletal post-surgical and physical therapy pain relief, and payers must be able to distinguish this item from other, non-covered items. VibraCool® products are "intended for the temporary relief of minor injuries (muscle or tendon aches) and the treatment of myofascial pain post-surgery. It is also indicated for use prior to or during physical therapy to treat myofascial pain caused by trigger points, restricted motion and muscle tension." The system is applied topically to the target area or proximal in the same dermatome as pain for up to 20 minutes. The Ice Pack accessory thaws within 25 minutes, 10-15 minutes next to skin. VibraCool® Pro is packaged with a 2 or 4 chamber ice pack. Replacements are 2 or 10 per pack.

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 reusable ice pack accessory capable of transmitting vibration when frozen, configured for use with a vibrating motor for focal mechanical stimulation.

Preliminary Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

The VibraCool® Pro Ice Pack is an accessory to VibraCool® Pro, which does not fall into a DMEPOS benefit category. Therefore, the VibraCool® Pro Ice Pack does not fall under a DMEPOS benefit category.

Preliminary Medicare Payment Determination

No Medicare payment. Pricing Indicator = 00

Agenda Item # 7
ZIDA Wearable Neuromodulation System - HCP230703TF2YL

Topic/Issue

Request to establish a new HCPCS Level II code to identify ZIDA Wearable Neuromodulation System.

Applicant's suggested language: EXXXX, “Posterior tibial neurostimulator, transcutaneous for urinary control”

Summary of Applicant's Submission

Zida LLC submitted a request to establish a new HCPCS Level II code to identify ZIDA Wearable Neuromodulation System. ZIDA Wearable Neuromodulation System received the Food and Drug Administration’s (FDA’s) 510(k) clearance on March 19, 2021. ZIDA Wearable Neuromodulation System is indicated for the treatment of overactive bladder (OAB) and the associated symptoms of urinary urgency, urinary frequency, and urge incontinence. ZIDA Wearable Neuromodulation System is a home-use system designed to deliver non-invasive access to the sacral nerve plexus through transcutaneous electrical stimulation of the posterior tibial nerve. The method of treatment is referred to as transcutaneous tibial nerve stimulation (TTNS). TTNS delivers treatment with efficacy equivalent to the current standard of care, percutaneous tibial nerve stimulation (PTNS), which is covered by Medicare and other third-party payers when the service is provided in a medical facility by a medical professional using Current Procedural Terminology (CPT®) code 64566, “posterior tibial neurostimulation, percutaneous needle electrode, single treatment”. Clinical evidence demonstrates that TTNS is as safe and effective as the covered office based PTNS treatment. The primary difference between TTNS and PTNS is the means of delivering the neurostimulation signal. PTNS uses a percutaneous delivery system where a minimally invasive needle is inserted into the skin above the medial malleolus and serves as an electrode. ZIDA Wearable Neuromodulation System employs sock-based, non-invasive transcutaneous contacts that deliver the neuromodulation signal through the skin to the posterior tibial nerve. PTNS/TTNS differ from Transcutaneous Electrical Nerve Stimulation (TENS). TENS’s mechanism of action aims to provide a degree of symptomatic pain relief by stimulating the pain gate mechanism. PTNS/TTNS’s mechanism of action delivers electrical pulses to the sacral nerve plexus via the tibial nerve. In simple terms, the goal of TENS is to distract the brain from physical stimuli, whereas the goal of PTNS/TTNS is to prevent the brain from sending the wrong signals to the bladder plexus. ZIDA Wearable Neuromodulation System consists of a control unit (a battery-powered neuromodulation pulse generator) that connects to the ZIDA control sock. The control sock is designed with two embedded electrodes that self-locate precisely over the tibial nerve and the inside arch of the foot. Zida's patented delivery system ensures the proper placement of the neuromodulation contacts for 95% of the patient population. Therapy is as easy as donning the sock and connecting the Control Unit, which was designed for ease of operation by the OAB patient population. Zida's TTNS device removes a significant barrier to PTNS treatment, such as the travel and time required by patients to get PTNS therapy, which involves 12 consecutive 30-minute sessions at a physician's office and bi-monthly maintenance sessions. This barrier particularly hinders access to care for patients with a disability and those living in rural areas.

CMS Preliminary HCPCS Coding Recommendation

1. Establish a new HCPCS Level II code EXXXX, "Transcutaneous tibial nerve stimulator"

2. Establish a new HCPCS Level II code EXXXX, "Form fitting conductive garment for delivery of electrical stimulation, e.g., tens or nmes to a small or localized area of the body (with conductive fibers separated from the patient's skin by layers of fabric)"

3. Revise existing HCPCS Level II code E0731, "Form fitting conductive garment for delivery of tens or nmes (with conductive fibers separated from the patient's skin by layers of fabric)" to instead read "Form fitting conductive garment for delivery of electrical stimulation, e.g., tens or nmes to a large or multiple area of the body (with conductive fibers separated from the patient's skin by layers of fabric)"

We recommend establishing a new garment code because the electrodes are attached to the socks, and it will be replaced every 6 months. The existing HCPCS Level II code E0731, "Form fitting conductive garment for delivery of tens or nmes (with conductive fibers separated from the patient's skin by layers of fabric)", does not describe the size of the garment, and hence the revision to include small and large to differentiate the code.

Preliminary Medicare Benefit Category Determination

Durable Medical Equipment.

DME is defined in Medicare regulations at title 42 Code of Federal Regulations (CFR) 414.202 as equipment furnished by a supplier or a home health agency that meets all of 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.

When clarifying the meaning of "durable" in regulations (CMS-1577-F, November 10, 2011), we noted that a multi-component device may be a system consisting of durable and nondurable components that together serve a medical purpose. As explained in that regulation, 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 nondurable, even if other components that are part of the device are durable. According to the applicant, the Control Unit is a battery-powered neuromodulation pulse generator that can be rented and used by successive patients. The Control Unit delivers signals in the form of electrical pulses. The Control Sock, which transfers the electrical neuromodulation signal from the control unit to the tibial nerve through the embedded contacts, cannot be used by successive patients due to health and contamination concerns.

We consider the Control Unit to be the durable component of this device because it is the component that initiates the electrical pulses, which are the medically necessary function of this device and allow the device to provide its neuromodulation therapy. The Control Unit meets all of the conditions listed in Medicare regulations at title 42 Code of Federal Regulations (CFR) 414.202, and thus the ZIDA Wearable Neuromodulation System is DME.

Preliminary Medicare Payment Determination

As CMS is creating two new HCPCS codes for the Zida Wearable Neuromodulation System, there will be two payment determinations.

For the control unit, no 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. Potential appropriate sources for such commercial pricing information can also include payments made by Medicare Advantage plans, as well as verifiable information from supplier invoices and non-Medicare payer data. 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.

We invite the applicant and members of the public to send us any available pricing information for the Zida Control Unit from these pricing sources described under § 414.238(c).

For the Control Sock, we located other similarly sized electrode garments (e.g., socks, sleeves, gloves) currently on the market. The Control Sock provides an electrical signal that stimulates the joint tissue to reduce the pain. This is similar to the function of the non-invasive sleeves, socks, or gloves that are available to reduce the pain and symptoms of arthritis. In accordance with regulations at 42 CFR § 414.238(c), we will be using internet retail prices for these comparable items, to price the Control Sock.

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 (for capped rental items, the last 6 months of 1986), deflation factors are applied against current pricing in order to approximate the base period price. The annual deflation factors are specified in program instructions (Medicare Claims Processing Manual, Chapter 23, Section 60.3) and the deflated amounts are then increased by the update factors specified in section 1834(a)(14) of the Act for DME.

We found several internet prices in August 2023 and the median of these prices is $58.74[1,2,3,4,5]. As this median price will be used in calculating the fee schedule and the amount is less than $150, payment would be made on an inexpensive or routinely purchased items basis in accordance with our regulations at 42 CFR 414.220. The average 2023 purchased fee schedule amount for EXXXX would be approximately $37.37.

Pricing Indicator = 32

[1] $75.00 - https://www.alimed.com/sock-conductive-fabric.html
[2] $89.25 - https://www.alimed.com/conductive-garment-glove.html
[3] $58.74 - https://www.atcmedical.com/Diagnostics/Nerve_Stimulation/FAGAR130/product.aspx
[4] $36.95 - https://www.tenspros.com/conductive-stimulation-sock-GU4025.html
[5] $43.97 - https://www.amazon.com/Silver-Conductive-Socks-Tens-Machine/dp/B07X27JXFT/ref=sr_1_3_sspa?keywords=Conductive%2BTherapy%2BShop&qid=1693502120&sr=8-3-spons&sp_csd=d2lkZ2V0TmFtZT1zcF9hdGY&th=1

Agenda Item # 8
HDF Assist Module - HCP230111XGWH3

Topic/Issue

Request to establish a new HCPCS Level II code to identify HDF Assist Module.

Applicant's suggested language: XXXXX, “The hdf assist module is indicated for use, with an approved dialysis machine, for treatment of patients with acute or chronic renal failure or whenever hemodiafiltration is prescribed by a physician”

Summary of Applicant's Submission

Specialty Renal Products submitted a request to establish a new HCPCS Level II code to identify HDF Assist Module (HDF). The HDF received the Food and Drug Administration’s (FDA’s) 510(k) clearance on May 13, 2022. The HDF Assist Module is indicated for use, with an approved dialysis machine, for treatment of patients with acute or chronic renal failure or whenever hemodiafiltration is prescribed by a physician. The HDF works in conjunction with a qualified host high permeability (UF controlled) hemodialysis machine and its accessories (i.e., bloodlines, dialysate, concentrates, etc.), the HDF Assist Module accessories (infusion set and substitution filter), appropriately purified water and ultrapure dialysate for hemodialysis, and a high permeability hemodialyzer/hemodiafilter (i.e., the OLPUr™ MD 220 Hemodiafilter).

CMS Preliminary HCPCS Coding Recommendation

CMS has not identified a program operating need for Medicare or other payers to establish a new Level II code to identify HDF Assist Module. This item is intended for use with a dialysis machine included in the clinical encounter payment, which is typically dialysis treatment for End-Stage Renal Disease.

Agenda Item # 9
iNAP One Sleep Therapy System Console - HCP230607VM24W

Topic/Issue

Request to establish a new HCPCS Level II code to identify the iNAP One Sleep Therapy System Console.

Applicant's suggested language: XXXXX, “Intermittent oral negative pressure device (nap) device”

Summary of Applicant's Submission

Somnics Inc. submitted a request to establish a new HCPCS Level II code to identify the iNAP One Sleep Therapy System Console. iNAP One Sleep Therapy System Console received the Food and Drug Administration’s (FDA’s) 510(k) clearance on May 26, 2020. The iNAP One Sleep Therapy System consists of six main components. The components are a console (for which Somnics Inc. is requesting a HCPCS Level II code), a saliva container, a saliva absorbent (iNAP DryPad), a flexible polymer tubing (iNAP Tubing Set), a soft polymer oral interface (iNAP Oral Interface) and a software application for mobile devices (iNAP Care). The function of the iNAP One Sleep Therapy System is to develop an intermittent negative pressure gradient in the user's oral cavity. The negative pressure in the oral cavity is set as -40 mmHg (-54 cmH_2O). The iNAP One Sleep Therapy System Console works by generating a gentle intermittent negative pressure and is driven by a built-in rechargeable lithium battery. In addition to the battery, the console contains the pressure pump, electronics and sensors that detect the amount of negative pressure within the user’s mouth.

CMS Preliminary HCPCS Coding Recommendation

Existing HCPCS Level II code E0600, “Respiratory suction pump, home model, portable or stationary, electric” describes the iNAP One Sleep Therapy System Console.

The predicate product to the iNAP One Sleep Therapy System Console, the Winx® Sleep Therapy System, was previously assigned existing HCPCS Level II code E0600 by CMS. In December 2022, the iNAP One Sleep Therapy System Console underwent the code verification process through the Pricing, Data Analysis and Coding contractor and it was decided to maintain assignment to that code E0600. CMS agrees the iNAP One Sleep Therapy System Console, a portable electrical suction pump that generates negative pressure in the oral cavity, is similar to other devices in existing HCPCS Level II code E0600.

Preliminary Medicare Benefit Category Determination

Durable Medical Equipment.

The current Medicare policy and prior established benefit category determination of DME for HCPCS code E0600 apply to the iNAP One Sleep Therapy System Console.

Also, Chapter 15, Section 110.3 of the Medical Benefit Policy Manual (CMS Pub. 100-02) indicates that payment may be made for replacement of essential accessories such as

mouthpieces, tubes, etc., for necessary DME, if the patient owns or is purchasing the equipment. Thus, the existing HCPCS codes for accessories are available for the iNAP One Sleep Therapy System: A7047, “Oral interface used with respiratory suction pump, each”; A7001, “Canister, non-disposable, used with suction pump, each”; A7002, “Tubing, used with suction pump, each”; and E9900, “Miscellaneous DME supply or accessory, not otherwise specified.”

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing code E0600 apply to this product, if covered. The average 2023 rental fee schedule amount for months 1 through 3 is $58.79, and the average rental fee schedule amount for months 4 through 13 is $44.09.

The average fee schedule amount is the average of the 2023 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 = 36

Agenda Item # 10
VOCSN VC and VOCSN VC Pro - HCP23063079G6K

Topic/Issue

Request to establish a new HCPCS Level II code to identify VOCSN VC and VOCSN VC Pro ventilators.

Applicant's suggested language: XXXXX, "Home ventilator, dual-function respiratory device for invasive or non-invasive ventilator support, also performs additional function of cough stimulation, includes all accessories, components and supplies for all functions"

Summary of Applicant's Submission

React Health submitted a request to establish a new HCPCS Level II code to identify VOCSN VC and VOCSN VC Pro ventilators. VOCSN Unified Respiratory System received the Food and Drug Administration's (FDA's) 510(k) clearance on April 7, 2017. VOCSN VC and VOCSN VC Pro ventilators combine ventilation and cough stimulation into one integrated device. VOCSN VC may be used for invasive and noninvasive applications. Existing codes for separate ventilation and cough stimulation devices are: E0465, "Home ventilator, any type, used with invasive interface;" E0466, "Home ventilator, any type, used with non-invasive interface;" and E0482, "Cough stimulating device, alternating positive & negative airway pressure." Existing code for 5 in 1 multi-function respiratory device is E0467, "Home ventilator, multi-function respiratory device, also performs any or all of the additional functions of oxygen concentration, drug nebulization, aspiration, & cough stimulation, includes all accessories, components & supplies for all functions." VOCSN VC combines only two primary and clinically beneficial products. There are several clinical and user benefits of integrating ventilation and cough stimulating therapy into one device. With VOCSN VC, caregivers can seamlessly switch between therapies with the touch of a button and no longer need to change the patient circuit between therapies. VOCSN VC weighs 12.5 pounds, has a 9-hour battery, and is controlled through an intuitive touchscreen interface and user-friendly operating system. VOCSN VC enables caregivers to spend less time managing ventilators and more time caring for patients.

CMS Preliminary HCPCS Coding Recommendation

Establish a new HCPCS Level II code EXXXX, "Home ventilator, dual-function respiratory device, also performs additional function of cough stimulation, includes all accessories, components and supplies for all functions."

Preliminary Medicare Benefit Category Determination

Durable Medical Equipment.

DME is defined in Medicare regulations at title 42 Code of Federal Regulations (CFR) 414.202 as equipment furnished by a supplier or a home health agency that meets all of 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 VOCSN VC devices meet these requirements to be classified as DME. Additionally, they fall under the multi-function ventilators definition in 42 CFR §414.222(f)(1).

Preliminary Medicare Payment Determination

In the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) for calendar year (CY) 2019 final rule, we finalized payment rules for multi-function ventilators or ventilators that perform functions of other DME (83 FR 57042). These payment rules are outlined in 42 CFR §414.222(f). Cough stimulating devices (as indicated by HCPCS code E0482) are classified under the capped rental payment class described in § 414.229. Ventilators (as indicated by HCPCS codes E0465, E0466, and E0467) are classified under the items requiring frequent and substantial servicing payment class in § 414.222.

Per §414.222(f)(2), the monthly rental fee schedule amount for this multi-function ventilator is equal to the monthly rental fee schedule amount for the ventilator established in paragraph (c) and paragraph (d) of this section plus the monthly cost for the cough stimulating function, which is calculated by dividing the purchase fee for the item by 60. For example, the 2023 monthly rental fee schedule amount for Alabama for the ventilator is $1,078.99 and the purchase fee schedule amount of $5,599.80 for Alabama for the cough stimulator divided by 60 is $93.33. The 2023 monthly rental fee schedule amount for Alabama for this multifunction ventilator would therefore be $1,172.32 ($1,078.99 + $93.33). The 2023 fee schedule amounts would be increased by the 2024 annual covered item update factor to calculate the 2024 fee schedule amounts.

Pricing Indicator = 31

Agenda Item # 11
Et Control - HCP230630ETU8C

Topic/Issue

Request to establish a new HCPCS Level II code to identify Et Control.

Applicant's suggested language: XXXXX, “End-tidal Control software device to assist anesthesia care delivery”

Summary of Applicant's Submission

GE HealthCare submitted a request to establish a new HCPCS Level II code to identify Et Control (EtC). Et Control received the Food and Drug Administration’s (FDA’s) pre-market approval (PMA) classification on March 17, 2022. The End-tidal Control software device is used to assist anesthesia care delivery in all settings. End-tidal Control is a Class III software medical device that integrates into the anesthesia machine to automatically adjust gas and anesthetic inflows to meet clinician-determined, patient-specific, end-tidal concentration targets. The EtC software device requires the anesthesia provider to set clinical targets for end-tidal, or expired, concentrations for oxygen and anesthetics rather than traditional manual anesthesia delivery focused on inhaled concentrations for oxygen and anesthetics. This software device-driven oxygen and anesthetic monitoring and adjustments have been demonstrated to enable the safe and efficacious use of lower gas flows during anesthesia, “low-flow anesthesia,” with favorable results for patients (airway humidification, temperature regulation) and the environment (reduced greenhouse gas emissions). The underlying “fuzzy logic” software technology first monitors end-tidal gases and then adjusts the gas and anesthetic flows to attain and maintain delivery to target levels. “Fuzzy logic” software is used in various industries, including artificial intelligence applications, to control machine outputs based on multiple input variables. In this case, the “fuzzy logic” utilizes end-tidal gas concentrations, fresh gas flow settings, and vaporizer status to make frequent adjustments titrated against the end-tidal target concentrations measured by a gas analysis module. EtC was approved for use on patients > 18 years, and is registered under a novel FDA product code, which was created for EtC.

CMS Preliminary HCPCS Coding Recommendation

EtC is not suitable for coding in the HCPCS Level II code set because it is used in facility settings during procedures reported using a HCPCS Level I Current Procedural Terminology (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 # 12
TytoHome™ System - HCP230629G0JV5

Topic/Issue

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

Applicant's suggested language: SXXXX, "Remote synchronous and asynchronous physical exams system for heart and lung auscultation, exam of external ear and tympanic membrane, skin, throat, heart rate and temperature for use in the home, including all hardware and software"

Summary of Applicant's Submission

Tyto Care Inc. submitted a request to establish a new HCPCS Level II code to identify the TytoHome™ System. The TytoHome™ System includes the TytoHome™ hardware kit (TytoHome™ Device and accessories) and a proprietary, software-based digital platform that enables telehealth-based interactions between a patient at home, and a clinician (synchronously and asynchronously), to perform remote physical examinations of heart and lung sounds, heartrate, temperature and imaging and video of throat, ear drum canal and skin. The TytoHome™ hardware kit consists of Tyto Device™ base unit, with a built-in camera and thermometer; reusable stethoscope, reusable otoscope adaptor plus disposable ear caps for ear exams, and reusable tongue depressor (two components) for throat exams. The Tyto Thermometer received the Food and Drug Administration's (FDA's) 510(k) clearance on March 27, 2019. The Tyto Stethoscope received the Food and Drug Administration's (FDA's) 510(k) clearance on October 19, 2016. The Tyto Otoscope and Exam Camera are exempt from the premarket notification procedures by the Food and Drug Administration (FDA).

CMS Preliminary HCPCS Coding Recommendation

Our understanding is that TytoHome™ hardware kit would be used by the patient at home exclusively to perform remote physical examination for a telehealth-based interaction with a clinician. A proprietary, software-based digital platform would enable a telehealth-based interaction between a patient at home, and a clinician. We have not identified a specific need for this TytoHome™ System to be separately paid, since we believe that a particular payer may elect to pay for the service in which this system is used. For instance, Medicare would typically reflect the costs of the system in the payment for the physician service/procedure, if it is used, and as such it would not be separately payable.

Agenda Item # 13
VECTRA™ Drug Delivery Microsponge - HCP23063003PFV

Topic/Issue

Request to establish a new HCPCS Level II code to identify VECTRA™ drug delivery microsponge.

Applicant's Suggested Language: XXXXX, “Degradable polymer microsponge for localized drug delivery in the nasal sinus, with single-use nasal sinus delivery system”

Summary of Applicant's Submission

Hemostasis, LLC submitted a request to establish a new HCPCS Level II code to identify the VECTRA™ drug delivery microsponge system for use in localized drug delivery to the sinus ostia to treat nasal disorders including post-operative care following endoscopic nasal surgery. VECTRA™ drug delivery microsponge is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). The VECTRA™ degradable microsponge sinus drug delivery system was specifically engineered for use as a drug delivery device to provide sustained delivery of medicines (e.g., steroids) to treat nasal disorders while maintaining an open lumen between the sinus and nasal cavity. VECTRA™ is comprised of a compressed microsponge that rapidly wicks the medicine and immediately expands to fill the space desired for treatment, and a sterile, single-use insertion tool to facilitate placement in the sinus. The degradable microsponge is supplied preloaded on one end of the sinus insertion tool, while the opposite end connects to a syringe containing the medicine to be delivered to the sinus. VECTRA™ has been evaluated for suitability with many drug suspensions including mometasone furoate, triamcinolone acetonide, budesonide, fluticasone, and dexamethasone. The frontal degradable polymer microsponge can absorb up to 0.4 ml of medicine and can expand up to 7 mm x 15 mm. The drug dosage varies based on the patient's needs. After several days of treatment, the VECTRA™ degradable polymer microsponge is naturally eliminated via mucociliary action, assisted by daily irrigation with fluid as prescribed by a licensed healthcare provider.

CMS Preliminary HCPCS Coding Recommendation

Our understanding is that the VECTRA™ drug delivery microsponge is not suitable for inclusion in the HCPCS Level II code set because it is used during a procedure and certain items are considered bundled into the facility payment. We have not identified a specific need for this microsponge 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 # 14
Natural Cycles – HCP230626HDWY2

Topic/Issue

Request to establish a new HCPCS Level II code to identify Natural Cycles.

Applicant's suggested language: XXXXX, "Annual subscription-based software application for preventing a pregnancy (FDA-cleared), including algorithmic analysis of patient-specific data (i.e., temperature, menstrual cycle dates), and provision of patient-specific contraception recommendations"

Summary of Applicant's Submission

Natural Cycles USA Corp. submitted a request to establish a new HCPCS Level II code to identify Natural Cycles (NC). Natural Cycles received the Food and Drug Administration's (FDA's) De Novo clearance on August 10, 2018, followed by a 510(k) marketing authorization pathway on June 24, 2021. NC is a subscription-based software application (app) that runs on the world wide web or on mobile phones, and is used in conjunction with patient-specific data and a woman's basal temperature taken by a basal thermometer as a method of fertility control (i.e., contraception). The NC individualized algorithm continuously analyzes patient-specific data to display individualized daily fertility status. The algorithm uses basal body temperature, menstruation data, and optional luteinizing hormone test results to determine the fertile window. It confirms ovulation by analyzing temperature shifts caused by hormones. The user takes their temperature most mornings when they awake and enter that reading into the app. The algorithm then learns the cycle pattern and assigns a daily fertility status, which is provided as either a red (fertile) or a green (non-fertile) day. Unlike other fertility awareness-based methods, this software application adapts to each woman's cycle, predicting and confirming their specific ovulation. As part of the annual subscription, a thermometer is provided. Users can also purchase a wearable device (e.g., the Oura ring or Apple Watch) as an alternative to the thermometer, or make use of existing wearables on the market that are integrated with this app.

CMS Preliminary HCPCS Coding Recommendation

Establish a new HCPCS Level II code AXXXX, "Fertility software application, fda cleared, per course of treatment, includes accessories (e.g., thermometer)"

Preliminary Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

DME is defined in Medicare regulations at title 42 Code of Federal Regulations (CFR) 414.202 as equipment furnished by a supplier or a home health agency that meets all of 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 for equipment to be classified as DME. Software applications (apps) are not devices, equipment, or supplies and therefore would not fall under a DMEPOS benefit category. The DME benefit is for equipment such as a wheelchair, hospital bed, ventilator, or oxygen concentrator rented to a patient for use in their home. Standalone software apps do not work unless the patient also has a smartphone, computer or another type of durable device that would enable use of the software. These durable devices are generally useful to individuals in the absence of illness or injury and are therefore not DME. Without the durable device which runs the software app, the software would not work. Therefore, standalone software apps are not DME.

Whether or not the software 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 Indicator = 00

Agenda Item # 15
Leva Pelvic Health System – HCP2306304CXRL

Topic/Issue

Request to establish a new HCPCS Level II Code to identify Leva Pelvic Health System.

Applicant's suggested language: EXXXX, "Prescription intra-vaginal multiple motion sensor device with integrated software for pelvic floor muscle therapy in the treatment of female pelvic floor disorders (e.g., stress, mixed and mild to moderate urgency urinary incontinence, chronic fecal incontinence, pelvic floor muscle weakness)"

Summary of Applicant's Submission

Axena Health Inc. submitted a request to establish a new HCPCS Level II code to identify Leva Pelvic Health System (Leva device). Leva Pelvic Health System received the Food and Drug Administration's (FDA's) 510(k) clearance on June 30, 2023. Leva is a prescription medical device that combines motion-based, multi-sensor technology embedded in an intra-vaginal probe with integrated software to provide pelvic floor muscle therapy (PFMT). It is indicated for the treatment of female pelvic floor disorders and impairments (e.g., stress, mixed and mild to moderate urgency urinary incontinence (UI), chronic fecal incontinence (FI), pelvic floor muscle weakness). The Leva device is a multi-use by single-user for use at-home twice daily. The Leva device consist of an intra-vaginal probe with motion sensors and software; neither component works without the other. The Leva device's intra-vaginal probe contains small, flexible intra-vaginal movement-based sensors that detect the motion (not force or pressure) produced during pelvic floor muscle (PFM) contraction and relaxation. The software depicts this motion in real-time to enable the user to perform PFMT correctly and consistently. The Leva device's integrated software also provides directional didactics if the user performs an incorrect motion, such as bearing down. Published clinical evidence supports the efficacy of the Leva device in the treatment of UI and FI. A substantial amount of published clinical data also confirms its superiority over traditional PFMT in patients with stress UI and mixed UI, including a large randomized controlled trial (RCT) demonstrating long term durable results. Currently, providers are using a miscellaneous code for claims, triggering commercial payer prior authorization requirements which payers have indicated is not desirable and would not be necessary if a specific HCPCS code describing the Leva device was available. Commercial payers have expressly requested that a specific HCPCS code be established for the Leva device and certain DME providers have stated they are unable to service patients while a miscellaneous code applies to the Leva device. Commercial payers cover the Leva device based on its differentiated mechanism of action (i.e., motion detection to guide active PFMT), the fact that it is a prescription device, and its substantial clinical evidence (including RCTs and real-world evidence).

CMS Preliminary HCPCS Coding Recommendation

Establish a new HCPCS Level II code SXXXX, "Intra-vaginal motion sensor biofeedback device"

Preliminary Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

DME is defined in Medicare regulations at title 42 Code of Federal Regulations (CFR) 414.202 as equipment furnished by a supplier or a home health agency that meets all of 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 Leva Pelvic Health System does not meet three of these conditions as follows:

- **Ability to withstand repeated use –** The Leva Pelvic Health System is a single-patient use item, as explained in the application and supported by the FDA 510(k) approval as a single patient device. DME is a benefit for rental of equipment and therefore DME items must be able to withstand repeated use by successive patients. The regulation is in accordance with Section 1861(s)(6) of the Social Security Act which sets forth the DME benefit including rental of DME, although purchase of DME items is allowed in limited situations such as section 1834(a)(4) of the Social Security Act for custom DME.

- **Expected Life of at Least Three Years –** As stated in the application, the Leva device has an expected lifetime of one year as opposed to the required expected life of at least three years.

- **Generally Not Useful to a Person in the Absence of an Illness or Injury –** The Leva Pelvic Health System relies on a patient's smartphone to provide biofeedback to the patient while using the intra-vaginal probe. An individual's smartphone is useful to an individual in the absence of an illness or injury.

In addition, please take note that as stated in Chapter 1, Part 1, Section 30.1.1 of the Medicare National Coverage Determinations Manual (CMS Pub. 100-03), home use of biofeedback therapy for the treatment of urinary incontinence is not covered by Medicare.

Preliminary Medicare Payment Determination

No Medicare payment. Pricing Indicator = 00

Agenda Item # 16
Restorex Penile Traction Device - HCP23061702CGD

Topic/Issue

Request to establish a new HCPCS Level II code to identify Restorex Penile Traction Device.

Applicant's suggested language: XXXXX, "Penile traction therapy 2nd generation)"

Summary of Applicant's Submission

PathRight Medical submitted a request to establish a new HCPCS Level II code to identify Restorex Penile Traction Device. Restorex Penile Traction Device is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). Restorex Penile Traction Device is a second generation penile traction therapy (2-PTT). A new HCPCS Level II code would apply to 2-PTT devices which demonstrate efficacy in clinical trials to improve penile deformity or length with 1 hour of daily use or less and provide >3 lbs. of consistent penile traction throughout the treatment course. PTT devices are intended to correct physical penile abnormalities including loss of length, curvature, indentation, or hourglass deformities resulting from congenital or acquired medical conditions, trauma, or iatrogenic interventions. First generation devices include those which require 2-9 hours of daily use to achieve outcomes and/or provide <3 lbs. of traction force. Again, second generation devices, such as this one, are those which demonstrate clinical improvements (in clinical studies) with 1 hour or less of daily use and >3 lbs. of penile traction. 2-PTT devices function by grasping the glans of the penis and applying mechanical traction away from the body with or without counter-bending (as applicable). The devices are to be worn for 30-60 minutes daily.

CMS Preliminary HCPCS Coding Recommendation

Establish a new HCPCS Level II code SXXXX, "Penile contracture device"

CMS has not identified a claims processing need for Medicare or other government insurers to establish a new HCPCS Level II code to separately identify Restorex Penile Traction Device on a claim. However, information submitted by the applicant supported a claims processing need for non-governmental payors.

Preliminary Medicare Benefit Category Determination

No Medicare DMEPOS benefit category**.**

DME is defined in Medicare regulations at title 42 Code of Federal Regulations (CFR) 414.202 as equipment furnished by a supplier or a home health agency that meets all of 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 condition, Durable Medical Equipment is a benefit for rental of medical 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 Restorex Penile Device is intended for single patient use and therefore cannot withstand repeated use.

Section 1861(s)(9) of the Social Security Act provided Medicare Part B coverage for leg, arm, back, and neck braces. The Restorex Penile Traction Device is not intended for use on the leg, arm, back or neck and therefore does not fall within the Medicare Part B benefit category for leg, arm, back, and neck braces.

Thus, there is not a DMEPOS benefit category under Medicare Part B for a penile contracture device used in the home and, as such, it is not payable by Medicare. For guidance for other non-governmental payors, please refer to the insurer(s) in whose jurisdiction(s) claim would be filed.

Preliminary Medicare Payment Determination

No Medicare payment. Pricing Indicator = 00

Agenda Item # 17
ProVate Vaginal Support - HCP230628N8LUJ

Topic/Issue

Request to establish a new HCPCS Level II code to identify ProVate vaginal support.

Applicant's suggested language: AXXXX, “Pessary, non-rubber, disposable for self-insertion”

Summary of Applicant's Submission

Ingene submitted a request to establish a new HCPCS Level II code to identify ProVate vaginal support. ProVate vaginal support received the Food and Drug Administration’s (FDA’s) 510(k) clearance on July 8, 2019. The ProVate vaginal support is indicated for the temporary, nonsurgical management of pelvic organ prolapse in females. The device is made of a flexible skeleton covered by a soft elastomer. ProVate is a disposable, single-use, prescription only device. Each unit is intended to be used for up to seven days. The ProVate box will contain 10 individually packaged devices. Each user may be provided with up to 80 devices per year, 20 devices delivered to their home every 3 months. ProVate size-fitting is performed by a healthcare professional. The ProVate device comes in 6 sizes to accommodate various vaginal dimensions. The device is supplied in its compact (slender) mode, ready for use within a disposable applicator intended for the insertion of the device. The ProVate support is inserted into the vagina in a compacted mode within an applicator for comfortable insertion. When in the vagina, the plunger of the applicator is pressed (like with a tampon applicator) and the ProVate support expands into its ring shape to support the vaginal walls, and the applicator is removed and thrown away. At the end of its use (up to 7 days), the patient pulls the removal string, which collapses the device into its compact configuration, facilitating easy and painless removal. The device is then thrown away, and a new device can be inserted by the patient as needed. Once inserted, the circular shape of the ProVate is comparable to that of the predicate device (the currently available ring pessary), and the ring provides mechanical support to the prolapsed organs. Vaginal ring pessaries are the widely used pessary. However, existing ring pessaries are reusable only, rather large and intimidating, are associated with various adverse events (including discomfort, pain, discharge, bleeding, etc.) and with sexual disturbances, and in most cases require healthcare provider assistance to insert and remove, hence causing dependency upon the clinic.

CMS Preliminary HCPCS Coding Recommendation

1. Establish a new HCPCS Level II code AXXXX, “Pessary, disposable, any type”

2. Revise existing HCPCS Level II code A4561, “Pessary, rubber, any type” to instead read “Pessary, reusable, rubber, any type”

3. Revise existing HCPCS Level II code A4562, “Pessary, non rubber, any type” to instead read “Pessary, reusable, non rubber, any type”

We recommend adding reusable to existing HCPCS Level II code A4561 and A4162 to clearly distinguish it from the newly established HCPCS Level II code AXXXX. Also, we recognize a distinction in the replacement frequency for a disposable pessary device may be

up to seven (7) days, whereas one pessary per six months is the Medicare allowable replacement frequency for a reusable pessary. The distinction in duration of use contributes to revising existing codes A4561 and A4562.

Preliminary Medicare Benefit Category Determination

Prosthetic device.

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. Repairs, adjustments, and replacement of medically necessary prosthetic devices are covered. Coverage under this benefit includes pessary items.

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.

According to the applicant, ProVate Vaginal Support pessaries are furnished in a box which contains 10 individually packaged pessaries used by the patient for up to seven (7) days. One pessary per six months is the Medicare allowable replacement frequency for HCPCS code A4652. Payment for items described by HCPCS code AXXXX would be established using the 2023 average fee schedule amount for HCPCS code A4652, “Pessary, non rubber, any type” of $67.21 divided by 26 weeks (6 months) for approximately $2.59 for each pessary or $25.90 per box of ten pessaries.

The average fee schedule amount is the average of the 2023 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

Appendix A: 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.